National Clinical Guideline Centre

Draft

Appendix G

Pressure ulcer prevention and management

Clinical evidence tables

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Draft for Consultation

Commissioned by the National Institute for Health and Care Excellence

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Appendix G: Clinical evidence tables

G.1 Pressure ulcer prevention

G.1.1 Risk assessment

Table 1: Pancorbo 2006[173]

Reference	Method	Patient characteristics	Intervention	Results	Critical appraisal of review quality
Author and year: Pancorbo (2006) **Title:** Risk assessment scales for pressure ulcer prevention: a systematic review. Journal**:** Journa**l** of Advanced Nursing, 54 (1); 94-110.	**Design:** systematic review and meta-analysis **Source of funding:** grant from the Health Institute Carlos III, Ministry of Health and Consumer (Spain) **Search date**: 1966-2003 **Searched databases:** DARE; CINAHL; Medline; Current contents clinical medicine, social and behaviour science, life sciences; indice medico español; cuiden; centro Latinoamericano y del caribe de información en Ciencias de la Salud; Cochrane Library; EBSCO; ScienceDirect;	**Eligibility criteria:** all types of patients **Patient characteristics** Hospitalized patients (acute ward, medical ward, surgical ward, orthopaedic ward, internal medicine, geriatric ward, cardiovascular surgery, neurosurgery, orthopaedic surgery), ICU patients, home care patients, LTCF patients, rehabilitation patients, geriatric centre	**Predictive test** Braden scale; Norton scale; Waterlow scale; Andersen scale; Pressure Sore Prediction Score; Knoll scale; Modified Norton scale; Emina scale; Cubbin-Jackson scale;	See Appendix IV	The critical assessment guide developed for clinical practice guide for PU assessment and prevention (Rycroft-Malone & McInness 2002) was used to assess the quality of prospective cohort studies. Results of the assessment of the methodological quality are not reported.

Reference	Method	Patient characteristics	Intervention	Results	Critical appraisal of review quality
	Springer; InterSciencia; ProQuest; Pascal **Included study designs:** prospective cohort studies **Inclusion criteria:** the patients considered had no PU at the beginning of the study; drop-out rate of patients did not exceed 25 %; studies in French, Spanish, English or Portuguese **Number of included studies:** 32		Risk Assessment Pressure Sore; Fragmment scale; Douglas scale; Clinical judgement **Outcome:** Pressure ulcer development		

Table 2: Anthony 2003[12]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Anthony (2003) **Title:** A regression analysis of the Waterlow score in	**Patient group:** hospitalised patients of all ages **All patients**	**Predictive test 1:** the Waterlow scale **Outcome:** development of pressure ulcer stage I or above, according to the	**Outcome 1:** Incidence of PU **Outcome 2:**	**Value:** 0.4% **AUC:** 0.901	**Funding:** / **Limitations:** database cohort study; no report

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
pressure ulcer risk assessment. Journal**:** Clinical Rehabilitation, 17(2): 216-23. **Study type:** Database cohort study but participants followed prospectively **Selection patient:** Hospitalized patients. All patients admitted between 1996 and 2000 with a compatible Waterlow score on admission. **Predictive test:** Waterlow scale was used to assess PU risk at admission. Re-assessment unclear. Health professional were trained to screen the patients.	**Included N:** 45735 **Completed N:** 45735 **Drop-outs:** 0 **Group with hospital acquired PU** **Number of patients with a PU:** 203 had no PU on admission; 74 had a PU on admission **Age (mean years; median age (IQR); range):** 63.24; 64.70 (17.22); 0 to > 81 **Gender (m/f):** 81/122 **Days in hospital (mean days; median days (IQR)):** 31.98; 22.00 (34.50) **Group without hospital**	Torrance grading (Torrance, 1983) **Preventative methods:** not reported	Area under the ROC **Outcome 3:** Sensitivity and specificity Waterlow scale cut-off 10 **Outcome 4:** Sensitivity and specificity Waterlow scale cut-off 15	**95% CI:** 0.883-0.919 **Sensitivity:** 82.3% **Specificity**: 85.2% **Raw data** Outcome Yes / No Predictive test: Yes 167 6757 6924 No 36 38775 38811 203 45532 45735 **Sensitivity:** 48.8% **Specificity**: 94.5% **Raw data** Outcome Yes / No Predicti Yes 99 2519 2618	on re-assessment of predictive test; no report on duration of follow-up; no report on blinding; no imputation, no exclusion; not reported when patients dropped from the study; no report on inclusion and exclusion criteria; no report on use of preventative measures; no sub-analyses according to preventative measures. **Additional**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Outcome: The Torrance score was used to grade the PU. Health professional were trained to screen the patients. **Imputation:** no imputation, no exclusion **Number of events:** 203 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** An ROC curve is a plot of the true positive rate (sensitivity) against the false positive rate (1–specificity) for given	**acquired PU** **Age (mean years; median age (IQR); range):** 41.84; 44.50 (28.33); 0 to > 81 **Gender (m/f):** 21732/23800 **Days in hospital (mean days; median days (IQR)):** 3.40; 2.00 (2.00) **Inclusion criteria:** not reported **Exclusion criteria:** not reported		**Outcome 5:** Sensitivity and specificity Braden scale cut-off 20	ve test / No: 104, 43013, 43117 203, 45532, 45735 **Sensitivity:** 16.7% **Specificity**: 98.1% **Raw data** Outcome: Yes / No Predictive test: Yes: 34, 846, 880 No: 169, 44686, 44855 203, 45532, 45735	**outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
thresholds. A system that performs as one might expect would show a differing ratio of sensitivity to specificity as the threshold increases. **Setting:** the Queen's Hospital in Burton. **Blinding:** not reported					

Table 3: Chan 2009[46]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Chan (2009) **Title:** Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting.	**Patient group:** hospitalised patients aged 18 or above **All patients** **Included N:** 197 **Completed N:** 197	**Predictive test 1:** the Braden scale **Predictive test 2:** modified Braden scale (Kwong et al. 2005) **Outcome:** development of pressure ulcer stage I or above, according to the NPUAP (2007) classification.	**Outcome 1:** Incidence of PU (> 1 week; 9 days) **Outcome 2:** Area under the	**Value:** 9.10% **Value:** 0.736 **95% CI**: 0.632-0.841	**Funding:** / **Limitations:** predictive test measured only at admission; no report on blinding of researcher

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Journal**:** Journal of Clinical Nursing, 18: 1565-73 **Study type:** prospective cohort study **Selection patient:** Chinese patients aged 18 or above without a pressure ulcer on admission. Recruitment unclear. **Predictive test:** Braden and modified Braden were used to assess PU risk at admission. Researcher, a trained nurse, screened the patients. **Outcome:** skin assessment to detect PUs were performed	**Drop-outs:** 0 **Age (mean years (SD); range):** 79.4 (10.88); 35-98 **Gender (m/f):** 30/167 **Number of patients with a PU:** 18 **Number of patients without a PU:** 179 **Inclusion criteria:** Chinese; aged 18 or above; an expected stay of five days or more following admission; not ambulant; no PU on admission. **Exclusion criteria:** none	**Preventative methods:** preventative nursing intervention were performed but not described..	ROC **Outcome 3:** Sensitivity and specificity Braden scale cut-off 16 **Outcome 4:** Sensitivity and specificity Braden scale cut-off 17	**Sensitivity:** 66.7% **Specificity**: 64.2% **Raw data** |		Outcome		
		Yes	No	
Predictive test	Yes	12	64	76
	No	6	115	121
		18	179	197 | **Sensitivity:** 72.2% **Specificity**: 40.8% **Raw data** |		Outcome		
		Yes	No	
Predic	Yes	13	106	119		toward predictive test and outcome; no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no sub-analyses according to preventative measures. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
daily. Researcher, a trained nurse, screened the patients. Patient were observed until PU development, discharge, transfer or death. Observation period of maximum 9 days. **Imputation:** no imputation, no exclusion **Number of events:** 18 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** The receiver operating characteristic (ROC) curve determined the predictive validity of the Braden and			**Outcome 5:** Sensitivity and specificity Braden scale cut-off 18		

tive test	No	5	73	78
		18	179	197

Sensitivity: 88.9%

Specificity: 21.2%

Raw data

		Outcome		
		Yes	No	
Predictive test	Yes	16	141	157
	No	2	38	40
		18	179	197

Sensitivity: 38.9%

Specificity: 79.9%

Raw data

		Outcome		
		Yes	No	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
modified Braden scales. **Setting:** two orthopaedic wards of an acute care hospital in Hong Kong **Blinding:** blinding of researcher who assess risk and PU development not reported. Nurses performed preventative measures without knowing the scores of the Braden and modified Braden.			**Outcome 6:** Sensitivity and specificity modified-Braden scale cut-off 17	<table><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>7</td><td>36</td><td>43</td></tr><tr><td>No</td><td>11</td><td>143</td><td>154</td></tr><tr><td></td><td>18</td><td>179</td><td>197</td></tr></table> **Sensitivity:** 55.6% **Specificity**: 72.6% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>10</td><td>49</td><td>59</td></tr><tr><td>No</td><td>8</td><td>130</td><td>138</td></tr><tr><td></td><td>18</td><td>179</td><td>197</td></tr></table>	
			Outcome 7: Sensitivity and specificity modified-Braden scale cut-off 18	**Sensitivity:** 88.9% **Specificity**: 62.0% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr></table>	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Outcome 8: Sensitivity and specificity modified-Braden scale cut-off 19		

		Yes	No	
Predictive test	Yes	16	68	84
	No	2	111	113
		18	179	197

Table 4: Compton 2008[53]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Compton (2008) **Title:** Pressure ulcer predictors in ICU patients: nursing skin assessment versus objective parameters Journal**:** Journal of Wound Care, 17(10): 417-24. **Study type: database** cohort but participants were followed prospectively **Selection patient:** All patients admitted to the medical ICU between April 2001 and December 2004. **Predictive test:** Waterlow score at	**Patient group:** patients hospitalised in ICU. **All patients** **Included N:** 698 **Completed N:** 698 **Drop-outs:** 0 **Age (median yrs (IQ)):** 66 (56, 75, 25) **Gender (m/f):** 392/306 **Number of patients with a PU:** 121 **Number of patients without a PU:** 577 **Number of days before occurrence of PU (median days (IQ)):** 7 (4, 13)	**Predictive test 1:** the Waterlow scale **Outcome:** development of pressure ulcer stage II or above, according to the NPUAP (1999) classification. **Preventative methods:** not reported.	**Outcome 1:** Incidence of PU **Outcome 2:** Area under the ROC	**Value:** 17.3% **AUC:** 0.59 **95% CI:** 0.54-0.65	**Funding:** / **Limitations:** database cohort study; predictive test only assessed on admission; no report on maximum duration of follow-up; no report on blinding; no imputation, no exclusion; not reported when patients dropped from the study; no report on use of preventative measures; no sub-analyses according to

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
admission. The admitting nurse screened the patients **Outcome:** Occurrence of PU were recorded during the ICU treatment (median stay (IQ) before PU occurrence: 7 (4.13)) **Imputation:** no imputation, no exclusion **Number of events:** 121 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** The predictive capacity of the logistic regression function was assessed and	**Inclusion criteria:** patients admitted to the ICU for at least 72 hours; no pressure ulcer on admission **Exclusion criteria:** /				preventative measures; cut-off score of 0.5 does not exist **Additional outcomes:** logistic regression of 32 variables. Five parameters were identified as predictors and sensitivity and specificity was calculated. **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
compared with the Waterlow score by calculating the area under the curve of a receiving-operator characteristics curve. AUC, sensitivity specificity were displayed with 95% CI **Setting:** medical ICU of the Charité Campus Benjamin Franklin Berlin **Blinding:** not reported					

Table 5: Curley 2003[57]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Curley (2003) **Title:** Predicting pressure ulcer risk in pediatric patients: the Braden Q Scale Journal**:** Nursing Research, 52(1): 22-33. **Study type:** prospective cohort study **Selection patient:** PICU patients. Consecutive sample. **Predictive test:** Braden-Q was used to assess PU risk at enrolment. A trained nurse screened the patients. Patients	**Patient group:** paediatric patients hospitalised in PICU. **All patients** **Included N:** 322 **Completed N:** 322 **Drop-outs:** 0 **Age (mean months (SD)):** 36 (29) **Gender (m/f):** 193/129 **Number of patients with a PU:** 277 **Number of patients without a PU:** 45 **Inclusion criteria:** bedrest for at least 24 hours;	**Predictive test 1:** the Braden-Q scale (Quigley & Curley, 1996) **Outcome:** development of pressure ulcer stage II or above, according to the NPUAP (1989) classification. **Preventative methods:** not reported.	**Outcome 1:** Incidence of PU (> 1 week; 12 days) **Outcome 2:** Area under the ROC **Outcome 3:** Sensitivity and specificity Braden-Q scale cut-off 10	**Value:** 26.71% **AUC:** 0.830 **95% CI:** 0.76-0.91 **Sensitivity:** 3.5% **Specificity**: 100% **Raw data** Outcome: Yes / No Predictive test: Yes — 3 / 0 / 3 Predictive test: No — 83 / 236 / 319 Predictive test: 86 / 236 / 322	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on preventative measures; no sub-analyses according to preventative measures. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
were observed up to 3 times a week for 2 weeks, then once a week until discharge (stay: 3 – 12 days). **Outcome:** The skin assessment tool (Braden & Bergstorm, 1997) was used to detect the presence or absence of PUs. A trained nurse screened the patients. Patients were observed up to 3 times a week for 2 weeks, then once a week until discharge (stay: 3 – 12 days). **Imputation:** no imputation, no exclusion **Number of events:** 86 patients developed ulcers	age between 21 days and 8 years. **Exclusion criteria:** patients admitted to the PICU with a pre-existing PU; intra-cardiac shunting; unrepaired congenital heart disease		**Outcome 4:** Sensitivity and specificity Braden-Q scale cut-off 11 **Outcome 5:** Sensitivity and specificity Braden-Q scale cut-off 12	**Sensitivity:** 16.3% **Specificity**: 97.0% **Raw data** **Sensitivity:** 47.7% **Specificity**: 92.8% **Raw data**	

		Outcome		
		Yes	No	
Predictive test	Yes	14	7	21
	No	72	229	301
		86	236	322

		Outcome		
		Yes	No	
Predictive	Yes	41	17	58
	No	45	219	264

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Addressing missing data: not reported when patients dropped from the study **Statistical analysis:** Diagnostic probabilities (sensitivity, specificity, positive predictive value, and negative predicative value) were calculated over a range of possible Braden Q score. Receiver operator characteristic (ROC) curve analysis plotting sensitivity against 1 - specificity over the range of Braden Q scores was constructed to confirm the critical value of the Braden Q			**Outcome 6:** Sensitivity and specificity Braden-Q scale cut-off 13	test | | 86 | 236 | 322 **Sensitivity:** 67.4% **Specificity**: 89.0% **Raw data** | | | Outcome | | | | | Yes | No | | Predictive test | Yes | 58 | 26 | 84 | | No | 28 | 210 | 238 | | | 86 | 236 | 322 **Sensitivity:** 72.1% **Specificity**: 78.8% **Raw data** | | | Outcome | | | | | Yes | No | | Predic | Yes | 62 | 50 | 112	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Scale. The optimal cutoff point was determined by that which provided high sensitivity and adequate specificity. The likelihood ratio (LR) was measured to identify the ratio of the probabilities that a positive test results from a patient with pressure ulcers to that for a patient without pressure ulcers. **Setting:** three PICUs of three different hospitals in the US **Blinding:** the two nurses were blinded to other's assessment. Nurse I rated the Braden Q and nurse II rated the skin assessment tool.			**Outcome 7:** Sensitivity and specificity Braden-Q scale cut-off 14 **Outcome 8:** Sensitivity and specificity Braden-Q scale cut-off 15	tive test: No 24 186 210; 86 236 322 **Sensitivity:** 75.6% **Specificity**: 67.8% **Raw data** Outcome: Yes / No Predictive test: Yes 65 76 141; No 21 160 181; 86 236 322 **Sensitivity:** 88.4% **Specificity**: 58.1% **Raw data** Outcome: Yes / No	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Outcome 9: Sensitivity and specificity Braden-Q scale cut-off 16	<table><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>76</td><td>99</td><td>175</td></tr><tr><td>No</td><td>10</td><td>137</td><td>147</td></tr><tr><td></td><td>86</td><td>236</td><td>322</td></tr></table> **Sensitivity:** 91.9% **Specificity**: 44.1% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>79</td><td>132</td><td>211</td></tr><tr><td>No</td><td>7</td><td>104</td><td>111</td></tr><tr><td></td><td>86</td><td>236</td><td>322</td></tr></table>	
			Outcome 10:	**Sensitivity:** 100.0% **Specificity**: 30.1% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr></table>	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Sensitivity and specificity Braden-Q scale cut-off 17		

		Yes	No	
Predictive test	Yes	86	165	251
	No	0	71	71
		86	236	322

Sensitivity: 100.0%

Specificity: 19.9%

Raw data

		Outcome		
		Yes	No	
Predictive test	Yes	86	189	275
	No	0	47	47
		86	236	322

Outcome 11:

Sensitivity and specificity Braden-Q scale cut-off 18

Sensitivity: 100.0%

Specificity: 8.1%

Raw data

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Outcome 12: Sensitivity and specificity Braden-Q scale cut-off 19		
			Outcome 13: Sensitivity and		

		Outcome		
		Yes	No	
Predictive test	Yes	86	217	303
	No	0	19	19
		86	236	322

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			specificity Braden-Q scale cut-off 120		

Table 6: de Souza 2010[62]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: de Souza (2010) **Title:** Predictive validity of the Braden scale for pressure ulcer risk in elderly residents of long-term care facilities Journal**:** Geriatric nursing, 31(2): 95-104. **Study type:** prospective cohort study (secondary analysis)	**Patient group:** elderly patients residing in LTCFs. **All patients** **Included N:** 233 **Completed N:** 233 **Drop-outs:** 0 **Age (mean years (SD)):** 76.6 (9.2) **Gender (m/f):** 104/129 **Length of stay (mean**	**Predictive test 1:** the Braden scale (Braden and Bergstrom 1994) **Outcome:** development of pressure ulcer grade 1 or above, according to the EPUAP (2008) classification. **Preventative methods:** change of the patient's position and minimization of skin exposure to moisture	**Outcome 1:** Incidence of PU in total group (not reported) **Outcome 2:** Incidence of PU in subgroup (not reported) **Outcome 3:** Sensitivity and	**Value:** 18.9% **Value**: 39.4% **Sensitivity:** 75.0% **Specificity**: 75.7%	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on blinding; no sub-analyses according to preventative measures. Only

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Selection patient: Elderly patients residing in LTCF with a Braden score < 19. Recruitment strategy not reported. **Predictive test:** Braden scale was used to assess PU risk every 2 days for 3 months. Assessment were carried out by trained observers. **Outcome:** Skin assessment was performed every 2 days for 3 months. Assessment were carried out by trained observers. **Imputation:** no imputation, no exclusion **Number of events:** 44 patients developed	**days (SD); range):** 3685.37 (4266.4); 1-23360 **Number of patients with a PU:** 44 **Number of patients without a PU:** 189 **Subgroup (Braden score < 18)** **Included N:** 94 **Completed N:** 94 **Drop-outs:** 0 **Age (mean years (SD)):** 79.1 (9.6) **Gender (m/f):** 35/52 Length of stay (mean days (SD)): 3979.51 (5371.3) **Number of patients with a PU:** 37		specificity Braden scale cut-off 17 in total group // last assessment (3 months?) **Outcome 4:** Sensitivity and specificity Braden scale cut-off 17 in subgroup // last assessment (3 months?)	**Raw data** Outcome Yes / No Predictive test: Yes 33 46 79 No 11 143 154 44 189 233 **Sensitivity:** 56.8% **Specificity**: 71.9% **Raw data** Outcome Yes / No Predictive test: Yes 21 16 37 No 16 41 57 37 57 94	patients with a Braden score < 19 were included! Unclear if patients with a pressure ulcer at start of the study were included **Additional outcomes:** sensitivity and specificity on day 0 **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** The predictive validity of a test is determined by the sensitivity and specificity of the test. Sensitivity and specificity can be graphically represented by the receiver operating characteristic (ROC) curve that plots the true-positive rate (sensitivity) against the false-positive rate (1-specificity). The test is considered good when the ROC curve falls above the diagonal line. There is a quantitative and	**Number of patients without a PU:** 57 **Inclusion criteria:** aged 60 years and older; Braden score < 19; agreement to participate **Exclusion criteria:** /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
qualitative relationship between the area under the curve (AUC) and accuracy, which may be classified as excellent (0.80–0.90), very good (0.70–0.79), good (0.60–0.69), and poor (0.50–0.59). The patients were assessed for 3 consecutive months, and data from the first and last (before any of the aforementioned outcomes) assessments were used for statistical analysis. **Setting:** 4 LTCFs located in 3 cities in Southern Minas Gerais, Brazil. **Blinding:** no blinding					

Table 7: Feuchtinger 2007[75]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Feuchtinger (2007) **Title:** Pressure ulcer risk assessment immediately after cardiac surgery--does it make a difference? A comparison of three pressure ulcer risk assessment instruments within a cardiac surgery population Journal**:** Nursing in Critical Care, 12(1): 42-49. **Study type:** prospective cohort study **Selection patient:** ICU patients consecutively	**Patient group:** cardiac surgery ICU patients. **All patients** **Included N:** 53 **Completed N:** 53 completed assessment on admission to the ICU and day 1. 36 patients completed the assessment after day 2, 20 after day 3 and 17 after day 4. **Drop-outs:** 0 for assessment on admission to the ICU and day 1. 17 for assessment on day 2, another 16 for assessment on day 3 and another 3 for assessment on day 4. **Age (mean years (SD);**	**Predictive test 1:** the Braden scale (Bergstorm et al. 1987) **Predictive test 2:** the modified Norton scale (Bienstein, 1991) **Predictive test 2:** the four-factor model (Halfens et al. 2000) **Outcome:** development of pressure ulcer grade 1 or above, according to the EPUAP (2005a) classification. **Preventative methods:** Not reported	**Outcome 1:** Incidence of PU (1 day) **Outcome 2:** Incidence of PU (1 week) **Outcome 3:** Sensitivity and specificity Braden scale cut-off 9 // day 1	**Value:** 49% **Value**: 62.3% **Sensitivity:** 19.2% **Specificity**: 100.0% **Raw data** [illegible]	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on blinding; no report on preventative measures; no report on statistical analysis; no sub-analyses according to preventative measures. **Additional outcomes:** / **Notes:** /

		Outcome		
		Yes	No	
Predictive test	Yes	5	0	5
	No	21	27	48
		26	27	53

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
recruited after cardiac surgery. **Predictive test:** Braden scale, modified Norton scale and 4-factor model of Halfens (2000) were used to assess PU risk after surgery and the four following days. Assessment were carried out by trained observers. **Outcome:** Skin assessment was performed preoperative, postoperative and the four following days. Assessment were carried out by trained observers. **Imputation:** no imputation, no exclusion **Number of events:** 26	**range):** 62 (12.1); 25-83 **Gender (m/f):** 31/22 **Number of patients with a PU:** 33 **Number of patients without a PU:** 20 **Inclusion criteria:** cardiac surgery patients with a length of stay of ≥24h in ICU **Exclusion criteria:** /		**Outcome 4:** Sensitivity and specificity Braden scale cut-off 10 // day 1 **Outcome 5:** Sensitivity and specificity Braden scale cut-off 11 // day	**Sensitivity:** 23.1% **Specificity**: 100.0% **Raw data** Outcome: Yes / No Predictive test – Yes: 6 / 0 / 6 Predictive test – No: 20 / 27 / 47 Predictive test – : 26 / 27 / 53 **Sensitivity:** 30.8% **Specificity**: 100.0% **Raw data** Outcome: Yes / No Predictive – Yes: 8 / 0 / 8 Predictive – No: 18 / 27 / 45	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
patients developed ulcers **Addressing missing data:** 53 patients were assessed postoperative and on day 1. 36 patients were assessed on day 2, 20 on day 3 and 14 on day 4. **Statistical analysis:** Not reported **Setting:** ICU; no further information. **Blinding:** no blinding			1 **Outcome 6:** Sensitivity and specificity Braden scale cut-off 16 // day 1	test | | 26 | 27 | 53 **Sensitivity:** 76.9% **Specificity**: 29.6% **Raw data** | | | Outcome | | | | | Yes | No | | Predictive test | Yes | 20 | 19 | 39 | | No | 6 | 8 | 14 | | | 26 | 27 | 53 **Sensitivity:** 96.2% **Specificity**: 3.7% **Raw data** | | | Outcome | | | | | Yes | No | | Predic | Yes | 25 | 26 | 51	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Outcome 7: Sensitivity and specificity Braden scale cut-off 20 // day 1	tive test / No: 1, 1, 2 26, 27, 53 **Sensitivity:** 26.9% **Specificity**: 100% **Raw data** Outcome: Yes / No Predictive test: Yes: 7, 0, 7 No: 19, 27, 46 26, 27, 53	
			Outcome 8: Sensitivity and specificity modified Norton scale cut-off 19 // day 1	**Sensitivity:** 34.6% **Specificity**: 92.6% **Raw data** Outcome: Yes / No	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

Predictive test	Yes	9	2	11
	No	17	25	42
		26	27	53

Outcome 9:

Sensitivity and specificity modified Norton scale cut-off 21 // day 1

Sensitivity: 42.3%

Specificity: 88.9%

Raw data

		Outcome		
		Yes	No	
Predictive test	Yes	11	3	14
	No	15	24	39
		26	27	53

Outcome 10:

Sensitivity: 57.7%

Specificity: 48.1%

Raw data

		Outcome	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Sensitivity and specificity modified Norton scale cut-off 23 // day 1		
			Outcome 11: Sensitivity and specificity modified Norton scale cut-off 25 // day 1		

		Yes	No	
Predictive test	Yes	15	14	29
	No	11	13	24
		26	27	53

Sensitivity: 84.6%

Specificity: 29.6%

Raw data

		Outcome		
		Yes	No	
Predictive test	Yes	22	19	41
	No	4	8	12
		26	27	53

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			Outcome 12: Sensitivity and specificity 4-factor model cut-off 25 // day 1		

Table 8: Hatanaka 2007[96]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Hatanaka (2007) **Title:** A new predictive indicator for development of pressure ulcers in bedridden patients based on common laboratory tests results Journal Journal of Clinical Pathology, 61: 514-518. **Study type:** prospective cohort study **Selection patient:** Bedridden patients hospitalized for a respiratory disorder. Recruitment strategy	**Patient group:** bedridden hospitalized patients. **All patients** **Included N:** 149 **Completed N:149** **Drop-outs:** 0 **Age (mean years (SD)):** 71.6 (11.3) **Gender (m/f):** 104/45 **Number of patients with a PU:** 38 **Number of patients without a PU:** 111 **Inclusion criteria:** Required constant	**Predictive test 1:** the Braden scale **Outcome:** development of pressure ulcer was defined as more than grade 1 (closed-persistent erythema) **Preventative methods:** All patients were given a standard pressure-relieving mattress during hospitalization.	**Outcome 1:** Incidence of PU (5-79 days) **Outcome 2:** Area under the ROC Braden scale	**Value:** 25.5% **Value:** 0.56	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; predictive test only on admission; no report on blinding; no description of preventative measures; no sub-analyses according to preventative measures. **Additional**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
not reported. **Predictive test:** Braden scale was used to assess PU risk on admission. **Outcome:** Pressure ulcer development was observed over a three months period, hospital discharge or PU development. **Imputation:** no imputation, no exclusion **Number of events:** 38 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** A receiver operating characteristic (ROC)	attentive care or need of a considerable amount of assisted care **Exclusion criteria:** /				**outcomes:** AUC of new indicator based on laboratory results **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
curves analysis was performed. **Setting:** One hospital, Nara, Japan. **Blinding:** no blinding					

Table 9: Jalali 2005[105]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Jalali (2005) **Title:** Predicting pressure ulcer risk: comparing the predictive validity of 4 scales Journal Advances in Skin & Wound Care, 18(2): 92-97. **Study type:**	**Patient group:** hospitalized patients. **All patients** **Included N:** 230 **Completed N:** 230 **Drop-outs:** 0 **Age (mean years; range):** 60; 21-89 **Gender (m/f):** 100/130	**Predictive test 1:** the Braden scale (Bergstorm et al. 1987) **Predictive test 2:** the Norton scale (Norton, 1962) **Predictive test 3:** the Gosnell scale (Gosnell, 1973) **Predictive test 4:** the Waterlow scale (Waterlow 1985) **Outcome:** development of	**Outcome 1:** Incidence of PU (> 1 week; 2 weeks) **Outcome 2:** Sensitivity and specificity Braden scale (threshold very likely to be 18)	**Value:** 9.10% **Sensitivity:** 52.7% **Specificity**: 100.0% **Raw data** [ ] [ ] Outcome [ ]	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; predictive test only within 48h of admission; no report on

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
prospective cohort study **Selection patient:** Patients from a neurology, intensive care, orthopaedic and medical unit. Recruitment strategy not reported. **Predictive test:** Braden scale, Norton scale, Gosnell scale and Waterlow scale were used to assess PU risk within 48h of admission. Patients were screened by trained research staff. **Outcome:** Skin assessment was performed once every 24h for a maximum of 14 days to assess the presence or absence of a PU. Patients were screened by trained	**Number of patients with a PU:** Stage I: 18 Stage II: 48 Stage III: 8 **Pressure ulcer location:** Sacrum: 54 Buttocks: 10 Heels: 6 Scapula: 4 **Number of patients without a PU:** 156 **Inclusion criteria:** age of 21 years or older; admitted to the hospital within the past 48h; expected stay of 14days or longer;	pressure ulcer according to criteria of Bergstorm et al. (1994) **Preventative methods:** Common preventative and nursing measures were recorded.	**Outcome 3:** Sensitivity and specificity Norton scale threshold 16	<table><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>39</td><td>0</td><td>39</td></tr><tr><td>No</td><td>35</td><td>156</td><td>191</td></tr><tr><td></td><td>74</td><td>156</td><td>230</td></tr></table> **Sensitivity:** 48.6% **Specificity**: 100.0% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>36</td><td>0</td><td>36</td></tr><tr><td>No</td><td>38</td><td>156</td><td>194</td></tr><tr><td></td><td>74</td><td>156</td><td>230</td></tr></table> **Sensitivity:** 85.1% **Specificity**: 83.3% **Raw data**	blinding concerning skin assessment; unclear what is meant with assessment by 4 independent nurses; no description of preventative measures; no sub-analyses according to preventative measures; no report on thresholds of risk assessment tools. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
research staff. **Imputation:** no imputation, no exclusion **Number of events:** 74 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** Predictive power was measured by the overall considerations of sensitivity, specificity, positive predictive value, and negative predictive value. **Setting:** three educational hospitals in Kermanshah, Iran. **Blinding:** the four risk	no PU during initial skin assessment **Exclusion criteria:** /		**Outcome 4:** Sensitivity and specificity Grosnell scale cut-off 16 **Outcome 5:** Sensitivity and specificity Waterlow scale cut-off 16	<table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>63</td><td>26</td><td>89</td></tr><tr><td>No</td><td>11</td><td>130</td><td>141</td></tr><tr><td></td><td>74</td><td>156</td><td>230</td></tr></table> **Sensitivity:** 63.5% **Specificity**: 83.3% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>47</td><td>26</td><td>73</td></tr><tr><td>No</td><td>27</td><td>130</td><td>157</td></tr><tr><td></td><td>74</td><td>156</td><td>230</td></tr></table>	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
assessment tool were assessed by four independent research nurses; no information for skin assessment.					

Table 10: Kim 2009[115]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Kim (2009) **Title:** Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical ICU patients Journal Australian Journal of Advanced Nursing, 26(4): 87-94. **Study type:** prospective study	**Patient group:** surgical ICU patients ≥ 16 years. **All patients** **Included N:** 219 **Completed N:** 219 **Drop-outs:** 0 **Age (mean years (SD); range):** 58.1 (1.2); 16-98 **Gender (m/f):** 145/74 **Number of patients**	**Predictive test 1:** the Braden scale **Predictive test 2:** the Song and Choi scale (Song and Choi, 1991) **Predictive test 3:** the Cubbin and Jackson scale (Cubbin and Jackson, 1991) **Outcome:** development of pressure ulcer according to criteria of AHRQ (1994) **Preventative methods:**	**Outcome 1:** Incidence of PU (> 1 week; 90 days) **Outcome 2:** Area under the ROC Braden scale **Outcome 3:**	**Value:** 18.3% **Value:** 0.881	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; predictive test only at admission; blinding unclear; no sub-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Selection patient: Patients from a surgical intensive care unit. Recruitment strategy not reported. **Predictive test:** Braden scale, Song and Choi scale, Cubbin and Jackson scale were used to assess PU risk at admission. Patients were screened by a trained research nurse. **Outcome:** Skin assessment was performed daily between 10:00 and 11:00 am until discharge (stay: 3-90 days). Patients were screened by a trained research nurse. **Imputation:** no	**with a PU:** Stage I: 15 Stage II: 25 **Pressure ulcer location:** Coccyx: 25 Other: 15 **Number of patients without a PU:** 179 **Inclusion criteria:** age of 16 years or older; no existing PU on admission; admitted to the SICU **Exclusion criteria:** /	All patients received ordinary nursing interventions, especially those related to pressure ulcer prevention. Their position was changed every two hours and they were dried, cleaned and friction/shear managed to prevent pressure ulcers.	Area under the ROC Song and Choi scale **Outcome 4:** Area under the ROC Cubbin and Jackson scale **Outcome 5:** Sensitivity and specificity Braden scale cut-off 14	**Value:** 0.890 **Value:** 0.903 **Sensitivity:** 92.5% **Specificity**: 69.8% **Raw data** Predictive test: Yes: 37 / 54 / 91; No: 3 / 125 / 128; Outcome: 40 / 179 / 219	analyses according to preventative measures. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
imputation, no exclusion **Number of events:** 40 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** The parameters for evaluating the predictive validity of each assessment scale included sensitivity, specificity, PVP and PVN. The ROC curve shows how the sensitivity proportion (vertical axis) varies with the false-positive proportion (horizontal axis, 1-specificity) as the			**Outcome 6:** Sensitivity and specificity Song and Choi scale cut-off 21	**Sensitivity:** 95.0% **Specificity**: 69.3% **Raw data** Outcome: Yes / No Predictive test, Yes: 38 / 55 / 93 Predictive test, No: 2 / 124 / 126 40 / 179 / 219	
			Outcome 7: Sensitivity and specificity Cubbin and Jackson cut-off 28	**Sensitivity:** 95.0% **Specificity**: 81.6% **Raw data** Outcome: Yes / No Predictive, Yes: 38 / 33 / 71 Predictive, No: 2 / 146 / 148	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
decision criterion is varied. **Setting:** one surgical ICU of a South-Korean hospital. **Blinding:** the head-nurse assessed each scale and skin assessment tool.				test | | 40 | 179 | 219	

Table 11: Kwong 2005[126]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Kwong (2005) **Title:** Predicting pressure ulcer risk with the modified Braden, Braden, and Norton scales in acute care hospitals in Mainland China Journal**:** Applied Nursing Research, 18	**Patient group:** hospitalized patients of all ages. **All patients** **Included N:** 429 **Completed N:** 429 **Drop-outs:** 0 **Age (mean years (SD);**	**Predictive test 1:** the Braden scale (Braden and Bergstrom, 1987) **Predictive test 2:** the modified Braden scale (Pand and Wong, 1998) **Predictive test 3:** the Norton scale (Norton et al., 1975) **Outcome:** development of pressure ulcer according to criteria of the NPUAP (1989)	**Outcome 1:** Incidence of PU (> 1 week; 21 days) **Outcome 2:** Sensitivity and specificity Braden scale	**Value:** 2.1% **Sensitivity:** 88.9% **Specificity**: 71.9% **Raw data**	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; predictive test

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
(2); 122-128. **Study type:** prospective study **Selection patient:** Patients from any ward in two acute care hospitals. Recruitment strategy not reported. **Predictive test:** Braden scale, modified Braden scale and Norton scale were used to assess PU risk at admission. Patients were screened by trained nurses. **Outcome:** Skin assessment was performed daily until discharge, transfer or 21-day hospitalisation. Patients were screened by trained	**range):** 54.07 (16.9); 5-93 **Gender (m/f):** 253/176 **Number of patients with a PU:** Stage I: 8 Stage II: 1 **Pressure ulcer location:** Sacral area: 4 Right iliac region: 2 Abdomen: 1 Left knee: 1 Right ankle: 1 **Number of patients without a PU:** 420 **Inclusion criteria:** Free of PU within 24h of admission	**Preventative methods:** Nurses working in the ward relied on their clinical judgment to determine and perform preventative nursing interventions on the subjects. Preventative measures could be: turning every 2h, use of material to reduce pressure, keeping bed linen clean, dry, and smooth, keeping skin clean and dry, positioning, use of draw sheet for lifting patients, and massage of pressure points.	cut-off 14 **Outcome 3:** Sensitivity and specificity modified Braden scale cut-off 16	<table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>8</td><td>118</td><td>126</td></tr><tr><td>No</td><td>1</td><td>302</td><td>303</td></tr><tr><td></td><td>9</td><td>420</td><td>429</td></tr></table> **Sensitivity:** 88.9% **Specificity**: 75.0% **Raw data** <table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive test</td><td>Yes</td><td>8</td><td>105</td><td>113</td></tr><tr><td>No</td><td>1</td><td>315</td><td>316</td></tr><tr><td></td><td>9</td><td>420</td><td>429</td></tr></table> **Sensitivity:** 88.9% **Specificity**: 61.0%	only at admission; no blinding of scales and skin assessment; no sub-analyses according to preventative measures. **Additional outcomes:** / **Notes:** Pressure ulcers located to the iliac region and abdomen could be the result of medical devices. However, this is not stated in the article.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
nurses. **Imputation:** no imputation, no exclusion **Number of events:** 9 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** not reported **Setting:** two acute care hospitals in Mainland China. **Blinding:** three nurses form each ward assessed the three scales and skin condition independent of each other. No blinding between scale and PU development	**Exclusion criteria:** /		**Outcome 4:** Sensitivity and specificity Norton scale cut-off 14	**Raw data** Outcome Yes / No Predictive test: Yes 8 164 172 No 1 256 257 9 420 429	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
as one of the three nurses performed this assessment.					

Table 12: Lincoln 1986[133]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Lincoln (1986) **Title:** Use of the Norton Pressure Sore risk assessment scoring system with elderly patients in acute care Journal**:** Journal of Enterostomy Therapy, 13; 132-138. **Study type:** prospective study **Selection patient:**	**Patient group:** hospitalized medical-surgical patients aged 65 years and older. **All patients** **Included N:** 50 **Completed N:** 36 **Drop-outs:** 14 (stayed 3 days or less) **Age (mean years (SD); range):** 72.2 (15.8); 65-89 **Gender (m/f):** 23/27	**Predictive test 1:** the Norton scale (assessment on admission used) **Outcome:** development of pressure ulcer according to a 5-point scale: 0 = no change, 1 = erythema, 2 = superficial skin opening, 3 = a lesion extending into underlying tissue, 4 = involvement of muscle and bone **Preventative methods:** Preventative measures were given but not reported. Nurses giving prevention	**Outcome 1:** Incidence of PU (max. 26 days) **Outcome 2:** Sensitivity and specificity Norton scale cut-off 14	**Value:** 13.9% **Sensitivity:** 0.0% **Specificity**: 93.5% **Raw data** Outcome: Yes / No Predictive: Yes 0 2 2; No 5 29 34	**Funding:** the research was funded by the Dean's Research fund, Frances Payne Bolton School of Nursing, Case Western Reserve University **Limitations:** no imputation, no exclusion; low event rate; not reported when

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Hospitalized surgical-medical patients. Recruitment strategy not reported. **Predictive test:** Norton scale was used to assess PU risk at admission and every 3 days until discharge or death. Patients were screened by research assistants. **Outcome:** Skin assessment was performed at admission and every 3 days until discharge or death. Patients were screened by research assistants. **Imputation:** no imputation, no exclusion **Number of events:** 5 patients developed	**Length of stay (mean days; range):** 7.88; 2-26 **Number of patients with a PU:** 5 of the 36 **Pressure ulcer location:** Primarily on heels and elbows, and one sacral lesion **Number of patients without a PU:** 31 **Inclusion criteria:** Age over 65 years; absence of pressure sores on admission **Exclusion criteria:** /	were unaware of Norton score		test | | 5 | 31 | 36	patients dropped from the study; predictive test assessed on admission used; no blinding of; no sub-analyses according to preventative measures. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** not reported **Setting:** two divisions in a teaching hospital in the Midwest. **Blinding:** not reported					

Table 13: Ongoma 2005[170]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Ongoma (2009) **Title:** Predictive validity of pressure risk assessment scales in a private sector trauma intensive care unit	**Patient group:** ICU patients older than 18 years. **All patients** **Included N:** 66	**Predictive test 1:** the Sunderland Pressure Sore Risk Calculator (modified Cubbin and Jackson) (Lowery 1995) **Predictive test 2:** a modified Norton scale (hospital South Africa)	**Outcome 1:** Incidence of PU (1 week) **Outcome 2:**	**Value:** 37.9% **Sensitivity:** 80.0%	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Journal**:** Southern African Journal of Critical Care, 21 (2); 78-86. **Study type:** prospective study **Selection patient:** Patients admitted to the ICU of a private institution. Purposive sampling; not further specified. **Predictive test:** Sunderland Pressure Sore Risk Calculator (modified Cubbin and Jackson) and a modified Norton scale were used to assess PU risk at admission and on a weekly basis for three weeks or until discharge or death.	**Completed N:** 66 completed assessment on admission and after one week. 34 patients completed the assessment after 2 weeks and 17 after 3 weeks. **Drop-outs:** 0 for assessment on admission and after one week. 32 for assessment on week 2 and another 17 for assessment on week 3. **Age (range):** 18-65 **Gender (m/f):** 56/10 **Number of patients with a PU:** 25 **Pressure ulcer location (total of 44 PU):** Heels: 19 Occiput: 7	**Outcome:** development of pressure ulcer; criteria not specified **Preventative methods:** Not reported	Sensitivity and specificity Sunderland Pressure Sore Risk Calculator cut-off 35 // week 1 **Outcome 3:** Sensitivity and specificity modified Norton scale cut-off 20 / week 1	**Specificity**: 70.7% **Raw data** |		Outcome		
		Yes	No	
Predictive test	Yes	20	12	32
	No	5	29	34
		25	41	66 | **Sensitivity:** 92.0% **Specificity**: 29.3% **Raw data** |		Outcome		
		Yes	No	
Predictive test	Yes	23	29	52
	No	2	12	14
		25	41	66		blinding; unclear which is the modified Norton scale; no report on criteria of PU classification nor assessment; no report on preventative measure; no report no sub-analyses according to preventative measures. **Additional outcomes:** sensitivity and specificity on day 0 **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Outcome: PU development based on record review was performed daily. **Imputation:** no imputation, no exclusion **Number of events:** 25 patients developed ulcers **Addressing missing data:** 66 patients were assessed on admission and after one week. 34 patients were assessed after 2 weeks and 17 after 3 weeks. **Statistical analysis:** Inferential statistics were used to compare the total scores (predicted risk) with the outcome (pressure ulcer development), in order to determine	Buttocks: 7 Sacrum: 3 Ankles: 2 Knees: 2 Elbows: 1 Ears: 1 Nose: 1 Forehead: 1 **Number of patients without a PU:** 41 **Inclusion criteria:** Age between 18 and 65 years; No pressure ulcer on admission; Total bedrest due to injuries or medical interventions				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
their predictive values. **Setting:** the ICU of a private sector health care institution, South Africa. **Blinding:** not reported	**Exclusion criteria:** extensive burns in the back, buttocks and legs				

Table 14: Page 2011[172]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Page (2011) **Title:** Development and validation of pressure ulcer risk assessment tool for acute hospital patients Journal**:** Wound Repair and Regeneration, 19; 31-37. **Study type:** prospective study	**Patient group:** hospitalized patients. **All patients** **Included N:** 165 **Completed N:** 165 **Drop-outs:** 0 **Number of patients > 65 years:** 107 **Gender (m/f):** 87/78	**Predictive test 1:** The Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP) (Page 2011) **Outcome:** development of pressure ulcer grade 1; not further specified **Preventative methods:** A prevention protocol was implemented.	**Outcome 1:** Incidence of PU (not reported) **Outcome 2:** Area under the ROC TNH-PUPP **Outcome 3:**	**Value:** 4.2% **Value:** 0.90 **95% CI:** 0.82-0.99 **Sensitivity:** 100.0%	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on time of assessment of predictive test and outcome; not reported when patients dropped from

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Selection patient: Patients admitted to a general ward, critical care or emergency department of a hospital. Recruitment strategy not reported. **Predictive test:** The Northern Hospital Pressure Ulcer Prevention Plan was used to assess PU risk. Patients were screened by trained nurses. **Outcome:** PU development was identified by the nursing staff who received an education session of 30 minutes. **Imputation:** no imputation, no exclusion	**Length of stay (mean days (SD)):** 14.97 (22.29) **Number of patients with a PU:** 7 **Number of patients without a PU:** 158 **Inclusion criteria:** / **Exclusion criteria:** /		Sensitivity and specificity TNH-PUPP cut-off 1 **Outcome 4:** Sensitivity and specificity TNH-PUPP cut-off 2	**Specificity**: 34.2% **Raw data** |		Outcome		
		Yes	No	
Predictive test	Yes	7	104	111
	No	0	54	54
		7	158	165 | **Sensitivity:** 85.7% **Specificity**: 62.0% **Raw data** |		Outcome		
		Yes	No	
Predictive test	Yes	6	60	66
	No	1	98	99
		7	158	165		the study; no inclusion and exclusion criteria reported; no report on blinding; no report on criteria of PU classification; no report no sub-analyses according to preventative measures. **Additional outcomes:** **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Number of events: 7 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** The predictive accuracy of the TNH-PUPP was measured by the parameters area under the receiver operating curve (AUC), sensitivity, specificity, PPV, NPV, Youden Index, and prognostic separation index. An AUC of 1 indicates perfect prediction, whereas 0.5 represents the prediction expected by chance. Sensitivity,			**Outcome 5:** Sensitivity and specificity TNH-PUPP cut-off 3 **Outcome 6:** Sensitivity and specificity TNH-PUPP cut-off 4	**Sensitivity:** 71.4% **Specificity**: 81.0% **Raw data** **Sensitivity:** 71.4% **Specificity**: 88.0% **Raw data**	

		Outcome		
		Yes	No	
Predictive test	Yes	5	30	35
	No	2	128	130
		7	158	165

		Outcome		
		Yes	No	
Predictive test	Yes	5	19	24
	No	2	139	141
		7	158	165

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
specificity, PPV, and NPV values > 0.70 are reported to be evidence of high predictive accuracy. **Setting:** the general wards, critical care and emergency department of an acute, metropolitan, public teaching hospital in Melbourne, Australia. **Blinding:** not reported			**Outcome 7:** Sensitivity and specificity TNH-PUPP cut-off 5	**Sensitivity:** 42.9% **Specificity**: 96.2% **Raw data** Outcome: Yes / No Predictive test – Yes: 3, 6, 9 Predictive test – No: 4, 152, 156 7, 158, 165	
			Outcome 8: Sensitivity and specificity TNH-PUPP cut-off 6	**Sensitivity:** 57.1% **Specificity**: 99.4% **Raw data** Outcome: Yes / No Predictive – Yes: 4, 1, 5 Predictive – No: 3, 157, 160	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
				test | | 7 | 158 | 165	

Table 15: Serpa 2009[203]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Serpa (2009) **Title:** Predictive validity of Waterlow Scale for pressure ulcer development risk in hospitalized patients. Journal**:** Journal of Wound Ostomy & Continence Nursing, 36(6); 640-646. **Study type:** prospective study (secondary analysis)	**Patient group:** hospitalized patients older than 18 years. **All patients** **Included N:** 98 **Completed N:** 98 **Drop-outs:** 0 before three consecutive assessments **Age (mean years (SD); range):** 71.1 (15.5); 29-96 **Number of patients with a PU:**	**Predictive test 1:** the Portuguese Waterlow scale (Paranhos & Santos, 1999) **Outcome:** development of pressure ulcer; not further specified. **Preventative methods:** Not reported	**Outcome 1:** Incidence of PU (< 1 week; 2 days) **Outcome 2:** Area under the ROC first assessment (48h) **Outcome 3:** Area under the ROC second	**Value:** 7.1% **Value:** 0.64 **95% CI:** 0.35-0.93 **Value:** 0.59	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on blinding; no report on skin assessment and criteria of classification; no report on preventative measures; no sub-analyses according to preventative

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Selection patient: Patients at risk for PU from any ward in a general private hospital. Recruitment strategy not reported. **Predictive test:** Portuguese Waterlow scale was used to assess PU risk at admission. The patient was assessed for the first time and then at 48-hours intervals as long as the patient remained at risk or until PU development, discharge, transfer or death. **Outcome:** PU development; no further information. **Imputation:** no imputation, no	Stage I: 6 Stage II: 1 **Number of patients without a PU:** 91 **Inclusion criteria:** Age equal to 18 years or older; absence of PU at first assessment; hospitalized for a minimum period of 24 hours and a maximum period of 48 hours at first assessment; a total Braden Scale score equal to 18 or less and a Waterlow Scale score equal to 16 or more. **Exclusion criteria:** Additional criteria (data from another study):		assessment (4 days) **Outcome 4:** Area under the ROC third assessment (6 days) **Outcome 5:** Sensitivity and specificity Waterlow scale cut-off 17 // 48h **Outcome 6:** Sensitivity and	**95% CI:** 0.34-0.83 **Value:** 0.54 **95% CI:** 0.35-0.74 **Sensitivity:** 71.4% **Specificity**: 67.0% **Raw data** Outcome Yes / No Predic / Yes / 5 / 30 / 35	measures. Only patients at risk were included! **Additional outcomes:** / **Notes:** Braden scale scores were also collected, but no results of these scores were reported.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
exclusion **Number of events:** 7 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** The predictive validity of the Waterlow Scale for the development of PU in hospitalized patients was analyzed by using 2 methods: receiver operating characteristic (ROC) curve and likelihood ratio (LR). **Setting:** a medium-size general private hospital in the city of São Paulo, Brazil. **Blinding:** not	patients with chronic renal failure; patients on dialyse for more than 1 month; patients with liver insufficiency accompanied with ascites.		specificity Waterlow scale cut-off 20 // 4 days **Outcome 7:** Sensitivity and specificity Waterlow scale cut-off 20 // 6 days	tive test: No 2 61 63; 7 91 98 **Sensitivity:** 85.7% **Specificity**: 40.7% **Raw data** Outcome: Yes / No Predictive test: Yes 6 54 60; No 1 37 38; 7 91 98 **Sensitivity:** 85.7% **Specificity**: 33.0% **Raw data** Outcome: Yes / No	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
reported.				Predictive test: Yes 6 61 67; No 1 30 31; 7 91 98	

Table 16: Serpa 2011[204]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Serpa (2011) **Title:** Predictive validity of the Braden scale for pressure ulcer risk on critical care patients. Journal**:** Revista Latino-Americana de Enfermagem, 19(1); 50-57. **Study type:** prospective study (secondary analysis)	**Patient group:** ICU patients older than 18 years. **All patients** **Included N:** 72 **Completed N:** 72 **Drop-outs:** 0 before three consecutive assessments **Age (mean years (SD);):** 60.9 (16.5) **Number of patients**	**Predictive test 1:** the Portuguese Braden scale (Paranhos & Santos, 1999) **Outcome:** development of pressure ulcer; not further specified. **Preventative methods:** Not reported	**Outcome 1:** Incidence of PU (< 1 week; 2 days) **Outcome 2:** Area under the ROC first assessment (48h) **Outcome 3:**	**Value:** 11.1% **Value:** 0.788 **95% CI:** 0.29-1.00 **Value:** 0.789	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on blinding; no report on skin assessment and criteria of classification; no report on preventative measures; no sub-analyses

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Selection patient: Patients at risk for PU from an ICU. Recruitment strategy not reported. **Predictive test:** Portuguese Braden scale was used to assess PU risk at admission. The patient was assessed for the first time and then at 48-hours intervals as long as the patient remained at risk or until PU development, discharge, transfer or death. **Outcome:** PU development; no further information. **Imputation:** no imputation, no exclusion **Number of events:** 8	**with a PU:** Stage I: 3 Stage II: 5 **Number of patients without a PU:** 64 **Inclusion criteria:** Admitted to one of the four ICUs; age equal to 18 years or older; absence of PU at first assessment; hospitalized for a minimum period of 24 hours and a maximum period of 48 hours at first assessment; a total Braden Scale score equal to 18 or less; informed consent. **Exclusion criteria:** Additional criteria (data from another study):		Area under the ROC second assessment (4 days) **Outcome 4:** Area under the ROC third assessment (6 days) **Outcome 5:** Sensitivity and specificity Braden scale cut-off 12 // 48h	**95% CI:** 0.28-1.00 **Value:** 0.800 **95% CI:** 0.28-1.00 **Sensitivity:** 87.5% **Specificity**: 64.1% **Raw data** Outcome Yes / No Predictive: Yes 7 23 30 Predictive: No 1 41 42	according to preventative measures. Only patients at risk were included! **Additional outcomes:** / **Notes:** Braden scale scores were also collected, but no results of these scores were reported.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
patients developed ulcers **Addressing missing data:** patient stayed for a minimum of 6 days. **Statistical analysis:** Sensitivity was defied as the proportion of individuals with a positive test who develop a disease, and specificity as the proportion of individuals with a negative test who do not develop a disease. The ROC curve is a graphic plot of true positive values (sensitivity) on the ordinate and false positive values (1 – specificity) on the abscissa as a function of each cut-off point. There is an approximately linear quantitative-qualitative relationship between the area under the curve (AUC) and accuracy, which can be classified as follows:	patients with chronic renal failure; patients on dialyse for more than 1 month; patients with liver insufficiency accompanied with ascites.		**Outcome 6:** Sensitivity and specificity Braden scale cut-off 13 // 4 days **Outcome 7:** Sensitivity and specificity Braden scale cut-off 13 // 6 days	**Sensitivity:** 75.0% **Specificity**: 81.3% **Raw data** Outcome: Yes / No Predictive test – Yes: 6, 12, 18; No: 2, 52, 54; 8, 64, 72 **Sensitivity:** 75.0% **Specificity**: 82.8% **Raw data** Outcome: Yes / No Predic – Yes: 6, 11, 17; test: 8, 64, 72	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
excellent (0.80-0.90), very good (0.70-0.79), good (0.60-0.69), and poor (0.50-0.59) **Setting:** four ICUs of a large, non-profit charitable general hospital, Brazil. **Blinding:** not reported.				tive test: No: 2, 53, 55 : 8, 64, 72	

Table 17: Suriadi 2006[216]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Suriadi (2006) **Title:** A new instrument for predicting pressure ulcer risk in an intensive care unit. Journal**:** Journal of Tissue Viability, 16(3); 21-26.	**Patient group:** ICU patients of all age. **All patients** **Included N:** 105 **Completed N:** 105 **Drop-outs:** 0	**Predictive test 1:** the Braden scale **Outcome:** development of pressure ulcer according to the criteria of the NPUAP classification (Burd et al., 1992). **Preventative methods:**	**Outcome 1:** Incidence of PU (> 1 week; 22 days) **Outcome 2:** Area under the ROC	**Value:** 33.3% **Value:** 0.770 **95% CI:** 0.70-0.89	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Study type: prospective cohort study **Selection patient:** Patients admitted to an ICU. Recruitment strategy not reported. **Predictive test:** The Braden scale was used to assess PU risk after 24 hours. This assessment was repeated three times a week (stay: 3-22 days). Patients were screened by a research assistant. **Outcome:** Skin condition was assessed daily (stay: 3-22 days) by the primary researcher.	**Group PU+** **Age (mean years (SD); range):** 50.9 (17.0); 17-77 **Gender (m/f):** 24/11 **Number of patients with a PU:** Stage I: 21 Stage II: 14 **PU location:** Sacrum: 28 Heel: 4 Trochanter: 1 Elbow: 2 Vertebrae: 1 Scapula: 1 More than one PU: 3 **Group PU-**	Not reported	**Outcome 3:** Sensitivity and specificity Braden scale cut-off 14	**Sensitivity:** 80.0% **Specificity**: 54.3% **Raw data** Outcome: Yes / No Predictive test: Yes 28 32 60; No 7 38 45; 35 70 105	preventative measures; no sub-analyses according to preventative measures. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Imputation: no imputation, no exclusion **Number of events:** 35 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** In the statistical methods, diagnostic probabilities (sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV)) were calculated. In this study we also evaluated the likelihood ratio (LR) for this tools. A receiver-operating characteristic (ROC) curve plot of the sensitivity versus 1-	**Age PU- (mean years (SD); range):** 47.5 (17.6); 17-82 **Gender (m/f):** 48/22 **Number of patients without a PU:** 70 **Inclusion criteria:** Free of pressure ulcer; bedfast; could not walk. **Exclusion criteria:** Physically incapable of participating; refusal				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
specificity over the range of the Braden scale scores confirmed the cut-off value of the instrument **Setting:** an intensive care unit within Pontianak Public Hospital, Sei Jawi in West Kalimantan, Indonesia **Blinding:** The Braden scale was used by a research assistant and the skin condition was assessed by the primary researcher.					

Table 18: Suriadi 2008[215]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: Suriadi (2008) **Title:** Development of a new risk assessment	**Patient group:** ICU patients older than 18 yrs.	**Predictive test 1:** the Suriadi and Sanada scale **Outcome:** development of pressure ulcer according to	**Outcome 1:** Cumulative incidence of PU	**Unit 1:** 27% **Unit 2:** 31.6% **Total:** 28.5%	**Funding:** / **Limitations:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
scale for predicting pressure ulcers in an intensive care unit. Journal**:** British Association of Critical Care Nurses, 13(1); 34-43. **Study type:** prospective cohort study **Selection patient:** Patients admitted to an ICU. Patients were selected by the researcher. **Predictive test:** The SS (Suriadi and Sanada) scale was used to assess PU risk within 24 hours. Body temperature was repeated once a day. Patients were screened by a	**All patients** **Included N:** 253 **Completed N:** 253 **Drop-outs:** 0 **ICU 1** **Included N:** 174 **Completed N:** 174 **Drop-outs:** 0 **Age (mean years (SD)):** 55.2 (18.4) **Gender (m/f):** 104/70 **Number of patients with a PU:** Stage I: 20 Stage II: 22 Stage III: 5 Stage IV: 1	the criteria of the NPUAP classification (Ayello et al. 2003). **Preventative methods:** Not reported	**Outcome 2:** Incidence density of PU **Outcome 3:** Area under the ROC **Outcome 4:** Sensitivity and specificity SS scale cut-off 0	**Unit 1:** 0.060/100 person days **Unit 2:** 0.059/100 person days **Value:** 0.888 **95% CI:** 0.84-0.93 **Sensitivity:** 100.0% **Specificity**: 0.0% **Raw data** Outcome Yes / No Predictive test: Yes 72 181 253 No 0 0 0 72 181 253	only part predictive test repeated; end of observation PU development not reported; no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on preventative measures; no sub-analyses according to preventative measures; no report on withdrawal. **Additional outcomes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
research assistant. **Outcome:** Skin condition was assessed daily by a researcher. **Imputation:** no imputation, no exclusion **Number of events:** 72 patients developed ulcers **Addressing missing data:** not reported when patients dropped from the study **Statistical analysis:** To evaluate the accuracy of the S.S. scale, diagnostic probabilities [sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV)	One patient had more than one PU **PU location:** Sacrum: 44 Heel: 2 Trochanter: 1 Malleolus: 1 **ICU 2** **Included N:** 79 **Completed N:** 79 **Drop-outs:** 0 **Age (mean years (SD)):** 42.6 (18.8) **Gender (m/f):** 54/25 **Number of patients with a PU:** Stage I: 12 Stage II: 13		**Outcome 5:** Sensitivity and specificity SS scale cut-off 2 **Outcome 6:** Sensitivity and specificity SS scale cut-off 3	**Sensitivity:** 97.2% **Specificity**: 42.0% **Raw data** **Sensitivity:** 97.2% **Specificity**: 53.0% **Raw data**	**Notes:** /

		Outcome		
		Yes	No	
Predictive test	Yes	70	105	175
	No	2	76	78
		72	181	253

		Outcome		
		Yes	No	
Predictive test	Yes	70	85	155
	No	2	96	98
		72	181	253

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
and the likelihood ratio (LR)] were calculated for the range of the S.S. score. Area under the curve (AUC) of the ROC was calculated to assess the overall validity of the scale Incidence density is computed as the number of persons developing new pressure ulcers (numerator) divided by the total person-days [sum of all the days over which each patient participated in the study (denominator)] **Setting:** two intensive care units of two hospitals in Pontianak, Indonesia **Blinding:** two nurses being assessors used	**PU location:** Sacrum: 25 **Inclusion criteria:** Aged 18 yrs or more; admitted to the ICU at least 24h before enrolment; bedfast; no existing PU at time of enrolment; ability to give informed consent; Indonesian origin. **Exclusion criteria:** Active skin disease; previous enrolment in the study; physically incapable of participating; length of stay < 72 h after initial data collection.		**Outcome 7:** Sensitivity and specificity SS scale cut-off 4	**Sensitivity:** 80.6% **Specificity**: 82.9% **Raw data** Outcome: Yes / No Predictive test: Yes 58 31 89; No 14 150 164; 72 181 253 **Sensitivity:** 72.2% **Specificity**: 86.7% **Raw data** Outcome: Yes / No Predictive: Yes 52 24 76; No 20 157 177	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
their assigned scale to independently assess the patients.			**Outcome 8:** Sensitivity and specificity SS scale cut-off 5	**Sensitivity:** 61.1% **Specificity**: 92.3% **Raw data** Predictive test: Yes, 44, 14, 58; No, 28, 167, 195; 72, 181, 253 (Outcome: Yes / No) **Outcome 9:** Sensitivity and specificity SS scale cut-off 6 **Sensitivity:** 58.3% **Specificity**: 95.0% **Raw data** Predic Yes 42 9 51	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
				tive test: No 30 172 202 72 181 253	
			Outcome 10: Sensitivity and specificity SS scale cut-off 7	**Sensitivity:** 6.9% **Specificity**: 100.0% **Raw data** Outcome: Yes / No Predictive test: Yes 5 0 5 No 67 181 248 72 181 253	
			Outcome 11: Sensitivity and specificity SS		

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			scale cut-off 9		

G.1.1.1 Risk assessment – clinical effectiveness

Table 19: Saleh 2009[192]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Saleh (2009)* **Title:** The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients Journal**:** Journal of Clinical Nursing, 18; 1923-29.	**Patient group:** hospitalized patients with PU, and/or a Braden score of ≤18 (i.e. high risk group) **All patients** **Randomised 9 wards; N:** not reported	**Group 1: Braden scale group**. All nurses received a mandatory wound care management study day, PU prevention training programme and specific training on the application of the Braden scale. The nurses were required to implement the Braden scale after their training ('post-intervention')	**Outcome 1:** Incidence of PU	**Group 1:** 16/74 **Group 2:** 17/76 **Group 3:** 16/106 NB the numbers with pressure ulcers pre-training were: Group 1: 26/79 Group 2: 27/91	**Funding:** / **Limitations:** sequence generation not reported; allocation concealment not reported; no blinding; no report on baseline difference regarding presence of PU on admission; no intention-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study type: cluster randomized controlled trial; wards were the unit of allocation **Sequence generation:** not reported **Allocation concealment: not reported Blinding:** not reported **Addressing incomplete outcome data:** no intention-to-treat analysis. 198 patients were excluded because they were discharged before 8 weeks (total study period) **Statistical analysis:** Data were analysed by using descriptive and inferential statistical procedures (tests).	**Completed N:** 256 **Drop-outs:** not reported **Group 1** **Randomised 3 wards (male medical, isolation, male orthopaedic and spinal surgery); N:** not reported **Completed N:** 74 **Dropouts:** not reported **Age:** / **Gender (m/f):** / **Group 2** **Randomised 3 wards (rehabilitation, renal and neurosurgery); N:** not reported **Completed N:** 76	**Group 2: Training group:** All nurses received a mandatory wound care management study day, PU prevention training programme and training on the application of the Braden scale. Implementation of the Braden scale was not required. **Group 3: Clinical judgement group:** All nurses received a mandatory wound care management study day. **All groups:** all patients were monitored before and after training (pre- and post-intervention) and preventative measures were employed accordingly and included following categories: Protective mattresses such as the standard hospital bed		Group 3: 30/95	to-treat analyses and high dropout (discharge before end of study period); patients with PU before intervention included. Significant differences in baseline characteristics such as medical diagnosis, referral to the wound care team, protective measures, use of barrier creams and vitamin therapy. Group A had a higher proportion of people at severe risk of PU development Very high risk of bias! **Additional outcomes:** association was measured with PU incidence. AUC for Braden scale and clinical judgement were reported.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
The inferential statistics may be parametric or nonparametric. Chi-square test was used to test independence of nominal variables. Student t test for independent groups and one way ANOVA were not used to test differences between respectively two or more than two groups because the data were not normally distributed. Mann-Whitney U (MW) test and Kruskal-Wallis (KW) test were used to test differences between respectively two or more than two groups with data that were at least ordinal, but not sufficiently normally distributed to warrant parametric testing. Logistic	**Dropouts:** not reported **Age:** / **Gender (m/f):** / **Group 3** **Randomised 3 wards (female medical, oncology and VIP medical-surgical) ; N:** not reported **Completed N:** 106 **Dropouts:** not reported **Age:** / **Gender (m/f):** / **Inclusion criteria:** Braden scale ≤ 18 and/or having a PU stage I-IV. **Exclusion criteria:** Patients with a PU stage	mattress (Stryker®, Inc., Hamilton, ON, Canada), alternating pressure relief system Therakair® (Kinetic Concepts, Inc., San Antonio, TX, USA), Gen Air 8000® (Genadyne Inc., Great Neck, NY, USA), Atmosair® (Kinetic Concepts, Inc., USA) and gel overlay or air fluidised bed (Clinitron®, Hill-Rom, Inc., Batesville, IN, USA); Creams and skin barriers; Vitamin supplements and special nutritional formulas; Patients' turning (positioning) schedules every two, three to four, or six hours. Reasons for allocation of interventions not stated and person making decision unclear. 19.2% of patients were referred for wound management; 46.8% received barrier creams and			**Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
regression analysis was used to produce a predictive model from those recorded variables which are related to PU development. ROC curve analysis was used to show the effects of the Braden scale compared to nurses' clinical judgement in relation to PU development. **Baseline differences:** Baseline differences for medical diagnosis, protective measures, use of barrier creams and vitamin therapy. **Study power/sample size:** A priori sample size calculation indicated a sample size of 108 patients. Final sample size was higher than calculated.	I-IV and a Braden score > 18	39.9% received vitamins – these differed across groups.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: Military hospital, Riyadh, Saudi Arabia **Length of study:** eight weeks **Assessment of PUs:** A tissue viability nurse specialist and two trained staff nurses assed the wounds. **Classification of PUs:** US Agency for Health Care Policy and Research (1992). **Multiple ulcers:** PU at start and patient could have developed a new ulcer. If the patient developed more than one PU lesion, only the first one was taken into account. Number of patients with multiple ulcers not reported					

** The authors were contacted for additional information. This publication is part of a doctoral thesis and can be retrieved on https://www.dora.dmu.ac.uk/handle/2086/4343*

Table 14: Webster 2011[242]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Webster (2011) **Title:** Pressure ulcers: effectiveness of risk-assessment tools. A randomized controlled trial (the ULCER trial) Journal**:** BMJ Quality & Safety, 20 (4); 297-306 **Study type:** randomized controlled trial **Sequence generation:** a computer-generated randomized list was used to allocate the patients. Block and stratified randomization according to type of patient	**Patient group:** hospitalized patients older than 18 years with or without a PU **All patients** **Randomised N:** 1231 **Completed N:** 1231 **Drop-outs:** 0 **Group 1** **Randomised N:** 411 **Completed N:** 411 **Dropouts:** 0 **Age (mean yrs (SD); range):** 62.6 (19.6); 18-100 **Gender (m/f):** 200/211	**Group 1:** the Waterlow scale **Group 2:** the Ramstadius scale **Group 3:** Clinical judgement. **All groups:** prevention measures were initiated on the basis of risk and documented. There were no differences between groups in the use of special mattresses, documentation of an explicit pressure care plan, referral to the specialist skin integrity nurse or referral to a dietician; more referrals to the specialist nurse came from the clinical judgement group, but this difference was not statistically significant.	**Outcome 1:** Incidence of new PU (all stages)	**Group 1:** 31/411 **Group 2:** 22/410 **Group 3:** 28/410 **P value:** 0.44 **OR from multivariable analysis (247 missing patients):** **Group 1 versus group 3:** OR 1.06 (95%CI 0.59 to 1.91) **Group 2 versus group 3:** OR 0.60 (95%CI 0.31 to 1.13) **Group 1:** 21/411	**Funding:** / **Limitations:** health care professional not blinded and risk of contamination/learning within the ward ; patients with PU before intervention included (5-6%). **Additional outcomes:** process of care between the three groups were measured. Predictor of pressure injury were calculated. **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(medical/oncological), presence/absence of PU on admission and mobility status. **Allocation concealment:** allocation was concealed using a phone randomisation method and patients and investigator did not know the allocation schedule; method not reported **Blinding:** patient and outcome assessor were blinded to group assignment. **Addressing incomplete outcome data:** Intention-to-treat analysis. 7 patients had missing data on comorbidity; 247 excluded from model because data were not available.	**Ability to turn independently:** 374 **Wheelchair dependent:** 30 **Pressure ulcer on admission:** 25 **Length of stay (mean days (SD); range):** 8.8 (9.5); 1-98 **Group 2** **Randomised N:** 410 **Completed N:** 410 **Dropouts:** 0 **Age (mean yrs (SD); range):** 63.2 (19.2); 18-98 **Gender (m/f):** 205/205 **Ability to turn independently:** 368 **Wheelchair dependent:**	Patients randomised – the appropriate instrument was placed in the patient's medical record for use by the ward nurse.	**Outcome 2:** Incidence of PU (stage I) **Outcome 3:** Incidence of PU (stage II)	**Group 2:** 18/410 **Group 3:** 20/410 **Group 1:** 10/411 **Group 2:** 4/410 **Group 3:** 8/410	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Baseline clinical and demographic characteristics were compared using frequencies or means and standard deviations (SD). The inter-rater agreement was assessed using the percentage agreement between raters. For the primary outcome, the OR and their 95% CIs were calculated for the proportion of patients with pressure ulcers in each group. Logistic regression models were used to determine risk factors associated with patients developing a pressure ulcer after admission. The initial logistic regression model incorporated	19 **Pressure ulcer on admission:** 25 **Length of stay (mean days (SD); range):** 9.4 (99.9); 1-81 **Group 3** **Randomised N:** 410 **Completed N:** 410 **Dropouts:** 0 **Age (mean yrs (SD); range):** 61.9 (19.0); 19-100 **Gender (m/f):** 214/196 **Ability to turn independently:** 373 **Wheelchair dependent:** 29 **Pressure ulcer on admission:** 21				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
all variables that were significant in the univariate analyses, and also adjusted for the treatment group. Using this initial model, the backwards elimination was used to the select final model. As the vast majority of inpatient dietician reviews are for malnutrition, referral to a dietician was used in the models as a proxy for malnutrition. Regression models are adjusted for potential confounding of treatment group. **Baseline differences:** Statistical difference was calculated for mean hours in emergency department (p=0.56) and average length of stay (p=0.38).	**Length of stay (mean days (SD); range):** 8.5 (8.5); 1-81 **Inclusion criteria:** admitted through the emergency department or any outpatient department **Exclusion criteria:** hospital stay < 3 days; hospitalized more than 24h before baseline assessment				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: A priori sample size calculation indicated a sample size of 466 patients per group. Final sample size lower than calculated. **Setting:** Internal medicine ward and oncological ward at the Royal Brisbane and Women's Hospital, Australia **Length of study:** not reported; length of stay: range 1-98 days **Assessment of PUs:** Research assistants trained in pressure ulcer staging asses the wounds using a standardized assessment method (Black et al. 2007).					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: not reported					

G.1.2 Skin assessment

Table 20: Vanderwee 2007[236]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Vanderwee, 2007 **Title**: Non-blanchable erythema as an indicator for the need for PU prevention: a randomized-controlled trial **Journal:** Journal of Clinical Nursing, 2007;16: 325–335 **Study type**: RCT Sequence generation: based on randomization tables generated with the software package SPSS	Patient group: Patients with an expected hospitalization of at least three days admitted between May 2000 and March 2002 in 14 surgery, internal medicine and geriatric wards of six Belgian hospitals All patients Randomized N: 1,617 Completed N: 1,617 Drop-outs: 0 Group 1 Randomized N: 826 Completed N: 826 Dropouts: 0 Age: (median and interquartile range) 78 (70-86) years	Group 1 (NBE): Daily skin assessment with transparent disk. Preventative measures were started when NBE appeared. The patient continued to be observed daily. A transparent pressure disk with a size of 5 cm by 5 cm, was used to distinguish between blanchable (BE) and nonblanchable erythema (NBE). The nurse pressed the transparent disk on the erythema. If the erythema blanched, it was defined as BE. If	Outcome 1: Incidence of PU (grades 2-4) per 1,000 days (95% CI) Outcome 2: Median Time (days) to develop PU (grades 2-4) Median (IQR)	Group 1: 56/826Group 2: 53/791 Rate Ratio/1000 days: 1.07 95% CI: 0.7-2.5 Group 1: 4 (2-5) Group 2: 8 (4-16) P value: Mann-Whitney U test, p=0.001	Funding: This study was supported by a grant from the Ghent University and from Huntleigh Healthcare Limitations: No blinding; unclear allocation concealment (envelopes not said to be sealed or opaque) Additional outcomes: In the group using APAM, the incidence of pressure ulcers (grades 2–4) was

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
10 Allocation concealment: Serially numbered, closed envelopes were made available for each participating nursing unit. Each time a patient was admitted the envelope with the lowest number was opened. The envelope contained the patient's admission form on which the assignment of the patient was indicated, by means of a flow chart. The flow chart indicated whether the patient belonged to the control group or the NBE group, and whether to use a Polyethylene–Urethane Mattress (PUM) or an Alternating Pressure Air Mattress (APAM) if pressure redistribution was needed. Blinding: No blinding (for practical and ethical reasons) Addressing incomplete outcome data: No incomplete outcome	Gender (m/f): 332/494 Other relevant patient characteristics: Braden score on admission (median and interquartile range): 19 (16-21) Pressure ulcers: 56 (7%) Group 2 Randomized N: 791 Completed N: 791 Dropouts: 0 Age: (median and interquartile range) 79 (71-85) years Gender (m/f): 289/502 Braden score on admission (median and interquartile range): 19 (17-21) Pressure ulcers: 53 (7%) Inclusion criteria: Hospitalization of at least 3 days Exclusion criteria: -grade 2 pressure ulcer (abrasion or blister), grades 3 (superficial ulcer) and 4 (deep ulcer) on admission -age younger than 18 -bodyweight of over 140 kg -contra-indication for turning because of medical reasons	the erythema remained while pressing, it was defined as NBE When the NBE disappeared, the preventative measures were discontinued and restarted only if the NBE reappeared. Group 2 (Control): Braden score assessed initially and after 3 days if the score was 17 or more, plus daily skin assessment with transparent disk. Preventative measures were started if the Braden score was <17 or NBE appeared. If the Braden score was 17 or higher, the patient was scored again on the Braden scale three days later. Pressure points were observed daily Both groups: Patients received preventative measures according to	Kaplan Meier survival analysis (adjusted for the prevention protocols) Outcome 3: number receiving preventative measures (on the basis of their risk)	Log-rank test = 6.67, df =1, p=0.01 and the time to develop a PU was significantly higher in the control group than then NBEgroup Group 1: 128/826 Group 2: (219+32)/791 219 on the basis of Braden<17and 32 using skin assessment for people with Braden >17 Further details: Group 1: 128 at risk and received preventative treatment; of these 17/66 had PU on PUM and 9/62 on APAM. 698 were not at risk and of these 30 had a pressure ulcer. Overall there were 30/826 (3.6%) that were false negatives.	lower, but not significantly different in the NBE group (14.5%) compared with the control group (20.5%) (Fisher's exact test, P=0.42). In the group using PUM, the difference in the incidence of pressure ulcers (grades 2–4) approached significance (Fisher's exact test, P =0.052), the incidence being lower in the control group (14.2%) than in the NBE group (25.8%). In the intervention group, 16% of patients received preventative measures, in the control group 32% (Fisher's exact test, P < 0.001). The sensitivity of the risk assessment method used in the control group was 81.1% and the specificity 71.8%. The sensitivity of NBE as a

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
data Statistical analysis: The Mann–Whitney U-test was used for continuous variables that were not distributed normally. The Fisher's exact test was used for categorical variables. A Kaplan–Meier survival analysis was performed to evaluate the effect of the risk assessment method on the incidence of PU (grade 2 or higher). All analyses were carried out with the software package SPSS 10. A value of P < 0.05 was considered statistically significant. Baseline differences: The random assignment produced comparable intervention and control groups with regard to age, gender, Braden score on admission, medical specialty and primary diagnosis. Study power/sample size: Based on a PU (grade 2 or higher) incidence of 6%, a		the same pressure redistribution protocol. It consisted of pressure redistribution while sitting up and while in bed. During sitting in an (arm)chair, an air cushion (Airtech_, Huntleigh Healthcare, UK) was used for all patients and they had to stand up every two hours, alone or with some help. If the back of the armchair could be tilted backwards, the patient's legs were put on a footrest. If the back of the armchair could not be tilted backwards, the patient's feet were placed on the floor. The patients were randomized to either the PU Mattress (Tempur_-World Inc, Lexington, Kentucky USA), or to the APA Mattress (Alpha-XCell, Huntleigh Healthcare, UK). On the PUM,		Group 2: 251 at risk received preventative treatment; of these 19/134 had a PU on PUM and 24/117 had a PU on APAM. 540 were not at risk and of these 10 had a PU. Overall, there were 10/791 (1.3%) false negatives	method for assigning preventative measures was 46.6% and the specificity 86.8%. The time when prevention started was not significantly different in the two groups (Mann–Whitney U = 479, P = 0.28). The separate analyses for the PUM group and the APAM group did not reveal a significant difference either. Adjusted for the prevention protocols, the Kaplan–Meier survival analysis revealed a significant difference between control and NBE groups (Log-rank test=7.18, d.f.=1, p=0.007). Notes: any note the reviewer thinks may be important

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
sample size was calculated of 1,624 patients (812 in each group) to detect a difference of 3% in the incidence of PU between the NBE and control group (α= 0.05; power = 80%). Setting: 14 surgery, internal medicine and geriatric wards of six Belgian hospitals Length of study: The study was carried out between May 2000 and March 2002. Each nursing unit took part in the study for the duration of five months. Assessment of PUs: In the NBE group and in the control group, the skin was examined at all pressure points, by nursing staff on admission and then daily during the morning shift. The observed pressure points were the sacrum, heels, hips, ankles, shoulder, elbows, ears		patients were turned every four hours, as proved to be indicated in an earlier study (Defloor et al. 2005). On the APAM, no standardized position changes were carried out. In the experimental group (N=826), 66 patients received pressure redistribution by PUM and 62 by APAM. In the control group (N=791), 134 patients received pressure redistribution by PUM and 117 by APAM. Patients not assessed to be at risk received the prevention protocol normally used on the ward (not specified). Appeared that the ward nurses did both the Braden assessment and the			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and knees. Classification of PUs: European Pressure Ulcer Advisory Panel. A patient was considered to have a pressure ulcer when a pressure ulcer grades 2–4 were observed. Multiple ulcers: Unit of analysis was number of patients developing PU		skin assessment.			

G.1.3 Skin assessment

Table 21: Compton 2008[54]

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Author and year: Compton, 2008 **Title**: Pressure ulcer predictors in ICU patients: nursing skin assessment versus objective parameters **Journal:** Journal of Wound Care, 2008; 17 (10): 417-24 **Study type**: Prospective cohort study **Selection patient**: All patients admitted at ICU between April 2001 and December 2004 without a PU at admission and remaining at least 72 h were eligible for the study	**Patient group:** ICU patients **All patients:** 713 **Included N:** 698 **Completed N:** 698 **Drop-outs:** 0 **Age (median years, quartiles):** 66 ((56, 75, 25) **Gender (m/f):** 392/306 **Number of patients with a PU:** 121 (17%)	**Predictive factor** 1: Nursing skin assessment – moist skin / not moist skin on admission **Predictive factor** 2: Nursing skin assessment – oedematous skin / not oedematous skin on admission **Predictive factor** 3: Nursing skin assessment – mottled skin / not mottled skin on admission **Predictive factor** 4: Nursing skin assessment – livid skin / not livid skin on admission **Predictive factor** 5: Nursing skin assessment – centralised circulation / not centralised circulation on admission **Predictive factor** 6:	**Predictive factor** 1 – moist skin: **Predictive factor** 2 - oedematous skin:	Odds ratio from multivariable analysis: 2.350 (p value 0.001) Sensitivity: 76% (67-83%) Specificity: 65% (61-69%) Raw data Diagnostic odds ratio (unadjusted) DOR: 5.9 (3.84-9.03) Odds ratio from multivariable analysis: 2.245 (p value 0.002) Sensitivity: 64% (54-72%) Specificity: 77% (73-80%)	Funding: Supported by a research grant of the Robert-Bosch-Stiftung, Stuttgart, Germany Limitations: **Predictive factor** measured only at admission; no report on blinding of researcher toward **Predictive factor** and outcome; unclear if uninterpretable results were found; no information about preventative measures; no sub-analyses according to preventative measures.

		Outcome		
		Yes	No	
Predictive factor	Yes	92	202	294
	No	29	375	404
		121	577	698

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Predictive factor: Subjective nursing assessment of the skin condition on admission including the presence of moist skin, oedematous skin, mottled skin, livid skin, centralised circulation, cyanosis, reddened skin and hyperaemic skin. **Outcome**: Occurrence of PU (grades 2-4) during course of ICU treatment. PU were defined and graded according to the European Pressure Ulcer Advisory Panel classification system. Addressing missing data: To control for missing data, values of the continuous monitoring and laboratory variables were recorded into the point score used in the acute physiology score (APS) of the APACHE II severity-of-disease	**Number of patients without a PU:** 577 **Inclusion criteria:** ICU patient No PU on admission **Exclusion criteria:** Stay in the ICU less than 72 h	Nursing skin assessment – cyanosis / not cyanosis on admission **Predictive factor** 7: Nursing skin assessment – reddened skin / not reddened skin on admission **Predictive factor** 8: Nursing skin assessment – hyperaemic skin / not hyperaemic skin on admission Outcome: Occurrence of PU (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system in the course of ICU treatment Preventative methods: Not reported	**Predictive factor** 3 - mottled skin:	Raw data (Predictive factor: Yes — Outcome: Yes 77, No 135, 212; Predictive factor: No — Outcome: Yes 44, No 442, 486; 121, 577, 698) DOR 5.7 (4.05-8.11) Odds ratio from multivariable analysis: 2.021 (p value 0.016) Sensitivity: 33% (25-42%) Specificity: 92% (89-94%) Raw data (Predictive factor: Yes — Outcome: Yes 40, No 48, 88; Predictive factor: No — Outcome: Yes 81, No 529, 610; 121, 577, 698)	Additional outcomes: With unadjusted analysis measures relating to organ dysfunction, circulatory impairment and sepsis showed significant association with the occurrence of PU. Multiple regression analysis showed subjective nursing skin assessment to outweigh these parameters as PU predictors. A risk function comprised of 5 skin-related and gender yielded an overall correct PU prediction proportion of 84.6%. ROC analysis showed an AUC of 0.82

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
scoring system, where 0 to 4 points are assigned according to the extent of deviation from the physiological range. Therefore, only monitoring and laboratory variables used in the APS score were entered in the logistic regression model. **Statistical analysis:** Continuous data are displayed as median and quartiles and were compared between groups using Mann-Whitney U testing. Dichotomous parameters are displayed as absolute numbers and percentages and were compared between groups using the chi-square test or the Fisher's exact test. A two-sided p value < 0.05 was considered significant. Multiple stepwise			**Predictive factor** 4 - livid skin: **Predictive factor** 5 - centralised circulation	DOR: 5.4 (4.21-7.03) Odds ratio from multivariable analysis: not stated but not significant Sensitivity: 31% (23-40%) Specificity: 92% (89-94%) Raw data DOR 5.0 (3.92-6.5) Odds ratio from multivariable analysis: 2.396 (p value 0.001) Sensitivity: 71% (62-79%) Specificity: 70% (66-74%) Raw data	(0.79-0.86) compared with an AUC of 0.59 (0.54-0.65) obtained with the Waterlow scale on admission. Results were validated in 392 patients treated in the same ICU between January 2005 and May 2006, yielding an AUC of 0.8 (0.73-0.86) compared with 0.58 (0.50-0.66) with the Waterlow scale. Notes:

		Outcome		
		Yes	No	
Predictive factor	Yes	38	48	86
	No	83	529	612
		121	577	698

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
regression analysis was used to analyse which of the examined parameters predict PU risk in critically ill patients. 32 predictors were included (not stated how these were chosen), i.e. ratio of events/covariates = 121/32 = 3. These covariates included age and BMI, insulin therapy and blood glucose **Setting:** Intensive Care Unit, Charité Campus Benjamin Franklin, Berlin, Germany Blinding: no details			**Predictive factor** 6 - Cyanosis:		

		Outcome		
		Yes	No	
Predictive factor	Yes	86	171	257
	No	35	406	441
		121	577	698

DOR: 5.8 (3.95-8.61)

Odds ratio from multivariable analysis: values not stated but not significant

Sensitivity: 45% (36-55%)
Specificity: 81% (77-84%)
Raw data

		Outcome		
		Yes	No	
Predictive factor	Yes	55	111	166
	No	66	466	532
		121	577	698

DOR: 3.5 (2.63-4.64)
Odds ratio from multivariable analysis: 2.305 (p value 0.001)

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
			Predictive factor 7 - reddened skin:	Sensitivity: 69% (60-77%) Specificity: 70% (66-74%) Raw data [table 1] DOR: 5.1 (3.54-7.47)	
			Predictive factor 8 - Hyperaemic skin	Odds ratio from multivariable analysis: value not stated but not significant Sensitivity: 21% (15-30%) Specificity: 91% (89-93%) Raw data [table 2]	

		Outcome		
		Yes	No	
Predictive factor	Yes	83	172	255
	No	38	405	443
		121	577	698

		Outcome	

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments

		Yes	No	
Predictive factor	Yes	26	50	76
	No	95	527	622
		121	577	698

DOR: 2.9 (2.28-3.65)

Table 22: Konishi 2008[120]

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Author and year: Konishi, 2008 **Title**: A prospective study of blanchable erythema among university hospital patients **Journal:** International Wound Journal, 2008; 5(3): 470-5. **Study type**: Prospective cohort study	**Patient group:** Patients admitted in a university hospital free of PU and spending most of the day in bed. **All patients:** 493 **Included N:** 249 **Completed N:** 249 **Drop-outs:** 0	**Predictive factor**: Presence / absence of blanchable erythema assessed by pressing firmly on the skin with a finger and by looking for blanching followed by prompt return of color to the area after lifting the finger Outcome: Occurrence of PU development according to the National Pressure Ulcer Advisory Panel classification Preventative methods: Support surfaces, repositioning schedule, head of bed	Outcome 1: PU development (all grades)	Sensitivity: 75% (35-97%) Specificity: 77% (71-82%) Raw data	Funding: None reported Limitations: No information about time of follow-up; no report on blinding of researcher toward **Predictive factor** and outcome; unclear if uninterpretable results were found; no sub-analyses according to preventative

		Outcome		
		Yes	No	
Predictive factor	Yes	6	56	62
	No	2	185	187
		8	241	249

Unadjusted odds ratio =
DOR 95%CI 9.9 (1.94-50.49)

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Selection patient: Patients were admitted to 6 wards in a university hospital with 832 beds between February and April 2005. Six wards were ICU, surgical recovery room, gastroenterological surgery and medicine, internal medicine and cardiovascular and respiratory surgery. These were selected, as three had the highest percentages of bedridden patients, and the other three had the lowest percentages. All subjects were required to be free of pressure ulcers at the beginning of the study and spent most of the day in bed. **Predictive factor**: Daily assessment of the presence of blanchable erythema. To assess for blanchability, researchers pressed firmly on the skin with a	**Age (mean years (SD); range):** not reported **Gender (m/f):** not reported **Number of patients with a PU:** 8 (for all stages of PU development) i.e. 3% 4 (for PU (grades 2-4) development) i.e. 2% **Number of patients without a PU:** 241 Inclusion criteria: Admission in one of the 6 participating wards Free of PU Bedridden Exclusion criteria: none	maintained at 30°C or below; skin care, nutritional management. Risk assessment also conducted – it was unclear if the nurses conducting the skin assessment were blinded to this.	Outcome 2: PU (grades 2-4) development	Sensitivity: 75% (19-99%) Specificity: 76% (70-81%) Raw data (Predictive factor × Outcome) Predictive factor: Yes — Outcome: Yes 3, No 59, 62 Predictive factor: No — Outcome: Yes 1, No 186, 187 Total: Yes 4, No 245, 249 Unadjusted odds ratio = DOR 95%CI 9.4 (0.94-94.58)	measures. Additional outcomes: Identification of factors associated with the deterioration of blanchable erythema. The number of patients who had a risk under the item 'pressure', which is one of the triggering factors in the scale for predicting pressure ulcer development, was significantly higher in the deteriorated group (chi-squared=4.277, p= 0.039). Inadequate maintenance of support surfaces was observed in all six patients in

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
finger and lifted the finger and looked for blanching (sudden whitening of the skin), followed by prompt return of color to the area. **Outcome:** Occurrence of PU assessed by daily inspection. Pressure ulcers were defined by using the National Pressure Ulcer Advisory Panel classification **Addressing missing data:** No details **Statistical analysis:** To compare each parameter between the healed and the deteriorated groups, the chi-squared test and Mann-Whitney U test were performed using SPSS II for Windows for statistical analysis. P <					the deteriorated Group (chi-squared =0.228, p= 0.015). Notes:

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
0.05 was considered statistically significant. The probability of blanchable erythema resulting in pressure ulcer development was calculated in terms of sensitivity, specificity and positive likelihood ratio and diagnostic accuracy was examined. In the statistical methods, diagnostic probabilities (sensitivity, specificity and positive likelihood ratio) were calculated. **Setting:** Six wards in a university hospital with 832 beds, Ishikawa, Japan. **Blinding:** No details					

Table 23: Newman 1981[159]

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Author and year: Newman 1981 **Title**: Thermography as a predictor of sacral pressure sores **Journal:** Age and Ageing, 1981; 10: 14-8. **Study type**: Prospective cohort study **Selection patient**: New admissions to the geriatric assessment unit at the Southern General Hospital, Glasgow, over a 12-week period with unmarked skin who volunteered to participate in the study **Predictive factor**: Thermography with a prototype, low cost, portable, heat- sensitive	Patient group: 155 newly admitted in a 12-week period without pressure lesions 64 patients were not included because: could not be screened within 24 h (N=29) too ill to participate (N=11) refusal (N=11) miscellaneous (N=13) All patients Included N: 91 Completed N: 91 Drop-outs: 0 Age (mean years (SD); range): No details Gender (m/f): No details	**Predictive factor**: Thermography: presence of thermal anomaly (an area of the skin at least 1°C warmer than the surrounding skin). Outcome: Visual inspection: pressure sores with a skin break in the sacral region within 10 days after admission (i.e. 2+) Preventative methods: No details	Predictor: Thermal anomaly	Sensitivity: 100% (54-100%) Specificity: 74% (63-83%) Raw data Odds ratio = DOR (95% CI) 36.7 (1.41-952.24)	Funding: None reported Limitations: **Predictive factor** measured only at admission; no report on blinding of researcher toward **Predictive factor** and outcome; unclear if uninterpretable results were found; no information about preventative measures; no sub-analyses according to preventative measures. Additional outcomes: Patients with low Norton scores on admission developed more

		Outcome		
		Yes	No	
Predictive factor	Yes	6	22	28
	No	0	63	63
		6	85	91

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
thermograph was performed within 24 h after admission. Patients lay on one side for 10 to 15 minutes with the buttocks exposed to allow skin temperature to stabilize. The ward temperature was maintained between 21 and 26°C; relative humidity was seldom below 40% or above 60%. The camera was positioned as square as possible to the sacrum, ischium and hip. A small reflective marker stuck on to the patient simplified focusing. Thermal images (thermograms) were recorded on video-tape; the patient was then turned, and the procedure, including stabilization, was repeated for the other buttock. During the subsequent 4 weeks, patients admitted were similarly examined, but thermography was not	Number of patients with a PU: 6 (7%) Number of patients without a PU: 85 Inclusion criteria: New admission Unmarked skin Exclusion criteria: Pressure lesion on admission				frequently skin breaks within the subsequent 10 days than those with high scores. Two of the 58 control patients (4%) developed sores within a week of admission. Notes:

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
carried out. This control was established to determine whether the thermographic examination by itself had led to any change in the reported incidence of pressure sores. **Outcome:** Development of skin breakdown in the buttock region within 10 days of admission was reported by the nursing staff and photographed. Redness alone, however marked or persistent, was not categorized as a pressure sore. **Addressing missing data:** No details **Statistical analysis:** Only descriptive data **Setting:** Geriatric assessment unit at the Southern general Hospital,					

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Glasgow, Scotland **Blinding:** No details					

Table 24: Nixon 2007[161]

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Author and year: Nixon 2007 **Title**: Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study **Journal:** International Journal of Nursing Studies, 2006; 44: 655-663 **Study type**: Prospective cohort study **Selection patient**: Surgical in-patients admitted to St. James's University Hospital, Leeds between September 1998 and May 1999. **Predictive factor**: The classification scale used was adapted from	Patient group: Surgical in-patients All patients: 109 Included N: 109 Completed N: 97 Drop-outs: 12 Incomplete follow-up resulted from cancelled elective surgery and early discharge (N=4), patient request to discontinue (N=4) and presence of pressure ulcer at baseline assessment (N=4) Age (median years, quartiles): 75 (55-95) Gender (m/f): 38/59	**Predictive factor** 1: skin assessment according the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999) blanchable erythema (grade 1a) **Predictive factor** 2: non-blanchable erythema (grade 1b and above) Each **Predictive factor** represented the worst skin grade recorded at any time and on any site during hospital stay/preceding PU development Outcome: Occurrence of stage 2+ PU development according the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999) Preventative methods:	**Predictive factor** 1 - blanchable erythema: **Predictive factor** 2 – non-blanchable erythema:	Sensitivity: 75% (19-99%) Specificity: 10% (4-20%) Raw data (Grade 1a vs Grade 0 erythema) DOR: 0.33 (95%CI 0.03 to 3.66) Odds ratio from multivariable analysis (≥1b versus < 1b) 7.02 (95%CI 1.67 to 29.49)) Sensitivity: 73% (45-92%) Specificity: 74% (64-83%) Raw data (Grade 1b and 1b+ vs Grade 1a and Grade 0)	Funding: Jane Nixon has been reimbursed for attending conferences, has been paid speakers fees and received research funding from Huntleigh Healthcare Ltd. Funding awards from the Tissue Viability Society Training Fellowship (UK) and the Smith and Nephew Foundation Nursing Research Fellowship were made to Jane Nixon. These organizations peer reviewed the grant application and received a report of the findings. Limitations:

		Reference standard		
		Yes	No	
Predictive factor	Yes	3	55	58
	No	1	6	7
		4	61	65

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
international classification scales, (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999) in order to meet practical data collection requirements for the purpose of research. Specifically, Grade 0 (no skin changes) was included to clearly distinguish skin assessment of normal skin from missing data. In addition, alterations to intact skin were classified as blanching (1a), non-blanching (1b) and non-blanching with other skin changes including, local induration, oedema, pain, warmth or discoloration (1b+). **Outcome:** The classification scale used was adapted from international classification scales, (AHCPR (Agency for Health Care Policy and	Number of patients with a PU: 15 (15%) Number of patients without a PU: 82 Inclusion criteria: (a) Scheduled for elective major general or vascular surgery OR acute orthopaedic, vascular and general surgical admission. (b) Aged 55 years or over on day of surgery. (c) Expected length of stay of 5 or more days. Exclusion criteria: (a) General surgery sub-specialties including liver, urology and breast surgery. (b) Dark skin pigmentation which precluded reliable identification of skin erythema. (c) Skin conditions over	Limited details, but it appeared that all patients had either foam, alternating overlay or alternating replacement mattresses	I	<table><tr><td></td><td></td><td colspan="2">Outcome</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Predictive factor</td><td>Yes</td><td>11</td><td>21</td><td>32</td></tr><tr><td>No</td><td>4</td><td>61</td><td>65</td></tr><tr><td></td><td>15</td><td>82</td><td>97</td></tr></table> DOR: 7.99 (95%CI 2.30 to 27.80)	no report on blinding of researcher toward **Predictive factor** and outcome; unclear if uninterpretable results were found; no information about preventative measures; no sub-analyses according to preventative measures. Additional outcomes: There was significantly increased odds of pressure ulcer development associated with non-blanching erythema (7.98, p = 0.002) and non-blanching erythema with other skin

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
Research) 1992; EPUAP, 1999) in order to meet practical data collection requirements for the purpose of research. The dependent outcome variable 'pressure ulcer' was defined as a skin area assessed as >=Grade 2, that is, a superficial skin break/blister or worse. Grade 5 (black eschar) was included as a separate grade until wound debridement enabled classification by tissue layer. Addressing missing data: Variables were excluded from further analysis if the p value was >=0.2 (Altman, 1991) or >=25% of data was missing. Missing values were replaced by imputed data. **Statistical analysis:** A chi-square test was used to compare the	the sacrum, buttocks or heels which precluded reliable identification of pressure induced skin erythema.				changes (9.17, p = 0.035). Logistic regression modeling identified non-blanching erythema, pre-operative albumin, weight loss, and intra-operative minimum diastolic blood pressure, as independent predictors of Grade>=2 pressure ulcer development. Notes:

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
proportions of patients classified as having Grade 0, Grade 1a, Grade 1b and Grade 1b+ on any skin site preceding pressure ulcer development. Skin changes preceding pressure ulcer development were also classified by Grade, independently for each site, and the difference in frequency of pressure ulcers between Grades examined using Fisher's exact test. To identify which clinical signs of erythema were predictive of skin loss, the odds of pressure ulcer development for Grade 0, Grade 1a, 1b and 1b+ were examined using single factor logistic regression. To identify variables which independently are predictive of >=Grade 2 pressure ulcer development, the relationship between risk factors and pressure					

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
ulcer development was explored using a three stage process for patients who were pressure ulcer free at baseline. The 'worst' skin grade recorded at any time and on any site during hospital stay or preceding pressure ulcer development was used to categorise skin alteration as a risk factor. Unadjusted analysis used single factor logistic regression with a binary response of pressure ulcer or no pressure ulcer. Correlations between variables were then examined using Pearson's correlation coefficient for continuous data or Spearman's rank correlation for ordered categorical data. Where variables were correlated with a correlation coefficient of 40.7 and an associated p-value of 0.01 (Fielding					

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
et al., 1992), one was eliminated from further consideration. The final candidate variables were entered into a logistic regression model using forward stepwise selection. The p value determined entry (<0.25) and removal (40.9). The variables identified by the forward stepwise selection were then used as the basic model for further logistic regression analysis. Correlated variables were dropped and added systematically in order to determine the final model in which each variable independently predicted subsequent pressure ulcer development as assessed by the size of the p value. Key confounders included age, but not BMI or diabetes (both had p-values >0.2). Number of					

Reference	Patient Characteristics	Predictive factor Outcome	Outcome measures	Effect sizes	Comments
events/covariate = 15/8 =2 The model was determined only from patients with complete data for all candidate variables. Therefore, when the final set of variables was obtained the model was refitted with only those final variables in the model statement. Analyses were carried out using the Stata Statistical Software package. Setting: St. James University Hospital Leeds **Blinding:** no blinding					

I.1.1.1 Skin assessment – clinical effectiveness

Table 25: Vanderwee 2007[236]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Vanderwee, 2007 **Title**: Non-blanchable erythema as an indicator for the need for PU prevention: a randomized-controlled trial **Journal:** Journal of Clinical Nursing, 2007;16: 325–335 **Study type**: RCT **Sequence generation:** based on randomization tables generated with the software package SPSS 10 **Allocation concealment**: Serially numbered, closed envelopes were made available for each participating nursing unit. Each time a patient was admitted the envelope with the lowest number	**Patient group:** Patients with an expected hospitalization of at least three days admitted between May 2000 and March 2002 in 14 surgery, internal medicine and geriatric wards of six Belgian hospitals All patients Randomized N: 1,617 Completed N: 1,617 Drop-outs: 0 Group 1 Randomized N: 826 Completed N: 826 Dropouts: 0 Age: (median and interquartile range) 78 (70-86) years Gender (m/f): 332/494 Other relevant patient characteristics: Braden score on admission (median and interquartile range): 19 (16-21) Pressure ulcers: 56 (7%) Group 2	Group 1 (NBE): Daily skin assessment with transparent disk. Preventative measures were started when NBE appeared. The patient continued to be observed daily. A transparent pressure disk with a size of 5 cm by 5 cm, was used to distinguish between blanchable (BE) and nonblanchable erythema (NBE). The nurse pressed the transparent disk on the erythema. If the erythema blanched, it was defined as BE. If the erythema remained while pressing, it was defined as NBE When the NBE disappeared, the preventative measures were discontinued and restarted only if the NBE reappeared.	Outcome 1: Incidence of PU (grades 2-4) per 1,000 days (95% CI) Outcome 2: Median Time (days) to develop PU (grades 2-4) Median (IQR) Kaplan Meier survival analysis (adjusted for the prevention protocols) Outcome 3: number	Group 1: 56/826Group 2: 53/791 Rate Ratio/1000 days: 1.07 95% CI: 0.7-2.5 Group 1: 4 (2-5) Group 2: 8 (4-16) P value: Mann-Whitney U test, p=0.001 Log-rank test = 6.67, df =1, p=0.01 and the time to develop a PU was significantly higher in the control group than then NBEgroup Group 1: 128/826	Funding: This study was supported by a grant from the Ghent University and from Huntleigh Healthcare Limitations: No blinding; unclear allocation concealment (envelopes not said to be sealed or opaque) Additional outcomes: In the group using APAM, the incidence of pressure ulcers (grades 2–4) was lower, but not significantly different in the NBE group (14.5%) compared with the control group (20.5%) (Fisher's exact test, P=0.42). In the group using PUM, the difference in the incidence of pressure

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
was opened. The envelope contained the patient's admission form on which the assignment of the patient was indicated, by means of a flow chart. The flow chart indicated whether the patient belonged to the control group or the NBE group, and whether to use a Polyethylene–Urethane Mattress (PUM) or an Alternating Pressure Air Mattress (APAM) if pressure redistribution was needed. **Blinding:** No blinding (for practical and ethical reasons) Addressing incomplete outcome data: No incomplete outcome data **Statistical analysis:** The Mann–Whitney U-test was used for continuous variables that were not distributed normally. The Fisher's exact test was used for categorical variables. A Kaplan–	Randomized N: 791 Completed N: 791 Dropouts: 0 Age: (median and interquartile range) 79 (71-85) years Gender (m/f): 289/502 Braden score on admission (median and interquartile range): 19 (17-21) Pressure ulcers: 53 (7%) Inclusion criteria: Hospitalization of at least 3 days Exclusion criteria: -grade 2 pressure ulcer (abrasion or blister), grades 3 (superficial ulcer) and 4 (deep ulcer) on admission -age younger than 18 -bodyweight of over 140 kg -contra-indication for turning because of medical reasons	Group 2 (Control): Braden score assessed initially and after 3 days if the score was 17 or more, plus daily skin assessment with transparent disk. Preventative measures were started if the Braden score was <17 or NBE appeared. If the Braden score was 17 or higher, the patient was scored again on the Braden scale three days later. Pressure points were observed daily Both groups: Patients received preventative measures according to the same pressure redistribution protocol. It consisted of pressure redistribution while sitting up and while in bed. During sitting in an (arm)chair, an air cushion (Airtech_, Huntleigh Healthcare,	receiving preventative measures (on the basis of their risk)	Group 2: (219+32)/791 219 on the basis of Braden<17and 32 using skin assessment for people with Braden >17 Further details: Group 1: 128 at risk and received preventative treatment; of these 17/66 had PU on PUM and 9/62 on APAM. 698 were not at risk and of these 30 had a pressure ulcer. Overall there were 30/826 (3.6%) that were false negatives. Group 2: 251 at risk received preventative treatment; of these 19/134 had a PU on PUM and 24/117 had a PU on APAM. 540 were not at risk and of these 10 had a PU. Overall, there were	ulcers (grades 2–4) approached significance (Fisher's exact test, P =0.052), the incidence being lower in the control group (14.2%) than in the NBE group (25.8%). In the intervention group, 16% of patients received preventative measures, in the control group 32% (Fisher's exact test, P < 0.001). The sensitivity of the risk assessment method used in the control group was 81.1% and the specificity 71.8%. The sensitivity of NBE as a method for assigning preventative measures was 46.6% and the specificity 86.8%. The time when prevention started was not significantly different in the two groups (Mann–

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Meier survival analysis was performed to evaluate the effect of the risk assessment method on the incidence of PU (grade 2 or higher). All analyses were carried out with the software package SPSS 10. A value of P < 0.05 was considered statistically significant. Baseline differences: The random assignment produced comparable intervention and control groups with regard to age, gender, Braden score on admission, medical specialty and primary diagnosis. Study power/sample size: Based on a PU (grade 2 or higher) incidence of 6%, a sample size was calculated of 1,624 patients (812 in each group) to detect a difference of 3% in the incidence of PU between the NBE and control group (α= 0.05; power = 80%).		UK) was used for all patients and they had to stand up every two hours, alone or with some help. If the back of the armchair could be tilted backwards, the patient's legs were put on a footrest. If the back of the armchair could not be tilted backwards, the patient's feet were placed on the floor. The patients were randomized to either the PU Mattress (Tempur_-World Inc, Lexington, Kentucky USA), or to the APA Mattress (Alpha-XCell, Huntleigh Healthcare, UK). On the PUM, patients were turned every four hours, as proved to be indicated in an earlier study (Defloor et al. 2005). On the APAM, no standardized position changes were carried out. In the experimental		10/791 (1.3%) false negatives	Whitney U = 479, P = 0.28). The separate analyses for the PUM group and the APAM group did not reveal a significant difference either. Adjusted for the prevention protocols, the Kaplan–Meier survival analysis revealed a significant difference between control and NBE groups (Log-rank test=7.18, d.f.=1, p=0.007). Notes: any note the reviewer thinks may be important

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: 14 surgery, internal medicine and geriatric wards of six Belgian hospitals Length of study: The study was carried out between May 2000 and March 2002. Each nursing unit took part in the study for the duration of five months. Assessment of PUs: In the NBE group and in the control group, the skin was examined at all pressure points, by nursing staff on admission and then daily during the morning shift. The observed pressure points were the sacrum, heels, hips, ankles, shoulder, elbows, ears and knees. Classification of PUs: European Pressure Ulcer Advisory Panel. A patient was considered to have a pressure ulcer when a pressure ulcer grades 2–4 were observed.		group (N=826), 66 patients received pressure redistribution by PUM and 62 by APAM. In the control group (N=791), 134 patients received pressure redistribution by PUM and 117 by APAM. Patients not assessed to be at risk received the prevention protocol normally used on the ward (not specified). Appeared that the ward nurses did both the Braden assessment and the skin assessment.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: Unit of analysis was number of patients developing PU					

I.1.2 Repositioning

Table 26: Fineman 2006[76]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Fineman 2006 **Title:** Prone positioning can be safely performed in critically ill infants and children Journal**:** Paediatric Critical Care Medicine **Type of study:** RCT **Sequence generation:** Randomisation done using a permuted block sizes **Allocation concealment:** Each centre received serially numbered, opaque, sealed envelopes containing study assignments	**Patient group:** One hundred and two paediatric patients with acute lung injury. **All patients** Randomised N: 102 Completed N: 98 Drop-outs: 4 **Group 1** Randomised N: 51 Completed N: 47 Dropouts: 4 **Group 2** Randomised N: 51 Completed N: 51	**Group 1:** Prone positioning: a 2-hr cyclic rotation from full prone to right lateral/prone to full prone to left lateral/prone and then to full prone. Prone positioning continued each day during the acute phase of their Acute Lung Injury illness for a maximum of 7 days of treatment. Infants/toddlers were lifted up, turned 45°, and turned prone on their cushions. School-aged and adolescent patients were turned using the mummy technique. During each turn, the patient's head was kept in alignment with the body, avoiding hyperextension. **Group 2:** Supine positioning	**Outcome 1:** Adverse event (proportion of participants that developed stage II or greater pressure ulcers)	**Group 1:** 10/51 (19.60%) **Group 2:** 8/51 (15.69%)	**Funding:** not reported. **Limitations:** Blinding for outcome assessors not reported **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: not reported **Addressing incomplete outcome data:** not reported. Analysis were carried out on an intention-to-treat basis **Statistical analysis:** Wilcoxon's rank-sum test or Fisher's exact test, as appropriate, to compare prone and supine groups in their baseline characteristics and outcomes that were calculated on a per patient basis. **Baseline differences:** There were no significant differences between the prone and supine groups **Study power/sample size:** Study power not reported. **Setting:** Seven paediatric intensive care units that participate in the Paediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network in the United States	Dropouts: none **Inclusion criteria:** Paediatric patients (2 wks to 18 yrs) who were intubated and mechanically ventilated with a PaO2/FIO2 ratio of ≤300, bilaterally pulmonary infiltrates, and no clinical evidence of left atrial hypertension **Exclusion criteria:** <2 wks of age (newborn physiology), <42 wks post conceptual age (considered preterm), were unable to tolerate a position change (persistent hypotension, cerebral hypertension), had respiratory failure from cardiac disease, had hypoxemia without bilateral infiltrates, had received a bone marrow or lung transplant, were supported on extracorporeal membrane oxygenation, had a nonpulmonary condition that could be exacerbated by the prone position, or	All patients were maintained on standard hospital beds. Individually sized head, chest, pelvic, distal femoral and lower limb cushions were created using pressure-relieving material.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 28 days **Assessment of PUs:** Not reported **Classification of PUs:** not reported **Multiple ulcers:** Not reported	had participated in other clinical trials within the preceding 30 days.				

Table 27: Defloor 2005B[63]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Defloor 2005B **Title:** The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers Journal**:** International Journal of Nursing Studies **Type of study:** RCT **Sequence generation:** cluster randomisation done using a permuted block sizes. Cluster randomisation using computerised randomisation tables. **Allocation concealment:**	**Patient group:** 838 geriatric nursing home patients. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96). **All patients** Randomised N: 838 Completed N: 761 Drop-outs: 77 **Group 1** Randomised N: 65 Completed N: 63 Dropouts: 2 (1 died and 1 transferred to hospital)	**Group 1:** 2-hour turning scheme on a standard institutional mattress **Group 2:** 3-hour turning scheme on a standard institutional mattress **Group 3:** 4-hour turning scheme + pressure reducing mattress **Group 4:** 6-hour turning scheme + pressure reducing mattress. The turning schemes consisted in alternating a semi-Fowler position with a lateral position. **Group 5:** Standard care involving preventive nursing care based on clinical judgement of the nurses. Nurses did not use a pressure	**Outcome 1:** Development of all grades of ulcer (Non-blanchable erythema: redness which cannot be pressed away with the thumb and which lasts longer than I day (GRADE I in the Agency of Health Care Policy and Research (AHCPR) plus pressure ulcer lesions)	**Group 1:** 39/63 (61.9%) **Group 2:** 40/58 (69.0%) **Group 3:** 30/66 (45.5%) **Group 4:** 39/63 (61.9%) **Group 5:** 322/511 (63.0%)	**Funding:** not reported. **Limitations:** Intention-To-Treat analysis not reported. **Additional outcomes:**
			Outcome 2: Development of pressure ulcer lesion: blistering,	**Group 1:** 9/63 (14.3%) **Group 2:** 14/58 (24.1%) **Group 3:** 2/66 (3%) **Group 4:** 10/63 (15.9%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sealed envelope containing all room numbers in a random order. **Blinding:** Outcome assessors blinded **Addressing incomplete outcome data:** Gave details of what happened to drop outs and data of available patients **Statistical analysis:** The incidence of pressure ulcer lesions in relation to the different turning schemes was visualized using survival curves estimated according to the Kaplan-Meier method **Baseline differences:** No significant differences between the group **Study power/sample size:** Power analysis was performed using the national Belgian pressure ulcer prevalence figures. Desired power of 80% and a significance level of 0.05, a sample of 60 in	**Group 2** Randomised N: 65 Completed N: 58 Dropouts: 7 (5 transferred to hospital and 2 missing data) **Group 3** Randomised N: 67 Completed N: 66 Dropouts: 1 (missing data) **Group 4** Randomised N: 65 Completed N: 63 Dropouts: 2 (2 died) **Group 5** Randomised N: 576 Completed N: 511 Dropouts: 65 (20 died, 24 transferred to hospital and 21 missing data) **Inclusion criteria:** A Braden score of less than 17 or a Norton score of	ulcer risk assessment scale and were not familiar with those scales. Preventive care did not include turning.	superficial or deep pressure ulcer (grades II, III and IV in the AHCPR classification)	**Group 5:** 102/511 (20%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
each group was deemed sufficient. **Setting:** Eleven geriatric nursing homes in Flanders (Belgium) **Length of study:** 4-week study period **Assessment of PUs:** not reported **Classification of PUs: AHCPR** **Multiple ulcers:** N/A	less than 12; informed consent of patient/family **Exclusion criteria:** no reported				

Table 28: Smith 1990[208]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Smith 1990 **Title:** Preventing pressure ulcers in institutionalized elders: assessing the effects of small, unscheduled shifts in body position Journal**:** Decubitus **Type of study:** RCT **Sequence generation:**	**Patient group:** Participants ranged in age from 65 years to 91 years with a mean age of 80.55. Fourteen participants were women and five were men. Elderly patients: **All patients** **Randomised N:** 26	**Group 1:** Small shift in body (adjusting the position of a limb or body part by placing a small rolled towel to designated areas). A hand towel was used because it was efficient, convenient, and an existing resource. Shifts were completed in less than one minute. Sites for placement of rolled towel were under each arm, shoulder, hip, and leg.	**Outcome 1:** Development of pressure ulcer.	Throughout the second week of the study, one subject in each of the two groups developed a pressure ulcer which healed by the end of the study. The mean post-test Norton scores for the experimental group decreased to 9.44, while the control group increased to 12.5. There was no difference between post-test scores for the two groups.	**Funding:** not reported. **Limitations:** Allocation concealment not reported. Intention-To-Treat analysis not reported. Blinding not

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Participants were randomly assigned to the treatment or control group by drawing names from a hat. **Allocation concealment:** Not reported **Blinding:** Not reported **Addressing incomplete outcome data:** Provided details to missing data and used available patients **Statistical analysis:** **Baseline differences:** No significant differences between the group **Study power/sample size:** not reported **Setting:** Participants were drawn from a single, skilled, 100-bed long –term care facility in a large Midwestern metropolitan city. **Length of study:** 2-week study period **Assessment of PUs:** When a pressure ulcer was found, it was measured using a Medirule. Information	**Completed N:** 19 **Drop-outs:** 7 **Group 1** Randomised N: 14 Completed N: 9 Dropouts: 5 (3 found to have pressure ulcer before study and 2 missing data) **Group 2** Randomised N: 12 Completed N: 10 Dropouts: 2 (1 found to have pressure ulcer before study and 1missing data) **Inclusion criteria:** Patients who received a 14 or below on the Norton scale and were 65 years or older. **Exclusion criteria:** No details provided	**Group 2:** Turning every two hours. Both groups received normal, routine care and were turned every two hours.	**Outcome 2:**		reported. High rate of drop outs (difference between control and experimental greater than 10%). Small sample size. Clinically experimental group were more at risk. Narrative report of effect sizes was given. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
on the progression of pressure ulcer formation, chart information, and observations pertinent to the study were kept in a diary. **Classification of PUs:** not reported **Multiple ulcers:** no details					

Table 29: Vanderwee 2007 – cluster RCT[238]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Vanderwee 2007 **Title:** Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. Journal**:** JAN Original Research **Type of study:** RCT **Sequence generation:** Randomisation done at ward level using randomisation lists generated with the software package SPSS	**Patient group:** 838 geriatric nursing home patients. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96). **All patients** Randomised N: 235 Completed N: 235 Drop-outs: not reported **Group 1**	**Group 1:** 4 hours in a semi-Fowler 30° position and 2 hours in a lateral position 30°. The semi-Fowler position consisted of a 30° elevation of the head end and the foot end of the bed. In a lateral position, the position, the patient was rotated 30°, with their back supported with an ordinary pillow. **Group 2:** Repositioning was the same as above but with equal time intervals of 4 hours in lateral 30° as in semi-Fowler 30° position.	**Outcome 1:** Incidence of pressure ulcer (proportion of patients developing ulcer)	**Group 1:** 20/122 (16.4%) **Group 2:** 24/113 (21.2%)	**Funding:** not reported. **Limitations:** Intention-To-Treat analysis not reported. Blinding not reported. Allocation concealment not mentioned. Sample size was lower than the desired power needed.
			Outcome 2: The severity of pressure ulcer lesion	The majority of patients in the experimental group (17/122; 13.9%) and the control group (22/113; 19.5%) developed a grade 2 pressure ulcer. Three patients (2.5%) in the experimental group and two (1.8%) in the control group had a grade 3 or 4 pressure ulcer. No statistically significant difference in the severity of	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
12. **Allocation concealment:** Not reported **Blinding:** Not reported **Addressing incomplete outcome data:** None reported. No loss to follow up. **Statistical analysis:** Data were analysed using the software package SPSS version 12.0. **Baseline differences:** The two groups were comparable with respect to baseline and mobility characteristics. **Study power/sample size:** Sample size for the trial was calculated based on an incidence of pressure ulcer lesions (grade 2 or higher) in nursing homes of 17% (to detect a difference of 0.05; power = 80%). In order to detect a difference of 10% in the pressure ulcer incidence between the groups, 148 patients per group would have to be	Randomised N: 122 Completed N: 122 Dropouts: not reported **Group 2** Randomised N: 113 Completed N: 113 Dropouts: not reported **Inclusion criteria:** Patients were eligible for the study if they had no pressure ulcer lesion (grades 2, 3 or 4) (EPUAP 1999) at the start of the study, if they could be repositioned, and if they are expected to stay for >3 days in the nursing home. **Exclusion criteria:**	Patients in both groups were lying on a visco-elastic foam overlay mattress		pressure ulcer.	Results should be interpreted with caution. **Additional outcomes:**
			Outcome 3: Location of pressure ulcer lesion	**Group 1:** 13 patients (10.7%) developed a pressure ulcer at the sacral area; 7 patients (5.7%) on the heels or ankles. **Group 2:** 20 patients (17.7%) had a pressure ulcer on the sacrum and four (3.5%) on the heels or ankles. Difference between the two groups was not statistically significant.	
			Outcome 4: Time to developing pressure ulcer (analysed using a Kaplan-Meier survival analysis)	No statistically significant difference between the two turning protocols (Log Rank test = 1.18, d.f. = .1, p = 0.28). To account for the delay in which a pressure ulcer becomes visible on the skin surface, the survival analysis was repeated starting from day 4. No statistically significant difference was found (Log Rank test = 1.04, d.f. = 1; P = 0.31)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
included in the trial. **Setting:** 84 wards of 16 Belgian elder care nursing homes **Length of study:** 5-week study period **Assessment of PUs:** Occurrence of pressure ulcers was assessed daily by the nursing staff. The skin was observed at all the pressure arrears. **Classification system:** EPUAP-classification system **Multiple ulcers:** none reported					

Table 30: Moore 2011[148]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Moore 2011 **Title:** A randomised controlled clinical trial of repositioning, using the 30° tilt, for the prevention of pressure ulcers Journal**:** Journal of Clinical Nursing **Type of study:** RCT **Sequence generation:** Cluster randomisation using computerised randomisation **Allocation concealment:** Achieved through use of distance randomisation: statistician, not researcher controlled randomisation sequence. **Blinding:** Not reported **Addressing incomplete outcome data:** None reported. No loss to follow up reported. **Statistical analysis:** Data were analysed using SPSS version 13 on an intention to treat (ITT)	**Patient group:** 213 participants enrolled into study, 114 assigned to the control arm and 99 enrolled in the experimental arm. Seventy-nine percent were women, with 53% aged between 81-90 years, 13% aged between 91-100 years. Eighty-seven per cent of the participants were chair-fast and 77% had very limited activity **All patients** Randomised N: 213 Completed N: 213 Drop-outs: None reported **Group 1** Randomised N: 99 Completed N: 99 Dropouts: None reported **Group 2** Randomised N: 114 Completed N: 114 Dropouts: none reported	**Group 1:** repositioning by the clinical staff, using the 30° tilt (left side, back, right side, back) every three hours during the night. **Group 2:** Repositioning every six hours at night, using 90° lateral rotation. Night time was taken to mean between the hours of 8pm-8 am. No further manipulation of patient care was undertaken. Both groups were nursed during the day according to planned care. Pressure redistribution devises in current use on the bed and on the chair was continued. Patients' positions were altered every 2-3 hours.	**Outcome 1:** Incidence of pressure ulcer (proportion of patients developing ulcer)	**Group 1:** 3/99 (3%) **Group 2:** 13/114 (11%)	**Funding:** Health Research Board of Ireland Clinical Nursing and Midwifery Research Fellowship. **Limitations:** Blinding not reported. Sample size was lower than the desired power needed. Results should be interpreted with caution. **Additional outcomes:**
			Outcome 2: Time to pressure ulcer development	Group 1: Mean 26 days (range 3 days). Group 2: Mean 17 days (range 24 days)	
			Outcome 3: Location of pressure ulcer lesion	Ninety-four percent of pressure was located on the sacrum/buttocks. One was located on the knee, with no pressure ulcer on the heels. Sixteen pressure ulcers developed during the study period, seven classified as grade 1 (6 in control group; 1 in the experimental group). Nine classified as grade 2 (7 in control group; 2 in the experimental group).	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
basis. Differences between the two arms of the study assessed using the chi-squared test. Multiple regression analysis was conducted to determine which risk factors reflected pressure ulcer risk. **Baseline differences:** No statistical difference between the groups for age, sex and Braden activity scores. A statistically significant association was noted for Braden mobility scores, with more of the experimental group noted to be bed fast. **Study power/sample size:** Sample size was determined on the basis of an expected incidence of 15% in the control group and a 90% power to detect a reduction in pressure ulcer incidence from 15-10%. The sample size required was two groups of 398 participants. **Setting:** Participants	**Inclusion criteria:** An in-patient in a long term care of the older person hospital; >65 years; at risk of pressure ulcer development; no pressure ulcer at the time of recruitment to the study; no medical condition that would preclude the use of repositioning; consent to participate in the study. **Exclusion criteria:** Not reported				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
were selected from 12 long-term care of the older person hospital settings in the Republic of Ireland **Length of study:** 4-week study period **Assessment of PUs:** Patients' skin was assessed at each turning episode. If any changes in skin integrity were noted, the researcher was informed. The skin was then assessed by the assigned key staff member, the clinical nurse manager and the researcher. Agreement was achieved by comparing the participants' skin condition to the images on the EPUAP grading system. **Classification system:** EPUAP **Multiple ulcers:** none reported					

Table 31: Young 2004[249]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Young 2004 **Title:** The 30° tilt position vs the 90° lateral and supine positions in reducing the incidence of non-blanching erythema in a hospital inpatient population: a randomised controlled trial. Journal**:** Journal of Tissue Viability. **Type of study:** RCT **Sequence generation:** Randomisation was based on block allocation **Allocation concealment:** Sequential opening of sealed opaque envelopes. **Blinding:** Researcher was unaware of which method of repositioning had been used. **Addressing incomplete outcome data:** None reported. No loss to follow up reported.	**Patient group:** 46 participants with 23 randomised to the experimental arm and 23 to the control arm of the study. Mean age of 70.3 years **All patients** Randomised N: 46 Completed N: 46 Drop-outs: None reported **Group 1** Randomised N: 23 Completed N: 23 Dropouts: None reported **Group 2** Randomised N: 23 Completed N: 23 Dropouts: none reported **Inclusion criteria:** Elderly, at risk of developing pressure ulcers (confirmed	**Group 1:** 30° tilt position during the night. **Group 2:** 90° side-lying position during the night.	**Outcome 1:** Incidence of pressure ulcer (proportion of patients developing ulcer)	**Group 1:** 3/23 (13%) **Group 2:** 2/23 (9%)	**Funding:** Not reported **Limitations:** Study lacks generalisability (small sample size; one night study). Results should be interpreted with caution. **Additional comment:** Among the subjects who completed the study, the experimental intervention (30° tilt repositioning) was difficult to implement for 20 subjects (87%), whereas only five subjects (22%) in the control group (90° side-lying position) experienced difficulty with repositioning.
			Outcome 2: Location of pressure ulcer lesion	**Group 1:** one (4%) over the sacrum, 2 (9%) developed two discrete areas of damage (one on the left trochanter and heel, and the other on the right trochanter and heel). **Group 2:** 2 (9%) developed pressure damage at the sacrum.	
			Outcome 3: Patient acceptability	**Group 1:** 5/23 (22%) were unable to tolerate intervention **Group 2:** None reported for the control group	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Statistical comparisons were made on an intention-to-treat basis. Primary outcome analysed using Fisher's exact test **Baseline differences:** Groups were similar with respect to identified variables **Study power/sample size:** Eighty per cent power of detecting a difference, significant at a 5% level, 46 subjects were recruited into the study **Setting:** Acute inpatient district general hospital **Length of study:** One night **Assessment of PUs:** Non-blanching erythema was used as a definition of pressure damage. This is ascertained by applying light finger pressure to any reddened areas. If the area does not blanch under exertion then tissue damage is said to	by a Waterlow risk assessment score of above ten), able to lie 30° tilt position, had given informed consent **Exclusion criteria:** Not reported				Reported reasons for difficulty with repositioning includes: inability to get into and stay in position, joint stiffness, pain, anxiety.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
have occurred. **Classification of PUs:** no classification system but non-blanching erythema **Multiple ulcers:** not reported					

Table 32: Van Nieuwenhoven 2006[234]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Van Nieuwenhoven 2006 **Title:** Feasibility and effects of the semi recumbent position to prevent ventilator-associated pneumonia. Journal**:** Critical Care medical Journal. **Type of study:** RCT **Sequence generation:** Patients were randomly assigned on a one to one allocation basis. **Allocation concealment:** Closed, non transparent, numbered envelopes. **Blinding:** Investigators	**Patient group:** 221 participants with 112 randomised to the experimental arm and 109 to the control arm of the study. Mean age of 63.9 years **All patients** Randomised N: 221 Completed N: Not clear Drop-outs: Not clear **Group 1** Randomised N: 112 Completed N: Not clear Dropouts: Not clear	**Group 1:** Semi recumbent position. Aim was to achieve 45° position of the head and back. The 45° position was not achieved for 85% of the study time, and these patients more frequently changed position than supine positioned patients. **Group 2:** Standard care (supine position)	**Outcome 1:** Incidence of pressure ulcer (proportion of patients developing ulcer)	**Group 1:** 31/112 (28%) **Group 2:** 33/109 (9%)	**Funding:** Not reported **Limitations:** **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
remained blinded for the results of interim analysis **Addressing incomplete outcome data:** None reported. **Statistical analysis:** Power calculation was carried out. Study did not achieve estimated sample calculated. Intention to treat analysis done. **Baseline differences:** Groups were similar with respect to identified variables **Study power/sample size:** an expected total of 252 patients would be needed to reject the null hypothesis and an expected total sample size of 176 patients would be needed to accept the hypothesis. **Setting:** Adults patients admitted to four ICUs in three university hospitals in the Netherlands. **Length of study:** 7 days	**Group 2** Randomised N: 109 Completed N: not clear Dropouts: not clear **Inclusion criteria:** Adult patients intubated within 24hrs of ICU admission and had an expected duration of ventilation of at least 48hrs. **Exclusion criteria:** If patients were undergoing selective decontamination of their digestive tract or if they could not be randomised to one or two positions.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Pressure sore development was staged daily by research nurses **Classification of PUs:** NPUAP classification system **Multiple ulcers:** not reported					

I.1.3 Skin massage

Table 33: Duimel-Peeters 2007[71]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Duimel-Peeters, 2007 **Title**: The effectiveness of massage with and without dimethyl sulfoxide in preventing pressure ulcers: A randomized double-blind cross-over clinical trial in patients prone to pressure ulcers. **Journal:** International Journal of Nursing Studies, 2007; 44: 1285-95. **Study type**: Multicentric randomized double-blinded cross-over trial **Sequence generation:** Throwing a dice **Allocation:** not reported **Blinding:** Not reported Addressing incomplete outcome data:	**Patient group:** Residents of 8 Dutch nursing homes **All patients** Randomised N: 79 Completed N: Period 1: 78 Period 2: 64 Drop-outs: Period 1: 1 Period 2: 15 Some participants decided not to participate any longer Some health care workers got tired of applying the treatment as accurately as possible Gender: 69.6% female Age: mean 81.3, SD 9.76, range 45-97 Group 1 (period 1) Randomised N: 31 Completed N: 31 Dropouts: 0	Group 1: A 2–3-min massage of the coccyx, both heels and ankles with an indifferent cream (Cremor vaselini cetomacrogolis FNA; 'Vaseline'). This procedure was repeated every 6 h for 4 weeks Group 2: A 2–3-min massage of the coccyx, both heels and ankles with a dimethyl sulfoxide (DMSO) cream (5%), This procedure was repeated every 6 h for 4 weeks Group 3: position change only All groups: 30° position change	Outcome 1: Incidence of PU (%/period of 4 weeks) in period 1 Incidence of PU (%/period of 4 weeks) in period 2	Group 1: Period 1: 13/31 (41.9%) Period 2: 3/22 (13.6%) Group 2: Period 1: 18/29 (62.1%) Period 2: 3/25 (12.0%) Group 3: Period 1: 7/18 (38.9%) Period 2: 1/17 (5.9%) Period 1 P value=0.189 Period 2 P value=0.726 Period 1: Treatment 1 OR: 1.135 95% CI: P value: 0.834 Treatment 2: OR: 2.571 95% CI: P value: 0.126	Funding: none reported Limitations: Underpowered Randomization process by throwing a dice for 2 of the 3 interventions. Unclear allocation concealment Not clear whether outcome assessors were blinded. Relatively high dropout rate in period 2. Crossovers may also be inappropriate study design as they are reporting the number of patients with pressure ulcers then people who have had the outcome (PU) in period 1 shouldn't be entered in period 2 (because different population compared to the start of period 1 and they've already had the

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Not reported Statistical analysis: Differences in characteristics between patients in the various treatment groups were tested for each period with Chi-square tests for categorical data and t-tests for continuous data. Mann–Whitney and Kruskal–Wallis tests were used because of non-normality of some variables. Frequency tables for the outcome variable were constructed for each treatment period. Logistic regression was used to examine the results of each treatment in terms of pressure ulcer prevention. To correct for possible confounding variables, the following covariates were added (together and separately): length, weight, body mass index (BMI), length of	Age: not reported Gender (m/f): not reported Other relevant patient characteristics: none Group 2 (period 1) Randomised N: 29 Completed N: 29 Dropouts: 0 Age: not reported Gender (m/f): Not reported Other relevant patient characteristics: none Group 3 (period 1) Randomised N: 18 Completed N: 18 Dropouts: 0 Age: not reported Gender (m/f): Not reported Other relevant patient characteristics: none Group 1 (period 2) Randomised N: 28 Completed N: 22			Period 2: Treatment 1 OR: 2.526 95% CI: P value: 0.441 Treatment 2: OR: 2.182 95% CI: P value: 0.516	event you're looking for) and because there may be a time dependence to pressure ulcer development. Therefore we have only reported data from period 1. Additional outcomes: KM survival curves. Massaging with the indifferent cream or only changing of positions seemed to result in better pressure ulcer free prognosis than being massaged with the DMSO cream. As times goes on, the dashed and bold curves appear to grow further apart (until day 18), suggesting that the beneficial effects of only changing position relative to massaging with a DMSO-cream increase as treatment continued for a longer period. However, beyond day 18, the three treatments tended to have the same effects.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
stay on the ward (in months), age, sex, incontinence level, type of pressure-relieving cushions used and use of other preventive methods. Non-significant covariates were removed using backward deletion. Kaplan–Meier curves were constructed to obtain a clearer representation of the survival prognosis for each treatment. Baseline differences: Patients were not significantly different across periods with respect to age, sex, length, weight, BMI, length of stay on the ward, incontinence level, type of pressure-relieving cushions used and use of other preventive methods. Study power/sample size: No a priori sample size calculation Setting: Dutch nursing homes	Dropouts: 6 Age: not reported Gender (m/f): not reported Other relevant patient characteristics: none Group 2 (period 2) Randomised N: 27 Completed N: 25 Dropouts: 2 Age: not reported Gender (m/f): Not reported Other relevant patient characteristics: none Group 3 (period 2) Randomised N: 24 Completed N: 17 Dropouts: 7 Age: not reported Gender (m/f): Not reported Other relevant patient characteristics: none Inclusion criteria:				Notes: none

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 4 weeks in period 1 4 weeks in period 2 2 weeks wash-out period between periods 1 and 2 Assessment of PUs: Braden scale to assess PU risk (cut-off point of 20) PU were graded according to the four-grade system of the European Pressure Ulcer Advisory Panel using a transparent disk. Because of the reversibility of grade I ulcers, these ulcers were only recorded as pressure ulcers if they were still present after 4 h and if two external observers confirmed the nurse's rating of grade I. A transparent disk with a diameter of 6.5 cm was used to assess local redness. This involved first releasing the pressure on the body part, for example by changing the patient's position. If the local	1) have a light skin colour, 2) have resided in a long-stay ward of a nursing home for more than two months 3) rest on an anti-pressure ulcer mattress (i.e. poly urethane mattress or equivalent), 4) be willing to give informed consent or have this provided by their relative/legal representative 5) to be at high risk of developing pressure ulcers according to the Braden scale using a cut-off point of 20. Exclusion criteria: 1) already being treated with massage for another medical indication (and it was not possible to end this treatment) 2) undergoing surgery in the near future or had undergone surgery less than two weeks previously 3) had pressure ulcers already present at the				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
redness persisted after 10min, when pushing the convex lens against the skin, the grade 1 pressure ulcer was confirmed. Multiple ulcers: The outcome variable development of PU or not regardless of the number of PU	coccyx, heels or ankles (the only places that were massaged in this research 4) expected to have short length of stay 5) a short life expectancy (<10 months).				

I.1.4 Nutritional supplementation and hydration strategies

Table 34: Langer 2003[129]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
Author and year: Langer 2003 **Title:** Nutritional interventions for preventing and treating pressure ulcers (Review) **Journal:** Cochrane Database of Systematic Reviews 2003, Issue 4.	**N of studies:** 4 **Inclusion criteria:** **Population:** People of any age and sex with or without existing pressure ulcers, in any care setting, irrespective of primary diagnosis. A pressure ulcer was defined as an area of localised damage to the skin and underlying tissue caused by pressure, shear, friction and/or a combination of these for the purpose of this review. **Studies:** Randomised controlled trials (RCTs) of parallel or crossover design evaluating the effect of enteral and/or parenteral nutrition on the prevention and treatment of pressure ulcers by measuring the incidence of new ulcers, ulcer healing rates or	Clearly described nutritional supplementation (enteral or parenteral nutrition) or special diet. Comparisons between supplementary nutrition plus standard diet versus standard diet alone and between different types of supplementary nutrition (e.g. enteral vs. parenteral) were eligible.	Primary outcome: Incidence of pressure ulcers	Does the review address an appropriate question relevant to the guideline review question? yes Does the review collect the type of studies you consider relevant to the guideline review question? yes Was the literature search sufficiently rigorous to identify all relevant studies? yes Was study quality assessed reported? Yes but the study quality was in a narrative and no traffic lights or tables of quality were reported. Was an adequate description of the methodology used and included, and the methods used are appropriate to the question? yes	**Quality grade:** very low risk of bias

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
	changes in pressure ulcer severity. Controlled clinical trials (CCT) were only considered eligible for inclusion in the absence of RCTs. **Exclusion criteria:** see above for inclusion criteria				

Table 35: Craig 1998[56]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Craig 1998 **Title:** Use of a reduced-carbohydrate, modified-fat enteral formula for improving metabolic control and clinical outcomes in long-term care residents with type 2 diabetes: results of a pilot trial Journal**:** Nutrition, 1998, 14 (6), 529-534. **Type of study:** RCT double-blinded pilot trial **Sequence generation:**	**Patient group:** LTC residents with type 2 diabetes **All patients randomised** **N=** 34 **Completed:** 27 **Drop-outs:** 7 **Group 1:** **Randomised N:** 18 **Completed:** 16 at 4 weeks, 14 at 12 weeks **Dropouts:** 3 died **Age mean (sd):** 82 (3),	**Group 1**: disease-specific (reduced-carbohydrate, modified-fat) formula (Energy 1000 kcal, 41.8 g protein, 16.7% kcal – source sodium and calcium caseinates, 93.7g carbohydrate, 33.3% kcal – source maltodextrin, soy polysaccharide; fructose; fat 55.7 g, 50%kcal – source high-oleic safflower oil, soy oil). **Group 2:** standard high-carbohydrate formula (Energy 1060kcal, 44.4g protein, 16.7% kcal – source	**Outcome 1: Incidence of PU:**	**Group 1:** 7/17 (41.2%) **Group 2:** 8/15 (53.3%) **Relative risk:** 0.77 **95% CI:** 0.37 to 1.62	**Funding: supported by Ross Products Division, Ohio** **Limitations:** study aim was not to look at pressure ulcers, it was only an event experienced during the study. No details of sequence generation or allocation concealment. Small sample size.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
says randomised but no details of sequence generation **Allocation concealment:** no details of allocation concealment**.** **Blinding:** double-blinded but no details of who was blinded. **Addressing incomplete outcome data:** adequate. Available Case Analysis. **Statistical analysis:** ANOVA for continuous data; secondary outcomes Pearson chi-square test, Cochran-Mantel-Haenszel mean rank scores statistic for treatment group differences. **Baseline differences:** no significant differences. **Study power/sample size:** no power calculation very small sample size **Setting:** 2 long-term care facilities in USA. **Length of study:** 3 months	range 52-94 years **Males:** not reported **Group 2:** **Randomised N:** 16 **Completed:**14 at 4 weeks and 13 at 12 weeks **Dropouts:** 2 died, 1 removed due to uncontrolled blood glucose levels. **Age mean (sd):** 80 (2), range 52-100. **Males:** not reported **Inclusion criteria:** at least 50 years of age; history of type 2 diabetes mellitus or had documented hyperglycemia as evidenced by either a plasma glucose random measurement of >200mg/dL or a fasting plasma glucose >140mg/dL on tow occasions; required total enteral nutrition support by tube; were able to tolerate a volume of formula that maintained	sodium and calcium caseinates; carbohydrate 151.7g (includes soy fiber that provides 39 kcal and 14g of total dietary fiber per L) carbohydrate, 53.3% kcal – source maltodextrin, soy polysaccharide; fat 35.9g, 30.0% kcal – source high-oleic safflower oil, canola oil, MCT oil.			**Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: clinical outcomes collected daily but no details of how. **Classification of PUs:** not reported **Multiple ulcers:** not reported	body weight; informed consent provided. **Exclusion criteria:** see above.				

Table 36: Theilla 2007[221]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Theilla 2007[221] **Title:** A diet enriched in eicosapentanoic acid, gamma-linolenic acid and antioxidants in the prevention of new pressure ulcer formation in critically ill patients with acute lung injury: a randomised, prospective, controlled study **Journal:** Clinical Nutrition, 26, 752-757. **Type of study:** RCT **Sequence generation:** no details	**Patient group:** critically ill, mechanically ventilated patients suffering from acute lung injury (secondary outcome from a larger study on acute lung injury) **All patients** **Randomised N=100** **Completed N: 95** **Drop-outs:** 5 excluded due to diarrhoea or food intolerance (gastric residue larger than 250mL. **Group 1**	Group 1: same macronutrient diet as control group plus a lipids (elcosapentanoic acid (EPPA), gamma-linolenic acid (GLA)), vitamins A,C and E Group 2: macronutrient diet: ready to feed, high fat, low carbohydrate, enteral formula.	**Outcome 1: incidence of all pressure ulcers**	**Group 1:**8/46 (17.4%) **Group 2:** 10/49 (20.4%) **Relative risk:** 0.85 **95% CI:** 0.37 to 1.97	**Funding:** no details of funding **Limitations:** no details of sequence generation, allocation concealment. No blinding. BMI was higher in the intervention group at baseline. **Additional outcomes:** pressure ulcers at day 7 (all ulcers including those at start of
			Outcome 2: incidence of grade 2-4 pressure ulcers	**Group 1:** 4/49 (8.2%) **Group 2:** 6/49 (12.2%) **Relative risk:** 0.71 **95% CI:** 0.21 to 2.36	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Allocation concealment: no details **Blinding:** Not blinded. **Addressing incomplete outcome data:** no further drop-outs except those who were excluded as did not meet inclusion criteria as had diarrhoea or food intolerance **Statistical analysis:** ANOVA with repeated measure for difference between dependent variables. Chi-square test for associations between no-dependent variables **Baseline differences:** BMI was significantly higher in the study group **Study power/sample size:** no a priori sample size calculation given and small sample size. **Setting:** ICU, Israel. **length of study:** 7 days **Assessment of PUs:** NPUAP grading, assessed daily by researchers. **Classification of PUs:**	**Randomised N:** **Completed N: 46** **Dropouts:** **Age (mean +/-SD): 57.0 (18.7)** **Gender (Male): 29 (63.0)** **Diagnostic category for ICU admission:** **Medical: 28 (60.9%)** **Surgical: 18 (39.1%)** **Trauma: 0** **No. with pressure ulcers: 7/46** **Grade 1: n=5** **Grade 2: n=1** **Grade 3: n=1** **BMI (SD): 28.9 (6.2)kg/m2** **Group 2** **Randomised N:** **ITT N:49** **Dropouts:** **Age (mean+/-SD):62.3 (17.2)** **Gender (Male): 28 (57.1%)** **Diagnostic category for ICU admission**: **Medical: 34 (69.4%)** **Surgical: 15 (30.6%)**				study)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
NPUAP **Multiple ulcers:** not reported	**Trauma: 0** **No. with pressure ulcers: 14/49 (p=NS)** **Grade 1: n=6** **Grade 2: n=7** **Grade 3: n=1** **BMI (SD): 26.5 (5.4)kg/m2, p=0.05** **Inclusion criteria:** patients with acute lung injury defined by a PaO2/FIO2 ratio below 250. **Exclusion criteria:** patients with head trauma, cerebral bleeding, coagulation disorders, receiving steroids in a dose >0.25mg/kg/day methylprednisolone or non-steroidal anti-inflammatory agents, patients less than 18 years and pregnant patients. If diarrhoea occurred more than three times.				

Table 37: Olofosson 2007[169]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Olofsson 2007[169] **Title:** Malnutrition in hip fracture patients: an intervention study **Journal:** Journal of Clinical Nursing, 16(11), 2027-2038. **Sequence generation:** randomised to postoperative care in a geriatric ward with a special intervention programme or to conventional care in the orthopaedic department **Allocation concealment:** sealed, opaque envelopes stratified according to operation method. Nurse on duty at the orthopaedic dept, not involved in the study, opened the envelope. **Blinding:** the staff on the intervention ward was aware of the nature of the study, and the staff	**Patient group:** femoral neck fracture patients **All patients** **Randomised N:** 199 **Completed N:** 157 **Drop-outs:** 42 **Group 1** **Randomised N:** 102 **Completed N:** 83 **Dropouts:** 19 (18.6%) Six patients died during hospitalisation and five patients had missing MNA[(a)] (91 were assessed at 4 months), 3 patients died after discharge, one patient declined to continue and four patients had missing MNA[(a)]. **Group 2** **Randomised N:** 97 **Completed N:** 74 **Dropouts:** 23 (23%) Seven patients died during	**Group 1:** protein enriched meals (calculated at approximately 30 calories per kilo body weight) served during the first four postoperative days and longer if necessary. At lunch an appetizer was always served with the protein-enriched meals and a dessert at dinner. When the registered nurses suspected malnourishment on admission they found out when or why they had lost their appetite to discover whether the patients needed even more energy/calories. If there were problems in these areas, a dietician was consulted. They also received two nutritional and protein drinks (2x200ml) daily during whole hospitalisation period. Additional nutritional and protein drinks were served after every meal for patients who needed extra calories. If patients could not sleep or were anxious at night an extra meal was offered during the	**Outcome 1:** incidence of pressure ulcers	**Group 1:** 7/83 **Group 2:** 14/74 P=0.054 Those who did develop pressure ulcers were almost exclusively suffering from severe malnutrition.	**Funding:** grants from the Borgerskapet in Umea Research Foundation, the Dementia Fund, the Vardal Foundation, the Joint Committee of the Northern Health Region of Sweden, the JC Kempe Memorial Foundation, the Foundation of the Medical Faculty, University of Umea, the County Councils of Vasterbotten and the Swedish Research Council grant. **Limitations:** randomised to different wards. No blinding. Small study no power calculation.
			Outcome 2: time in hospital	**Group 1:** 27.4 (14.9) **Group 2:** 39.8 (41.9) P=0.019	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
working on the control ward was informed that a new care programme was being implemented and that it was being evaluated in the geriatric intervention ward. **Addressing incomplete outcome data:** explains what happened to all missing data. Available Case Analysis. Statistical analysis: Student's t-test was used to analyse differences in MNA[(a)] scores on admission and at the four-month follow-up between groups. **Statistical analysis:** Student's t-test to analyse differences in MNA[(a)] scores **Baseline differences:** there was a significantly higher score for the intervention group for heart failure at baseline. There were four patients missing data in the control group and one in the intervention group at this time.	hospitalisation, 8 patients had missing MNA[(a)] (82 were assessed at 4 months). Six patients died after discharge, 1 patient moved to another city and one patient had missing MNA[(a)]. **Inclusion criteria:** femoral neck fracture, aged 70 years or older, admitted consecutively to the orthopaedic dept of one hospital, from May 2000 to December 2002. **Exclusion criteria:** severe rheumatoid arthritis, severed hip osteoarthritis, severe renal failure, metastatic fracture and patients who were bedridden before their injury.	night shift. The environment around the meal was adjusted to facilitate good nutrition, by making the meal times nice and comfortable with no unnecessary noise, bustle or stress. Any aspect that might improve the patients' nutrition was considered eg they could choose their own food or ask what they wanted to eat. All physical problems that led to patients eating less were dealt with eg constipation, pain or bad oral hygiene. **Group 2:** postoperative care in the orthopaedic department in accordance with conventional postoperative care routines (described in table). Staffing ratio 1.01 nurses or aids per bed. Patients who needed a longer rehabilitation period were transferred to a general geriatric rehab ward but not to the ward where the intervention programme had been implemented (n=30). Staffing ratio was 1.07 nurses or aids per bed. All patients: received same preoperative treatment in the			**Additional outcomes:** compliance - the nutritional and protein drinks were served during the whole hospitalisation period in the intervention group but we do not know exactly how much were consumed. Should be noted when interpreting the results. Complications during hospitalisation were given in relation to the MNA[(a)] scores at baseline in each group (delirium, nutrition difficulties, constipation, pressure ulcers, urinary tract infection.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: small, no power calculation. **Setting:** orthopaedic department, Umea University Hospital Sweden. **Length of study:** four month follow-up **Assessment of PUs:** not specifically mentioned as not main aim of study. **Other assessments:** the mini mental state examination, organic brain syndrome scale and the geriatric depression scale were used. The MNA[(a)] was used to assess the patients' nutritional status. **Classification of PUs:** not reported **Multiple ulcers:** not reported.		orthopaedic department and had same mean waiting for surgery (25.1 hours in the control group and 24.6 hours in the intervention group, p=0.852).			Study was part of a multifactorial multidisciplinary intervention study.

(a) MNA – mini nutritional assessment scale

Table 38: Dennis 2005[67]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Dennis 2005[67] **Title:** Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial **Journal:** Lancet, 2005, 365, 755-763. **Study type:** Multicentre RCT **Sequence generation:** computer-generated **Allocation concealment:** international co-ordinating centre and computer-generated minimisation algorithm balanced treatment within each country **Blinding:** no blinding of assessment and treatment allocation. **Addressing incomplete outcome data:** adequate. Primary analyses ITT. **Statistical analysis:** Log-rank test	**Patient group:** elderly stroke patients in hospital **All patients randomised N=** 4023 **Completed:** **Drop-outs:** **Group 1:** **Randomised N:** 2016 **Completed:** 1767 **Dropouts:** 4 lost to follow-up, 3 vital status only, 241 died **Age mean (sd):** 71 (12) **Males: 1071 (53%)** **Nutritional status:** **Undernourished:** 156 (8%) **Normal:** 1550 (77%) **Overweight:** 310 (15%) **Glasgow coma scale verbal normal:** 1644 (82%) **Group 2:** **Randomised N:** 2007 **Completed:** 1740 **Dropouts:** 7 lost to follow-up, 5 vital status only, 253 died	**Group 1**: normal hospital diet plus oral supplements (360mL at 6.27 kJ/mL and 62.5g/L in protein every day) Most centres used commercially available supplements of suitable consistency for patients with mild swallowing impairments eg liquid, yoghurt, pudding. The supplements were prescribed on drug-administration charts to increase compliance and to allow monitoring of compliance by the hospital coordinator so that there was an increase in the total protein and energy intake of elderly patients in hospital. **Group 2:** normal hospital diet	**Outcome 1: Incidence of PU:**	**Group 1: 15/2016 (0.7%)** **Group 2: 26/2007 (1.3%)** **Relative risk: 0.57** **95% CI: 0.31 to 1.08**	**Funding:** grants from the HTA board of NHS research and development in the UK, the Stroke Association, the Chief Scientist Office of the Scottish Executive, and Chest, Heart and Stroke Scotland. The Royal Australasian College of Physicians supported the trial in Hawkes Bay, New Zealand. **Limitations:** aim not to look at pressure ulcers and there were no details of pressure ulcers at start of the trial. Pressure ulcers were classified as a complication. The authors state that the data needs to be interpreted with
			Outcome 2: length of stay in hospital – mean days (s.d)	**Group 1:** 34.0 (48.00) **Group 2:** 32.00 (46.00)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: no differences **Study power/sample size:** yes based on dichotomous outcome – dead or poor outcome (MRS[(a)] 3-5) at follow-up. 87% power 6000 participants. **Setting:** multicentre, UK **Length of study:** 6-months follow-up **Assessment of PUs:** not reported **How outcomes recorded:** postal questionnaire or structured telephone interview from patient, carer or proxy. **Classification of PUs:** not reported **Multiple ulcers:** not reported.	**Age mean (sd):** 71 (13) **Males:** 1078 (54%) **Nutritional status:** **Undernourished:** 158 (8%) **Normal:** 1542 (77%) **Overweight:** 307 (15%) **Glasgow coma scale verbal normal:** 1606 (80%) **Inclusion criteria:** patients admitted with a recent stroke (first or recurrent stroke no more than 7 days before admission) could be enrolled if they passed their swallow screen, the responsible clinician was uncertain whether to use oral nutritional supplements and the patient (or a relative) consented to enrolment. Enrolled within 30 days of admission, or within 30 days of a stroke occurring in hospital. **Exclusion criteria:** subarachnoid haemorrhage				caution because they could not mask the assessment to treatment allocation and it was not feasible for local source data to be verified for the occurrence of these. Trial was stopped before they reached their target as no funding was available to continue beyond 2004 and to ensure the trial was closed in an orderly manner. **Additional outcomes:** primary outcomes were death or poor outcome and overall survival. Aim of study was not to look at pressure ulcers.

(a) MRS is the modified Rankin scale which is a scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability. Scoring: 0 No symptoms at all; 1 No significant disability despite symptoms; able to carry out all usual duties and activities; 2 Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance; 3 Moderate disability; requiring some help, but able to walk without assistance; 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance; 5 Severe disability; bedridden, incontinent and requiring constant nursing care and attention; 6 Dead.

Table 39: Houwing 2003[102]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Houwing et al 2003[103] **Title:** A randomised, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients. Journal: Clinical Nutrition, 22(4),401-405 **Type of study:** Multicentre RCT **Sequence generation:** no details **Allocation concealment:** no details **Blinding:** double-blinded. Look and taste of both supplements were not identical but supplements were given in similar, blinded packages to mask the	**Patient group:** hip fracture patients **All patients randomised N=**103 **Drop-outs: 0** **Group 1:** **Randomised N:** 51 **Dropouts:** 0 **Age (mean):**81.5+/-0.9 **Sex (female):** 40/51 **Risk score CBO:** 11.1+/-0.3 **Group 2:** **Randomised N:** 52 **Dropouts:** 0 **Age (mean):** 80.5+/-1.3 **Sex (female):** 44/52 **Risk score CBO:** 11.2+/-0.2 **Inclusion criteria:** hip fracture, patient with a	**Group 1**: Standard diet with additional supplement. Supplement was a high-protein nutritional supplement enriched with arginine, zinc and antioxidants (400ml). Given immediately postoperatively for 4 weeks or until discharge **Group 2:** Standard diet with placebo: a non-caloric, water-based drink containing only sweeteners, colorants and flavourings (400ml)	**Outcome 1: incidence of all pressure ulcers**	**Group 1:**27/51 (55.1%) **Group 2:**30/52 (58.8%) **Relative risk:**0.037 **95% CI:**-0.16 to 0.23 **P value:** 0.420	**Funding:**Numico Research BV, Wageningen, the Netherlands **Limitations:** Unclear selection bias - no details of sequence generation or allocation concealment. **Additional outcomes:** total max wound size (cm^3), first day pressure ulcer, number of days with pressure ulcer. Notes: 57% developed PU within first 2 days of the study and 76% by the fourth
			Outcome 2: Incidence of grade 2 pressure ulcers	**Group 1:** 9/51 (17.6%) **Group 2:** 14/52 (26.9%) **Relative risk:** 0.66 **95% CI:** 0.31 to 1.38	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
differences. **Addressing incomplete outcome data:** no dropouts. ITT analysis. **Statistical analysis:** Distribution of variables evaluated visually by Kolmogorov-Smirnov test. Differences in continuous variables determined by Student's t-test or Mann-Whitney U-test. Difference in incidence rates by Fisher's exact test. Results adjusted for age or length of surgery by ANOVA. **Baseline differences:** no significant difference in baseline values. **Study power/sample size:** underpowered **Setting:** three centres in the Netherlands **Length of study:** 28 days or until discharge **Assessment of PUs:** PU assessed daily by nursing staff **Classification of PUs:** EPUAP classification	pressure risk score over 8 according to the CBO-risk assessment tool (four-point scoring tool including: mental status, neurology, mobility, nutritional status, nutritional intake, incontinence, age, temperature, medication and diabetes). **Exclusion criteria:** terminal care, metastatic hip fracture, insulin-dependent diabetes, renal disease (creatinine >176mmol/l, hepatic disease, morbid obesity (BMI>40), need for therapeutic diet incompatible with supplementation and pregnancy or lactation.				day

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
system **Multiple ulcers:** not reported					

Table 40: Bourdel-Marchasson 2000[33]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Bourdel-Marchasson (2000)[33] **Title:** A multi-centre trial of the effects of oral nutritional supplementation in critically ill older inpatients **Type of study:** multi-centre cluster-randomised RCT **Sequence generation:** 19 wards stratified by specialty and the wards randomised into 2 groups. No details on seq. gen. **Allocation concealment:** no details but multicentre stratified **Blinding:** not blinded (authors state it is not	**Patient group:** Critically ill older patients. **All patients** **Randomised N= 672** **Drop-outs: 173** **Group 1** **Randomised N: 295** **Completed N: 107** **Dropouts: 188** **Age mean (s.d): 83.6 (7.3)** **Male (%): 96 (32.5)** **Other baseline data:** **Stroke: 23.6%** **Falls and gait disturbance: 13.7%** **Heart failure and dyspnea: 13.1%** **Infectious diseases: 13.7%** **Digestive diseases: 3.2%**	Group 1: standard diet of 1800kcal/day plus 2 oral supplements of 200kcal each (30% protein, 20% fat, 50% carbohydrate in addition to minerals and vitamins such as zinc 1.8mg and vitamin C (15mg) Group 2: standard diet of 1800kcal/day	**Outcome 1: pressure ulcer (cumulative) incidence at end of follow-up**	**Group 1:** 118/295 (40%) **Group 2:** 181/377 (48%) **Relative risk:** 0.83 **95% CI:** 0.70 to 0.99	**Funding:** Projet Hospitalier de Recherche Clinique, Ministère de la Santé et de l'Action Humanitaire, Direction Générale de la Santé et la Direction des Hôpitaux. **Limitations:** 25 died in Intervention and 22 in control group. No details of sequence generation for cluster randomisation. No blinding. There were baseline differences but author did multivariate

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
easy to propose placebo oral supplements with similar taste and consistency in a double-blind manner. Also it could have a deleterious effect on the energy intake in the control group because in elderly hospitalised patients the volume rather than the energy content of food could limit voluntary energy intake). **Addressing incomplete outcome data:** for subjects who died or were discharged without pressure ulcers before the day 15, the date of death or discharge were considered as censoring the data. ITT analysis. **Statistical analysis:** Chi-square test for categorical variables and Student's t test for numerical variables after applying the Fisher test. Multiple hazard regression Cox model to adjust analysis. Homogeneity test used	**Delirium: 5.6%** **Dehydration: 2.9%** **Lower limb fractures: 0.3%** **Cancer: 1.1%** **Neurologic diseases: 2.4%** **Painful arthritis: 2.1%** **Deep Vein Thrombosis: 2.9%** **Miscellaneous medical diseases: 15.3%** **Group 2** **Randomised N: 377** **Completed N: 244** **Dropouts: 133** **Age mean (s.d):83.0 (7.1)** **Male (%): 139 (36.9)** **Other baseline data:** **Stroke: 6.8% (P<0.001)** **Falls and gait disturbance: 20.2% (p=0.02)** **Heart failure and dyspnea: 7.2% (p=0.009)** **Infectious diseases: 11% (N.S)** **Digestive disease: 14.4% (p<0.001)** **Delirium: 9.9% (p=0.001)** **Dehydration: 2.7% (N.S)**				analysis to account for these differences. There was a very high drop-out 63% in intervention group and 35% in control group. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and a multivariate Cox proportional hazard model. **Baseline differences:** the nutritional group included more patients with stroke, heart failure, and dyspnea and fewer with antecedent falls, delirium, lower limb fractures and digestive disease. The nutritional group had a lower risk of pressure ulcers, were less dependent (Kuntzman score) and a lower serum albumin level (indicates a higher risk for pressure ulcers) **Study power/sample size:** a priori power calculation not reported but large sample size. **Setting:** inpatients of hospital wards in Bordeaux or inpatients at geriatric units in Southwest France belonging to GAGE, a group for the evaluation and improvement of health care for the	**Lower limb fractures: 4.1% (p=0.004)** **Cancer: 4.8% (N.S)** **Neurologic diseases: 2.4% (N.S)** **Painful arthritis: 2.1% (N.S)** **DVT: 0 (N.S)** **Miscellaneous medical diseases: 14.4% (N.S)** **Inclusion criteria:** older than 65 years, in the acute phase of a critical illness, unable to move by themselves, and unable to eat independently at admission. **Exclusion criteria:** pressure ulcers at admission.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
elderly. **Length of study:** 15 days follow-up **Classification of PUs:** AHCPR **Assessment of PUs:** Norton scale to assess risk of developing pressure ulcers; Kuntzman scale assessed the activities of daily living. Ulcers graded by four grades defined by the Agency for Health Care Policy and Research. **Multiple ulcers:** not reported					

Table 41: Hartgrink 1998[95]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Hartgrink 1998[95] **Title:** Pressure sores and tube feeding in patients with a fracture of the hip: a randomised clinical trial **Journal:** Clinical	**Patient group: hip fracture patients** **All patients** **Randomised N=140** **Evaluable at admission: 129 (11 did not fulfil entry**	All patients received standard hospital diet. In case they were randomised to tube feeding, a nasogastric tube was given during surgery or within 12 hours afterwards. Actual feeding started within 24 hours.	**Outcome 1: pressure sore incidence (grade 2 or more) [no. evaluable at 2 weeks]**	**Group 1: 25/48 (44%)** **Group 2: 30/53 (57%)** **Relative risk: 0.92** **95% CI: 0.64 to 1.32**	**Funding: not stated.** **Limitations:** no details of sequence generation, allocation concealment and
			Outcome 3: Pressure sore	**Group 1: 30/48 (62.5%)** **Group 2: 37/53 (69.8%)**	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Nutrition 1998, 17 (6), 287-292. **Type of study:** single centre parallel RCT **Sequence generation:** no details. **Allocation concealment:** no details. **Blinding:** no blinding **Addressing incomplete outcome data:** adequate**,** per protocol analysis. **Statistical analysis:** Fisher's test **Baseline differences:** no differences **Study power/sample size:** no power calculation given. **Length of study:** 2 weeks treatment. **Assessment of PUs:** not reported **Classification of PUs:** (Stage 0=normal skin, 1=persistent erythema of the skin, stage 2=blister formation, stage 3=superficial (sub)cutaneous necrosis, stage 4=subcutaneous	**criteria)** **Drop-outs: 11 excluded at admission (randomisation not correctly performed).** **Evaluable at 1 week: 116** **Evaluable at 2 weeks: 101** **Group 1** **Randomised N: 70** **Evaluable at admission: 62** **Evaluable at 1 week: 54** **Evaluable at 2 weeks: 48** **Dropouts:** **Age (mean): 84.0 (7.1)** **Sex M/F: 10/52** **Time from entry to operation (min) mean (SD): 20.0 (16.3)** **Operation time (min): 58.2 (22.4)** **Pressure-sore risk score (mean, SD): 9.0 (1.3)** **Group 2** **Randomised N: 70** **Evaluable at admission: 67** **Evaluable at 1 week: 62** **Evaluable at 2 weeks: 53**	Group 1: Standard hospital diet plus tube feeding (1 litre Nutrison Steriflo Engergy-plus (1500kcal/l energy, 60 gram/l protein, Nutricia, Netherlands)). Administered with a feeding pump through a polyurethane nasogastric feeding tube. Tube feeding was to be given for 2 weeks and administered between 21:00 and 05:00 to minimise interference with the normal hospital diet. Nurses kept record of food offered and food left over. Calculation of energy and protein intake by diet and tube feeding done daily by dietician. Group 2: standard hospital diet.	**incidence (all grades) [no. available at 2 weeks]**	**Relative risk: 0.90** **95% CI: 0.68 to 1.19**	no blinding. High drop-out in both groups. Those who were still tube fed at 1 and 2 weeks were 25 and 16 patients respectively. Additional mortality: evaluable at week 1 and week 2.
			Outcome 2: pressure sore incidence (grade 2 or more) [no. available at 1 week]	**Group 1:20/54 (28%)** **Group 2: 30/62 (48%)** **Relative risk: 0.77** **95% CI: 0.50 to 1.18**	
			Outcome 4: pressure sore incidence (all grades) [no. available at 1 weeks]	**Group 1: 35/54 (64.8%)** **Group 2: 41/62 (66%)** **Relative risk: 0.98** **95% CI: 0.75 to 1.28**	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
necrosis, according to the Dutch consensus meeting for the prevention of pressure sores) **Multiple ulcers:** not reported	**Dropouts:** **Age (mean): 83.3 (8.1)** **Sex M/F: 6/6** **Time from entry to operation (min) mean (SD):21.1 (12.3)** **Operation time (min): 63.1 (23.4)** **Pressure-sore risk score (mean, SD):9.2 (1.3)** **Inclusion criteria:** fractured hip; pressure-sore risk score of 8 points or more (calculated as sum of points scored on 10 risk indices – mental status, neurology, mobility, nutritional status, incontinence, age, temperature, medication and diabetes). **Exclusion criteria:** Patients with pressure sores of grade 2 or more at admission (Dutch consensus).				

Table 42: Delmi 1990[65]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Delmi 1990[65] **Title:** dietary supplementation in elderly patients with fractured neck of the femur Journal**:** Lancet 1990, 28, 335 (8696); 1013-1016. **Type of study:** RCT **Sequence generation:** no details **Allocation concealment:** no details **Blinding:** no details **Addressing incomplete outcome data:** adequate **Statistical analysis:** unpaired t tests or U tests, and X2 and Fisher's exact tests for analysis of clinical course. **Baseline differences:** the 250HD plasma level was lower in non-supplemented patients (median 9.0nmol/l, range 2.3-61.5 vs 14.9, 4.2-87, p<0.05). **Study power/sample**	**Patient group:** elderly patients with fractures of the proximal femur. **All patients** **Randomised N=59** **Completed N: 49** **Drop-outs: 10 died (not included in analysis)** **Group 1** **Randomised N: 27** **Completed N: 21** **Dropouts: 6 died (not included in analysis)** **Age (mean SD and range): 80.4 (8.5,61-93)** **Female/Male: 24/3** **Triceps skinfold (mm): Women 12.1 (4.6)** **Men 5,7,10** **Upper arm circumference (mm):** **Women 251 (30)** **Men 255, 260, 260** **Group 2** **Randomised N: 32** **Completed N: 28**	**Group 1:** Daily oral nutrition supplements, for mean 28 days in addition to standard hospital diet. **Group 2:** control group 250ml oral nutritional supplement provided 254kcal, 20.4g protein, 29.5g carbohydrate, 5.8g lipid, 525mg calcium, 750 IU vitamin A, 25 IU vitamin D3, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals.	**Outcome 1: pressure ulcers at first hospital (orthopaedic)**	**Group 1**:2/27 (7.4%) **Group 2**:3/32 (9.38%)	**Funding:** not reported. **Limitations:** small sample. No details of sequence generation, allocation concealment or blinding. Difference at baseline for plasma level. **Notes:** most patients had nutritional deficiencies. The authors state that elderly are often malnourished and patients with fractured proximal femur seem especially under-nourished. Supplement was well tolerated and completely ingested so no side-effects observed.
			Outcome 2: pressure ulcers at 2nd hospital (recovery)	**Group 1:**0/9 (0%) **Group 2:**3/15 (20%)	
			Outcome 3: pressure ulcers at 6 months [figures used in CR]	**Group 1: 0/25 (0%)** **Group 2: 2/27 (7.4%)**	
			Outcome 4: total length of stay in orthopaedic ward and recovery hospital	**Group 1: median 24 days (range 13-157)** **Group 2: 40 (10-259)** **P=0.09**	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: no power calculation. **Setting:** orthopaedic unit of University hospital of Geneva **Length of study:** assessments made on days 14, 21 and 28 and at 6 months. **Assessment of PUs:** not reported **Classification of PUs:** not reported **Multiple ulcers:** not reported	**Dropouts: 4 died (not included in analysis)** **Age (mean SD and range): 82.9 (1.9, 66-96)** **Female/Male: 29/3** **Triceps skinfold (mm): Women 11.4 (5.7)** **Men 4,7, 13** **Upper arm circumference (mm):** **Women 261 (41)** **Men 230, 270, 290** ***Data for 3 men in each group** **Inclusion criteria:** patients over 60 years old admitted between March 1st and May 15th 1985 with a femoral neck fracture after an accidental fall. All patients were well-oriented, able to understand the aim of the study, and willing to cooperate. **Exclusion criteria:** Fractures from violent external trauma and pathological fractures due				**Outcomes also reported but not specified here:** severe anaemia, cardiac failure, infection and GI ulcer. These were given for first hospital (orthopaedic), 2nd hospital (recovery) and at 6 months.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	to tumours or non-osteoporotic osteopathies; dementia; renal, hepatic or endocrine disease, gastrectomy or malabsorption, or treatment with phenytoin, steroids, barbiturates, fluoride, or calcitonin.				

I.1.5 Pressure redistributing devices

Table 43: McInnes 2011[139]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
Author and year: McInnes 2011 **Title:** Support surfaces for pressure ulcers prevention (Review) **Journal:** Cochrane Database of Systematic Reviews 2011, Issue 4.	**Number of studies:** 53 **Inclusion criteria:** **Population:** people receiving health care who were thought at risk of developing pressure ulcers, in any settings. Patients could have existing pressure ulcers but only the incidence of new pressure ulcers was looked at. **Studies:** RCTs and quasi-randomised trials comparing support	Low-tech CLP support surfaces: • Standard foam mattresses • Alternative foam mattresses/overlays (eg convoluted foam, cubed foam) • Gel-filled mattresses/overlays • Fibre-filled mattresses/overlays • Air-filled mattresses/overlays • Water-filled mattresses/overlays • Bead-filled	**Primary outcomes:** incidence of pressure ulcers Grades of new pressure ulcers **Secondary outcomes:** cost of the devices; patient comfort; durability/longevity of the devices; acceptability of the devices for healthcare staff; quality of life	Does the review address an appropriate question relevant to the guideline review question? yes Does the review collect the type of studies you consider relevant to the guideline review question? yes Was the literature search sufficiently rigorous to identify all relevant studies? yes Was study quality assessed reported? yes Was an adequate description of the methodology used and included, and the methods used	**Quality grade:** very low risk of bias

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
	surfaces and measured the incidence of new pressure ulcers. **Exclusion criteria:** see above. **Population:** Studies: only reporting subjective measures of outcome; only reported proxy measures such as interface pressure. **Details of studies included:** 27 studies included participants without pre-existing pressure ulcers; 8 included patients with grade 1 or above pressure ulcers; 4 did not specify the grading of the pre-existing ulcers and one included people with grade 4 pressure ulcers only. 12 studies the baseline skin status was unclear. Five studies evaluated different operating table surfaces; 9 evaluated different surfaces in	mattresses/overlays • Sheepskins High-tech support surfaces: • AP mattresses/overlays • Air-fluidised beds • Low-air-loss beds Other support surfaces • Turning beds/frames • Operating table overlays • Wheelchair cushions • Limb protectors		are appropriate to the question? yes	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
	intensive care units; 8 confined evaluation to orthopaedic patients; one involved both A&E and ward setting; five were in extended care facilities; 3 were in nursing homes, 7 involved two or more different hospital wards; 15 did not specify the study setting. 11 trials evaluated cushions, 4 evaluated sheepskins, 4 looked at turning beds/tables; 16 examined overlays and 2 looked at mattress; 3 evaluated foam surfaces, 2 evaluated waffle surfaces. Many studies had multiple interventions. Many studies had a small sample size and only 20 reported a priori sample size calculation.				

Table 44: Briena 2010[36]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Brienza 2010	**Patient group:** Elderly, nursing home population	**Group 1:** skin protection cushion (SPC)	**Outcome 1:** Incidence of a	**Group 1 (SPC): 1/113 (0.9%)** **Group 2 (SFC): 8/119 (6.7%)**	**Funding:** not reported

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Title: A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions **Journal:** J Am Geriatr Soc (2010) December; 58 (12), 2308-2314. **Type of study:** randomised controlled trial **Sequence generation:** 1:1 randomisation scheme prepared by a research team member who was independent to those who had contact with participants. Randomised blocks of varying length used. **Allocation concealment:** adequate, see above. **Blinding:** not possible due to the differences in configuration and weight of the cushions, outcome assessors were masked. **Addressing incomplete outcome data:** missing data was due to voluntary withdrawal	who used wheelchairs as primary means of seating and mobility and were at-risk for developing pressure ulcers. **All patients** **Randomised N:** 232 (222 received intervention) **Completed N:** 190 **Drop-outs:** 42 Age: 86.7 (s.d 7.6 years) Ethnicity: 92.2% white. Gender: 84.9% female. **Group 1 (SPC)** **Randomised N:** 113 **Completed N:** 86 **Drop-outs:** 27 (6 did not receive intervention, 5 voluntarily withdrew, 16 other) **Age:**86.8 (s.d 7.4) **Gender (f):91 (80.5%)** **ethnicity (white):103 (91.2%)** **BMI:24.6 (s.d 4.4)** **Total Braden score:15.4 (s.d 1.4)** **Incontinent:97 (90.7%)**	**Group 2:** segmented foam cushion (SFC) **Treatment started with seating assessment by occupational therapist trained in seating and mobility.** **SPC group had a commercially available cushion with an incontinence cover. Selected from a group of three designed to improve tissue tolerance by reducing peak pressures near bony prominences, accommodating orthopaedic deformities through immersion, enveloping small irregularities at the seating interface without causing high pressure gradients, and dissipating heat and moisture. Solid seat inserts were provided. Multiple SPC group cushions were needed to allow for cushion selection based upon specific clinical conditions. Clinical judgment and expertise of the team was used to select a particular SPC cushion based on its compatibility with the subject's clinical needs and preferences.**	sitting-acquired pressure ulcer - ischial tuberosities ulcers	**P<0.04** **Stage 1 ulcers (n=1), stage 2 (n=7), and unstageable (n=1)**	**Limitations:** baseline differences. The study could not control for other support surfaces. **Additional outcomes:** N/A Notes: a pilot study was conducted prior to the clinical trial to assist in developing methods and to determine appropriate sample size. The authors state that the RCT could have lowered the risk level as the wheelchair fit and function was monitored and adjusted regularly. Pressure mapping used to assist in selection of skin protection wheel
			Outcome 2: Incidence of combined ischial tuberosities and sacral/coccyx pressure ulcers:	**Group 1 (SPC):** 12/113 (10.6%) **Group 2 (SFC):** 21/119 (17.6%) 33 participants had 38 IT and sacral /coccyx pressure ulcers. Stage 1 (n=6), stage 2 (n=29), stage 3 (n=2), unstageable (n=1). P: NS	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
death or other – examples given. ITT analysis used. Missing data covered with flow diagram. **Statistical analysis:** Rate of pressure ulcers ITT analysis. Kaplan-Meier used to estimate the cumulative incidence of pressure ulcers, with the log-rank statistic used to assess differences by treatment group. **Baseline differences:** no statistically significant differences except ambulation. Slightly fewer males in the SFC group (10.9%) than the SPC group (19.5%). **Study power/sample size:** power calculation done 90% power required a sample size of 234. **Setting:** 12 nursing homes (profit and non-profit) in the Greater Pittsburgh Area. 180 licensed beds. **Length of study:** 6 months.	**Ambulation: 0 feet: 67 (62.6%); </= 10 feet: 14 (13.1%), >10 feet: 26 (24.3%)** **Could not walk unassisted:** 62.6% **Could walk 3 meters or less**:13.1% **Could walk 3 meters or more:** 24.3% **Group 2 (SFC)** **Randomised N:** 119 **Completed N:** 94 **Drop-outs:** 25 (4 did not receive intervention, 6 voluntary withdrawn, 14 other, 1 discharged). **Age:86.6 (s.d 7.8)** **Gender (f):106 (89.1)** **ethnicity (white):111 (93.3%)** **BMI:25.0 (s.d 5.2)** **Total Braden score:15.5 (s.d 1.5)** **Incontinent:97 (85.8%)** **Ambulation: 0 feet: 86 (76.1%), </=10 feet: 5 (4.4%); > 10 feet 22 (19.5%)** **Could not walk**	**SFC group received a 7.6cm thick, segmented foam cushion fitted with an incontinence cover, and solid seat insert. This cushion was chosen as the control because it is representative of a large number of cushions currently used in nursing homes.** **Both groups: interface pressure measurement data was used to monitor the effects of adjustments made to the wheelchair. Each participant received a new, properly fitted wheelchair. Two models were used. One chair (Guardian Escort was used and floor to seat height is fixed at 51 cm, adjustments are possible, but not easily accomplished. Subjects needing an alternate seat-to-floor height were given a Breezy Ultra 4 wheelchair. The difference between groups for different wheelchair was non-significant.** **Wheelchairs and cushions were checked weekly be the seating specialist and repaired**			chair cushions.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Sitting-acquired pressure ulcer was those occurring primarily over the ischial tuberosities while sacral ulcers primarily result from excessive loading in bed. Weekly skin and risk assessments (Braden Score) were performed by a research nurse masked to the treatment assignment. Assessments continued until first incidence of a pressure ulcer, discharge from the facility, voluntary withdrawal from the study, death, or the study end date 6 months from the initiation of the seating intervention. **Classification of PUs:** **Multiple ulcers:** N/A	**unassisted:** 76.1% **Could walk 3 meters or less:** 4.4% **Could walk more than 3 meters:** 19.5% **Inclusion criteria: LTC resident 65 years of age or older; Braden score of </=18 (at risk for developing pressure ulcers; combined Braden Activity and Mobility Subscale score </=5; absence of ischial area pressure ulcers; tolerance for daily wheelchair sitting time >/=6 hours; and ability to accommodate seating and positioning needs with the wheelchair selected for use in this study.** **Exclusion criteria:** Body weight exceeding 113kg (exceeds wheelchair weight capacity); hip width exceeding 51cm (exceeds wheelchair width capacity); wheelchair seating requirements for head support, seat depth >46cm, or accommodation	**or adjusted as needed.**			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	of severe orthopaedic deformities of the pelvis, lower extremities or back that exceed the capability of the study wheelchairs; and current use of any cushioning material(s) other than the SFC or equivalent, or a lower quality cushion.				

Table 45: Demarre 2012[66]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Demarre 2012 **Title:** Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: a randomised-controlled clinical trial **Journal:** International Journal of Nursing Studies, 47 (2012), 416-426. **Type of study:** multi-centre RCT	**Patient group:** hospitalised patients. The wards were neurology (n=6), rehabilitation (n=3), cardiology (n=2), dermatology (n=1), pneumology (n=1), oncology (n=1) and chronic care (n=1) or a combination of different types of medical conditions (n=2). **All patients** **Randomised N:** 610 **Completed N:** 307 **Drop-outs:** 303	**Group 1:** ALPAM with multi-stage inflation and deflation of the air cells. The inflation curve of the air cell was identical to the deflation curve of t air cell. The head zone contained 3 air cells with a continuous low pressure, the heel zone contained 7 cells with a continuous ultra low pressure and the back and sacrum zone contained 10 alternating low pressure cells. A sensor at the sacral zone measured the applied pressure of the body on the mattress. The device consisted of a mattress and a control unit. Cycle times for	**Outcome 1:** Cumulative incidence of pressure ulcer grade II-IV (% developing a new pressure ulcer):	**Group 1:17/298 (**5.7%) **Group 2: 18/312 (**5.8%) P=0.97	**Funding:** Financially sponsored by Ghent University as part of a PhD study. Authors state that the mattresses and cushions were provided by Hill-Rom but they did not influence the study. **Limitations:** No blinding of outcome assessors. High drop-out in both groups. Both groups had some
			Outcome 2: Non-blanchable erythema (pressure Grade 1)	**Group 1:** 51/298 (17.1%) **Group 2:** 38/312 (12.2%) P=0.08	
			Outcome 3: excluding pressure ulcers (Grade II-IV) occurring in the first 3 days after admission in the study (which could	**Group 1:** (3.4%) **Group 2:** (4.2%) P=0.61 Binary logistic regression analysis: OR 1.17 (95% CI 0.553-	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: randomised on 1:1 ratio by simple randomisation. The sequence was based on computer-generated list of random numbers. **Allocation concealment:** Nurses contacted researcher and received a number for type of allocated mattress (first on computer generated list). **Blinding:** blinding not possible due to differences in external control unit of the mattresses studied. No information was given to the nurses regarding the differences in mattresses. Outcome assessors not blinded. **Addressing incomplete outcome data:** flow chart with detailed reasons for drop-out given. High drop-out (in both groups). ITT analysis used. **Statistical analysis:** data presented in %s and	**Group 1** **Randomised N:** 298 **Completed N:** 152 **Drop-outs:** 146 (PU category II-IV (n=17), losses to follow-up because of: technical problems (n=3), discomfort (n=11), reason not defined (n=3), transfer to another ward (n=15), discharge to home (n=40), death (n=15), discharge to another institution (n=42)) **Group 2** **Randomised N:** 312 **Completed N:** 155 **Drop-outs:** 157 (PU category II-IV (n=18), losses to follow-up because of: technical problems (n=3), discomfort (n=16), reason not defined (n=5), transfer to another ward (n=22), discharge to home (n=41), death (n=14), discharge to another institution (n=37), withdrawal of consent (n=1))	inflation and deflation were between 10 and 12 minutes. The air cell width was 10cm. **Group 2:** standard ALPAM. An ALPAM with a standard single-stage, steep inflation and deflation of the air cells. All air cells were alternating, the cycle time was 10 minutes and the air cell width was 10cm. An external manual control unit was used to adjust the mattress to the patient's weight. Both mattresses were covered with an identical mattress cover. No standard repositioning protocol was used in bed. An identical seating protocol was used in both groups. All patients were seated on a static air cushion. The control unit was disconnected during transport of the patient, resulting in an inflated mattress for 2 hours without alternating air cells.	have been caused by tissue damage prior to start of study)	2.455), x2 = 0.16, df=1, p=0.687)	patients with patients who had grade I ulcers already (15.4%). **Additional outcomes:** Incidence of grade II, grade III, Grade IV, incontinence-associated dermatitis. Incidence for various areas - pelvic area (sacral; hip); heel area (heel, ankle); other. Probability to remain pressure free.
			Outcome 4: Time to develop a pressure ulcer (median time)	**Group 1:** 5.0 days (IQR 3.0-8.5) **Group 2:** 8.0 days (IQR 3.0-8.5) Mann-Whitney U-test = 113, p=0.182.	
			Outcome 5: acceptability of the devices - number who withdrew due to discomfort	**Group 1:** 11/298 **Group 2:** 17/312	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
means if normally distributed data and medians of not normally distributed. T-tests used in normally distributed continuous data. Mann-Whitney u-tests for non-normally distributed continuous data. Chi-square and Fisher's exact tests for categorical variables. **Baseline differences:** no significant differences **Study power/sample size:** powered for 600 patients (300 in each group). **Setting:** 25 wards from 5 Belgian hospitals. **Length of study:** 14 days follow-up **Assessment of PUs:** pressure ulcers classified by EPUAP classification system. Skin assessment daily by nurses. Transparent plastic disc method used to observe non-blanchable erythema (Grade 1). **Classification of PUs:**	**Inclusion criteria:** at risk for pressure ulcer development according to the Braden scale. **Exclusion criteria:** having a pressure ulcer Grade II-IV on admission; the expected admission time in the hospital was < 3 days; aged < 18 years; there was a 'do not resuscitate code' specifying ending all therapeutic interventions; weight was less than 30kg or more than 160kg (mattress specification); Informed consent could not be obtained from patient or his/her legal representative.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: N/A					

Table 46: Van Leen 2011[233]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Van Leen (2011) **Title:** Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home **Journal:** Journal of Tissue Viability (2011), 20,30-34. **Type of study:** single centre RCT. **Sequence generation:** numbered envelopes **Allocation concealment:** numbered envelopes **Blinding:** not reported. **Addressing incomplete outcome data:** ITT analysis used. State that those who died did not develop pressure ulcers.	**Patient group:** nursing home residents **All patients** **Randomised N:** 83 **Completed N:** 74 **Drop-outs:** 5 died during study in group 1 and 4 died during study in group 2, none of the patients who died developed a pressure ulcer during their participation. **Group 1** **Randomised N:** 42 **Completed N:** 38 **Drop-outs:** 4 (died) **Age (mean, s.d):** 81.1 (8.37) Gender (females): 33 Norton 5-8 at start of	**Group 1:** combination of a standard 15cm cold foam mattress with a static air overlay **Group 2:** a standard 15cm cold foam mattress All patients: when out of bed, sitting on a static air pillow following the institutional PUPP. At night, nobody received repositioning conforming to this PU protocol. No repositioning was allowed before development of a grade 2 pressure ulcer.	**Outcome 1:** development of grade 2, 3 and 4 pressure ulcers (EPUAP classification) at the heel or in the sacral/hip region. **Incidence of pressure ulcers:**	**Group 1:** 2/42 ITT (4.8%) **Group 2:** 7/41 ITT (17.1%) P=0.088 (Fisher's exact test) (95% CI 1.3% to 25.9%)	**Funding:** no funding. **Limitations:** Ethical issues of not using repositioning. Limited details of sequence generation and allocation concealment. No details of blinding of outcome assessors. Small study. **Additional outcomes:** incidence of pressure ulcers in groups at Norton scale risk 5-8 and 9-12, for Grade 2,3
			Outcome 2: Incidence of Grade 2 ulcers:	**Group 1:** 0/42 **Group 2:** 1/41	
			Outcome 3: Incidence of Grade 3 ulcers:	**Group 1:** 1/42 **Group 2:** 5/41	
			Outcome 4: Incidence of Grade 4 ulcers	**Group 1:** 0/42 **Group 2:** 0/41	
			Outcome 5:		

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: using SPSS 15.0. No further details. **Baseline differences:** there were more patients in the intervention group with a very low Norton score (more pressure ulcer prone patients). **Study power/sample size:** power of 80% required 38 patients in each group **Setting:** Nursing home, De Naaldhorst, the Netherlands. **Length of study:** patients were followed for a period of 6 months. **Assessment of PUs:** not reported. Risk of pressure ulcers assessed by Norton scale. **Classification of PUs:** **Multiple ulcers:** not reported.	study: 26 (61.9%) Norton 9-12 at start of study: 16 (38.1%) Diagnoses Dementia: 31 (73.8%) CVA: 8 (19%) Rheumatoid arthritis: 1 (2.4%) Encephalopathy: 0 m. Parkinson: 1 (2.4%) Diabetes: 0 Arthrosis: 0 Hip fracture: 1 (2.4%) COPD: 0 **Group 2** **Randomised N:** 41 **Completed N:** 36 **Drop-outs:** 5 (died) **Age (mean, s.d):** 83.1 (7.86) Gender (females): 34 (82.9%) Norton 5-8 at start of study: 22 (53.7%) Norton 9-12 at start of study: 19 (46.3%) Diagnoses: Dementia: 31 (75.6%) CVA: 4 (9.8%)				and 4 ulcers The authors protocol is contrary to national guidelines for pressure ulcer prevention regarding repositioning for 2 reasons: interference in sleep and the higher workload for nursing staff and the accompanying higher costs.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Rheumatoid arthritis: 0 Encephalopathy: 1 (2.4%) m. Parkinson: 1 (2.4%) Diabetes: 1 (2.4%) Arthrosis: 1 (2.4%) Hip fracture: 1 (2.4%) COPD: 1 (2.4%) **Inclusion criteria:** age >65, Norton score between 5-12; informed consent of patients or representatives in case of mental disorders. **Exclusion criteria:** a pressure ulcer in the previous 6 months				

Table 47: Grisell 2008[90]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Grisell (2008) **Title:** Face tissue Pressure in Prone Positioning: a comparison of three face pillows while in the prone position for spinal surgery.	**Patient group:** elective surgery patients – thoracic, lumbar or thora-columbar spinal surgery that required prone positioning **All patients** **Randomised N:** 66	3 different types of face pillows that are used for prone positioning in the operating room: **Group 1:** a neoprene air filled bladder (dry flotation) device by ROHO **Group 2:** the OSI (orthopaedic	**Outcome 1:** incidence of pressure ulcers	**Group 1:** 0/22 **Group 2:** 10/22 **Group 3:** 0/22	**Funding:** Not reported. **Limitations:** Aimed at tissue interface pressures rather than incidence of pressure ulcers. No details of allocation
			Outcome 2: incidence of stage 1 pressure ulcers	**Group 1:** 0/22 **Group 2:** 8/22 **Group 3:** 0/22	
			Outcome 3: incidence of stage 2	**Group 1:** 0/22 **Group 2:** 8/22	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Journal: SPINE, 33 (26), 2938-2941. **Type of study**: prospective randomised trial **Sequence generation:** randomisation list mentioned and was consulted for assignment of positioner before start of surgery. Randomisation list was generated using website www.randomization.com – which uses randomly permutated blocks to assign each subject to a pillow. **Allocation concealment:** no details **Blinding:** the patient was unaware of their assigned positioner type at all times. No details of other blinding. **Addressing incomplete outcome data:** all patients completed the study. **Statistical analysis:** Nonparamateric statistical methods used	**Completed N:** 66 **Drop-outs:** 0 **Group 1** **Randomised N:** 22 **Completed N:** 22 **Drop-outs:** 0 **Group 2** **Randomised N:** 22 **Completed N:** 22 **Drop-outs:** 0 **Group 2** **Randomised N:** 22 **Completed N:** 22 **Drop-outs:** 0 **Inclusion criteria:** aged 18 to 65 years (inclusive); presenting to the operating room for elective thoracic, lumbar, or thora-columbar spinal surgery that required prone positioning were included. **Exclusion criteria:** patients with any facial skin ailment or lesion (rash,	systemc inc) (disposable polyurethane foam prone head positioner) **Group 3:** the Prone View Protective Helmet system (a disposable polyurethane foam head positioner) All patients: positioned prone on a Jackson table using standard positioning. A low profile pressure sensor was positioned between the subject's forehead and the pillow and between the subject's chin and the pillow. Procedures lasted from 1 to 12 hours.	pressure ulcers	**Group 3:** 0/22	concealment or blinding of outcome assessors. Small sample size. No details of population characteristics and baseline differences. Did not stratify by age, gender, surgery type, surgery location or surgery length (other than the requirement that surgery last at least 1 hour) **Additional outcomes:** tissue interface pressure Studies main aims were regarding tissue pressures. No statistics were used to evaluate the lengths of procedures but the authors state that

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
because of small sample sizes. Mann-Whitney U was used to analyse measures of central tendency and variability of the tissue pressures measured. The Friedman analysis was used to evaluate and assess the differences across time at each of the time variables measured. **Baseline differences:** no details **Study power/sample size:** 80% power required 20 patients in each group. **Setting:** surgery **Length of study:** no details except range of surgery times. **Assessment of PUs:** Authors say any pressure ulcers seen were staged according to the NPUAP staging system. **Classification of PUs:** **Multiple ulcers:** there were multiple ulcers but	abrasion infection, redness, inflammation, bruising); history of increased intraocular pressure or glaucoma; patients presented for emergent spinal surgery; patients for surgery that included any cervical level; patients whose major language was not English.				the average time for the procedures on each of the positioners was similar.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
gave details of number of patients.					

Table 48: Mistiaen 2010E[146]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Mistiaen (2010) **Title:** The effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home patients: A prospective multicenter randomized-controlled trial (ISRCTN17553857) Journal**:** Wound Rep Reg (2010), 18, 572-579. **Type of study:** multicenter prospective RCT **Sequence generation:** Randomisation scheme created in SPSS by assigning the intervention to a random	**Patient group:** nursing home patients **All patients** **Randomised N:** 588 **Completed N:** 543 **Drop-outs:** 45 **Group 1** **Randomised N:** 295 **Completed N:** 271 **Drop-outs:** 24 Gender (female %): 71% Age mean (range): 78 (26-97) Barthel score mean: 9.9 Patients with risk on pressure ulcer % (Braden score </=20): 70 Patients with risk on	**Group 1:** All usual care and the application of the Australian Medical Sheepskin (AMS) (hi-temp, urine resistant, size XXL) as an overlay on top of the standard mattress in the area of the buttocks. An extra AMS at the bottom of the bed and in the (wheel) chair was also permitted. The application of the AMS started no later than 48 hours after admission. The AMS was then applied during the first 30 days after admission or until a patient died or was discharged, whichever came first. All other usual pressure ulcer preventive interventions such as mobilisation and repositioning could be added as	**Outcome 1:** incidence of sacral pressure ulcers in the first 30 days after admission	**Group 1:** 24/271 (8.9%) ACA **Group 2:** 40/272 (14.7%) ACA Two-sided x^2, p=0.035	**Funding:** grant from the Efficacy Research Program, round 2007, of the Netherlands Organisation for Health Research and Development. **Limitations:** no blinding . Unclear addressing of incomplete outcome data. **Additional outcomes:** onset day of pressure ulcers; usual care components by intervention group
			Outcome 2: incidence of pressure ulcers on other areas	**Group 1:** 16.4% **Group 2:** 15.1% X^2, p=0.69	
			Outcome 4: comfort of the sheepskin as experienced by the patients (self-developed seven-time questionnaire with a five-point rating answer structure) – softness, itching, smell, warmth, tickling, comfort, if	(209 filled out questionnaire) Too warm: one third Recommend AMS to other patients: 52%, no judgement 26%, would not recommend 22%. Compliance to AMS: Group 1: 1/3 of patients in the sheepskin group discontinued the use of the MAS, mostly	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
sample of around 50% in a list of 1,500 numbers and assigning the control group to the rest Randomisation was done on admission day or at least within 48 hours after admission. **Allocation concealment:** Adequate. The sequence generation was then blinded on a paper list numbered 1 through 1,500 by a secretary not further involved in the project. The admitting nurse called the principal investigator who then disclosed the allocation from the blinded list to the nurse, who then disclosed to patient. **Blinding:** Not possible to blind if someone is in the experimental group or not, only the patient allocation itself was blinded to all parties involved. Checking was done to see that allocated intervention was correctly applied.	pressure ulcer % (Braden score </=18): 47 BMI mean: 24.6 **Group 2** **Randomised N:** 293 **Completed N:** 272 **Drop-outs:** 21 Gender (female %): 67% Age mean (range): 78 (27-98) Barthel score mean: 9.4 Patients with risk on pressure ulcer % (Braden score </=20): 71 Patients with risk on pressure ulcer % (Braden score </=18): 47 BMI mean: 25.6 **Inclusion criteria:** patients newly admitted for a primarily somatic reason, adult (aged 18 years and older), expected stay >1 week **Exclusion criteria:** pressure ulcers on the sacrum at admission, having darkly pigmented	co-interventions as far as were usual care in the nursing homes. All other nursing care could be continued as usual (including incontinence materials) **Group 2:** Control group received usual care only, including all the pressure-reducing interventions and other preventive actions, normally taken in the participating nursing homes. The application, in any form, of the AMS was forbidden in this group during the first 30 days after admission. In both groups: the regular/usual mattresses were applied (differed from institution to institution and even ward to ward). Wound care specialists were allowed to start with a special pressure-reducing mattress for a patient during the observation period when they considered this necessary and was required to be noted on the daily observation form.	would recommend to other patients; additional comments	within the first week and mainly because they found it too warm. The sheepskin was almost never applied under the heels or in the chair. In the control group, 1.7% of the observable days was spent with an AMS, this occurred in the beginning of the study period, because it was then not entirely clear to the nurses when they were allowed to give an AMS to the patients.	(table given). No significant differences in usual care component.
			Mean onset day of pressure ulcers (days after admission):	**Group 1:** 12 **Group 2:** 9	
			Outcome 5: ease of use of the sheepskin as experienced by the care personnel (measured by group interviews with ward nurses on three occasions)	Nurses did not encounter difficulties in using AMS in daily practice, but it did make it slightly more difficult to change bed linen in bed-ridden patients. Also the dirty sheepskins needed separate linen bags caused some inconvenience.	
			Outcome 6: quality of life (visual analog scale 0=worst health status ever	**Group 1:** 62.1 **Group 2:** 61.3 Student's t test p=0.71	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: ITT analysis was used. Main reason for not obtaining outcome data was primarily nurses forgetting to send the forms or discarded by accident when a patient died or was discharged home or transferred to another institution or lost in the mail. Characteristics of lost to follow-up patients vs analysed patients were given (no statistically significant differences) **Statistical analysis:** primary outcome (incidence) was conducted with multilevel binary logistic regression analysis. **Baseline differences:** No difference for gender, age, Braden score, Barthel score and BMI or medical diagnosis or prior surgery in month before admission. no significant differences between nursing homes	skin (because of difficulty in diagnosing grade 1 pressure ulcer), and known allergy to wool; admitted for a primarily psycho-geriatric reason.		100=the best that could be imagined) mean	Mean quality of life for patients without sacral pressure ulcers: **Group 1:** 63 **Group 2:** 53 Student's t test, p=0.003	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
in the proportion of patients that were randomised to the intervention or control group. **Study power/sample size:** 80% power 750 (2x375) required. **Setting:** 8 nursing homes (23 nursing wards), the Netherlands. **Length of study:** observations continued until day 30 after admission **Assessment of PUs:** daily skin observations, used EPUAP grading system. Used photographic series of the various pressure ulcer grades as well as transparent disks that nurses pressed against erythema by hand to see whether the area blanched under pressure. If uncertain they called a specialised nurse. All cases of pressure ulcers were reported to a wound care specialist who checked the observation,					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
gave care instructions and monitored the progress of the ulcer. Risk assessment: Braden scale. **Classification of PUs:** **Multiple ulcers:** N/A					

Table 49: Malbrain 2010[136]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Malbrain 2010 **Title:** A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients Journal**:** Journal of Tissue Viability (2010), 19, 7-15 **Type of study: pilot randomised controlled trial** **Sequence generation:**	**Patient group:** patients in ICU with high pressure ulcer risk (Norton score</=8 requiring mechanical ventilation for at least 5 days, with either intact skin or pressure ulcers **All patients** **Randomised N:** 16 **Completed N:** 15 **Drop-outs:** one death but know that this participant developed a sacral persistent erythema (category 1) immediately	**Group 1:** ROHO dry floatation mattress overlay **Group 2:** the NIMBUS 3 active alternating pressure mattress Both groups were given standard treatment according to Belgian consensus protocol. Repositioning every 2 hours from semi-Fowler to the right/left lateral 30 degrees position. Two-way stretch sheet and a low friction slide sheet used for repositioning. Pillow between calves and interface, which is standard protocol in Belgium. Additional nutritional	**Outcome 1: incidence of pressure ulcers (all grades)**	**Group 1: 2/8 (25%)** **Group 2: 2/8 (25%)**	**Funding:** no details **Limitations:** very small sample size; unclear allocation concealment. Single blinded. Baseline differences. **Additional outcomes:** healing of ulcers. Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
envelopes shuffled **Allocation concealment:** envelopes were identical, shuffled and placed in a box but no mention of opaque. **Blinding:** single blinded **Addressing incomplete outcome data:** adequate **Statistical analysis:** T-test and Fisher's exact test. **Baseline differences:** statistically significant difference in age and per-albumin. **Study power/sample size:** power calculation not given but very small sample size. **Setting: ICU,** Belgium **Length of study:** not reported but average given for both groups as 15 (s.d 14) in the NIMBUS group and 12.2 (s.d 5.5) in the ROHO group **Assessment of PUs:** PUSH tool **Classification of PUs:** **Multiple ulcers:** all were	prior to death. **Group 1** **Randomised N:** 8 **Completed N:** 8 **Drop-outs:** 0 **Age (years): 71.5 (s.d 11.8)** **Sex F/M: 3/5** **BMI (kg/m2): 22.1 (s.d 2.7)** **Pre-albumin (mg/dl): 20.3 (s.d 12.4)** **Norton score: 7 (s.d 0)** **APACHE II score: 20.4 (s.d 7.5)** **SOFA score: 11.4 (s.d 3.2)** **CRP day 1 (mg/dl): 10.1 (s.d 14.1)** **% Semi-Fowler position: 58.1 (s.d 7.5)** **% lateral decubitus: 41 (s.d 17.2)** **Group 2** **Randomised N:** 8 **Completed N:** 7 **Drop-outs:** 1 died **Age (years): 56.9 (s.d 16.3)**	support. All had indwelling urinary catheters. Skin was inspected daily and documented.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
recorded.	**Sex F/M: 5/3** **BMI (kg/m2): 24.2 (s.d 6.5)** **Pre-albumin (mg/dl): 6.7 (s.d 3.6)** **Norton score: 7.4 (s.d 1.1)** **APACHE II score: 22.8 (s.d 4.6)** **SOFA score: 11.8 (s.d 2.7)** **CRP day 1 (mg/dl): 10.3 (s.d 8.2)** **% Semi-Fowler position: 54.9 (s.d 11.8)** **% lateral decubitus: 37.1 (s.d 11.2)** **Inclusion criteria:** patients in ICU with high pressure ulcer risk (Norton score</=8 requiring mechanical ventilation for at least 5 days, with either intact skin or pressure ulcers **Exclusion criteria:** if consent refused or if at time admitted not at least one of the mattresses available.				

Table 50: Vermette 2012[240]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Vermette 2012** **Title: Cost-effectiveness of an air-inflated static overlay for pressure ulcer prevention: a randomised controlled trial** Journal**: Wounds 2012; 24 (8); 207-214** **Type of study:** randomised controlled trial **Sequence generation:** no details **Allocation concealment:** yes **Blinding:** no **Addressing incomplete outcome data:** ITT analysis. **Statistical analysis:** Fisher's exact test and X2 test for categorical variables and unpaired t-test and Mann-Whitney statistic test used to compare continuous variables; incidence of pressure ulcers	**Patient group:** hospitalised patients on a medical, surgical, active geriatric or an ICU ward **All patients** **Randomised N:** 110 **Completed N:** 110 **Drop-outs:** 0 Trial completion was defined as discharge from hospital, death, improved total Braden score above 14, removal of thesurface due to discomfort, a total of 14 days of participation free of pressure ulcer, or development of a pressure ulcer. Discharge: n=24 Death: n=10 Improvement in their general status resulting a Braden score of 15 or more: 20 Request for support surface change due to discomfort: n=4 Reached the maximum	**Group 1:** the Waffle overlay is **a** plastic inflated static overlay (ISO) which reduces pressure and requires proper inflation (air between the mattress and skin) to optimise the prevention of pressure ulcers. **Group 2:** two rented overlays: RIK overlay is for patients weighing <200lb at moderate to very high risk of pressure ulcers (Braden score of </=14), it is a microfluid static overlay (MSO) that has no memory foam and allows for reduction of pressure over bony prominences. The other surface was a TheraKair Visio mattress which is a low air loss dynamic mattress (LALDM) with pulsation. A Gore-Tex cover helps to control shearing forces and humidity. It is used for patients at moderate to very high risk who require edematous management, weigh 200lb to 300lb, or ar bottoming out the microfluid static overlay.	**Outcome 1:** incidence of pressure ulcers (ISO vs MSO or LALDM)	**Group 1:** 2/55 (4%) **Group 2:** 6/55 (11%) P=0.2706	**Funding:** no funding; project towards a Master's degree. **Limitations:** no details of sequence generation; no blinding. **Additional outcomes:**
			Outcome 2: Comfort (ISO vs MSO or LALDM)	**Group 1:** 29/34 (85%) **Group 2:** 24/27 (89%)	
			Outcome 3: incidence of pressure ulcers (ISO vs MSO)	**Group 1:** 2/55 (4%) **Group 2:** 6/50 (12%) P=0.1269	
			Outcome 4: Comfort (ISO vs MSO)	**Group 1:** 29/34 (85%) **Group 2:** 24/27 (89%) P=1.00	
			Outcome 5: Incidence of pressure ulcers: ISO vs LALDM (not reported but deduced from figures)	**Group 1:** 2/55 (4%) **Group 2:** 0/5 (0%)	
			Outcome 6: Comfort: ISO vs LALDM (not reported but deduced from figures)	**Group 1:** 29/34 (85%) **Group 2:** 3/3 (100%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
evaluated using logistic regression analysis. **Baseline differences:** **Setting:** acute care facility (medical, surgical, active geriatric or an ICU wards) **Length of study:** 2 weeks **Assessment of PUs:** skin assessments 3 times per week and categorised as NPUAP grades. **Classification of PUs:** **Multiple ulcers:** N/A	study period set at 14 days: n=43 Developed a pressure ulcer: n=8 **M/F:** 44/66 Age: 77.8 years (range 20-99 years; median 80.5) Diagnoses: CVA n=18 (16%); decrease in general status n=15 (14%); hip fracture n=14 (15%); pneumonia n=8 (7%). **Group 1** **Randomised N:** 55 **Completed N:** 55 **Drop-outs:** 0 Discharge: n=14 Death: n=4 Improvement in their general status resulting a Braden score of 15 or more: n=9 Request for support surface change due to discomfort: n=4 Reached the maximum study period set at 14 days: n=22 Developed a pressure ulcer: n=2	Other interventions: positioning schedule was used to promote turning every 2 hours. Memory aids in care plans and in rooms for staff to make hand checks to confirm there was air between the mattress and skin of the ISO (to verify proper inflation); proper functioning of the MSO and LALDM; preventative measures such as moisturinsing the sacral area; positioning; minimising elevation of the head of the bed to <30 degrees; avoiding massage over a bony prominence; using a 30 degrees side-lying angle position; and using pillows to keep feet and ankles off the mattress.	Logistic regression analysis for confounding variables Pressure ulcer development (with no confounder BMI Weight Hemoglobin (Hb) Hematocrit (Ht): Diabetic: Surgery during study:	**OR (of ulcer when on exptl surface versus control (CI 95%):** 0.308 (0.059-1.6), p=0.1613 0.263 (0.050-1.400), p=0.1176 0.268 (0.051.1422), p=0.1221 0.373 (0.070-1.981), p=0.2468 0.375 (0.070-2.005), p=0.2514) 0.263 (0.047-1.466), p=0.1276) 0.399 (0.072-2.230), p=0.2956)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	M/F: 23/32 Age: 77.9 9(SD 14.6) Braden at enrolment: 12.3 (SD 1.3) BMI: < 18, n=10; 18-25, n=35; >25, n=10. Diabetic: n=16 Unable to consent: n=31 Bed rest: n=22 Days in study: 9.2 (SD 4.8) **Group 2** **Randomised N:** 55 **Completed N:** 55 **Drop-outs:** 0 Discharge: n=10 Death: n=7 Improvement in their general status resulting a Braden score of 15 or more: 11 Request for support surface change due to discomfort: n= 0 Reached the maximum study period set at 14 days: n= 21 Developed a pressure ulcer: n=6 **M/F:** 21/34				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Age: 77.7 (SD 10.6) Braden at enrolment: 11.8 (SD 1.6) BMI: < 18, n=6; 18-25 n=26; >25 n=23. Diabetic: n=6 Unable to consent: n=31 Bed rest: n=27 Days in study: 9.9 (SD 4.4) **Inclusion criteria:** 18 years or older; without skin lesions(s) per visual inspection; weighing <300 pounds; able to give informed consent; considered at moderate to very high risk of developing a pressure ulcer (scoring 14 or less on the Braden scale). **Exclusion criteria:** as above				

Table 51: Cassino 2013[44]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cassino (2013)	Patient group: long-term care patients	Group 1: Three-dimensional overlay (AIARTEX), made of 3-D macro-porous material, 9mm	Outcome 1: incidence of pressure ulcers	Group 1: 0/35 Group 2: 1/37	Funding: sponsored by Herniamesh Srl (Chivasso, Turin,

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Title: A controlled, randomised study on the effectiveness of two overlays in the treatment of decubitus ulcers **Journal:** Minerva Chirurgia Type of study: multicentre RCT Sequence generation: randomised 1:1 ratio Allocation concealment: inadequate, closed envelopes opened at moment of assignment Blinding: no, open trial Addressing incomplete outcome data: details given of what occurred to patients, only one who was not specified. ITT analysis used. Statistical analysis: two-tailed test or X^2 Baseline differences: no difference for age, weight, BMI, Norton and Braden scores. There were higher grades of pressure ulcers in the 3-D overlay group but	All patients Randomised N: 72 Completed N: 28 Drop-outs: Age (year): 85.4 Sex (f/m): 55/17 Group 1 Randomised N: 35 Completed N: 17 Drop-outs: 18 Age (year): 84.9 Sex (f/m): not reported Grade of pressure ulcers: Grade 1: 11 (24%) Grade 2: 12 (27%) Grade 3: 12 (27%) Grade 4: 22% Group 2 Randomised N: 37 Completed N: 11 Drop-outs: 26 Age (year): 85.9 Sex (f/m): not reported Grade 1: 16 (36%) Grade 2: 16 (36%) Grade 3: 9 (20%) Grade 4: 3 (7%)	thick, made completely of polyester and weighing 800grams, consisting of 2 parallel layers, one on top of the other, linked by transverse monofilaments. The function of the upper layer is to drain any exudates and convey them to the lower level by gravity and capillary action through the transverse monofilaments. Group 2: dry viscoelastic polyurethane polymer overlay (AKTON) 15.9mm thick, made of vulcanised rubber with a strong memory for shape, weighing 35kg			Italy) Limitations: baseline differences for grade of pressure ulcers, but the higher grades were in the intervention group. Additional outcomes: ease of assistance and bed, making (nursing evaluation)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistical significance not given for this. Study power/sample size: no power calculation given, small study Setting: 8 long-term care Italian centres Length of study: 12 weeks Assessment of PUs: Norton and Braden scales Classification of PUs: EPUAP-NPUAP Multiple ulcers: does not mention how chose one ulcer from multiple ulcers	Inclusion criteria: informed consent, aged >18 years, Braden score >6 and <14, Norton score of >5 and < 12; patients with EPUAP-NPUAP stages I to IV pressure ulcers; BMI >16 and <40; Exclusion criteria: patients without pressure ulcers; infection, terminal patients, immunosuppressive or antiblastic therapies; pregnant women; patients who need different aids; allergies to overlay materials; AIDS, HCV; patients enrolled in other studies in the 3 preceeding months.				

Table 52: Ricci 2013[183]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ricci (2013) **Title:** A new pressure-relieving mattress overlay	**Patient group:** long-term unit patients at moderate/high risk of pressure ulcer development (according	**Group 1:** 3-D mattress overlay (AIARTEX) (a macro-porous 3-D material (9mm thick)) made in polyester flame retardant. Two parallel and superimposed	**Outcome 1:** incidence of pressure ulcers	**Group 1; 0/25** **Group 2: 0/25**	**Funding:** sponsored by Herniamesh Srl **Limitations:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Journal**:** EWMA Journal, 13 (1), 27-32. **Type of study:** randomised controlled trial **Sequence generation:** computer generated pre-defined assignment list **Allocation concealment:** sealed envelopes **Blinding:** **Addressing incomplete outcome data:** no drop-outs **Statistical analysis:** not reported. **Baseline differences:** Norton score was lower in the intervention group than the control group (p=0.042). No difference in Braden scale scores or other factors. **Study power/sample size:** no power calculation **Setting:** 2 long-term care units with 150 beds in total **Length of study:** 4 weeks **Assessment of PUs:**	to Braden scale) **All patients** Randomised N: 50 Completed N: 50 Drop-outs: 0 **Group 1** **Randomised N: 25** **Completed N: 25** **Drop-outs:** 0 **Age: 83.6 (6.9)** **Gender (f/m): 19/6** **Group 2** **Randomised N: 25** **Completed N: 25** **Drop-outs:** 0 **Age: 85.8 (8.4)** **Gender (f/m): 23/2** **Inclusion criteria: 65 years or older; Braden scale socre >8 and <14; Norton scale >6 and <12; pressure ulcer stages 0-1, expected hospital stay>28 days;** **Exclusion criteria: pressure ulcer stage 2-4;**	layers connected by transversal suspensory monofilaments. It is highly porous (with pores larger than 1mm) and elastic. Group 2: Visco-elastic mattress overlay (AKTON)(15.9mm thick). Made of vulcanised cross-linked rubber material which keeps its shape. Both groups: repositioned every 2 hours, alternating lateral (30%) and supine position; standard foam mattress used.	**Outcome 2:** comfort at day 28 (good) **Outcome 2:** comfort at day 28 (excellent)	**Group 1: 20/25** **Group 2:24/25** **Group 1: 5/25** **Group 2: 1/25**	unclear allocation concealment, baseline difference in Norton scores. **Additional outcomes:** change of the ulcer size (if present)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
digital planimetry, photography and WBP score **Classification of Pus:** EPUAP-NPUAP **Multiple ulcers:** N/A	**terminal or severely compromising illness; AIDS or hepatitis C; ongoing systemic corticosteroid therapy, immune-suppressant therapy or chemotherapy; enrolment within the past 3 months in any study related to wound healing; allergy to mattress overlay components.**				

I.1.6 Pressure redistributing devices for the prevention of heel ulcers

Table 53: Cadue 2008[42]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cadue (2008) **Title**: Prevention of heel pressure sores with a foam body-support device. A randomised controlled trial in a medical intensive care unit; 37 (1 suppl. Part 1); 30-60. **Journal:** Presse Medical 2008 Type of study: RCT Sequence generation: 'randomisation table was used to allocate 70 patients into 2 groups'. The two groups were formed randomly by following a randomisation table (yes) Allocation concealment: translated as sealed envelope (yes) Blinding: translated to: the physiotherapist and nurse assessed the stage of the lesion daily – but	Patient group: patients in intensive care setting All patients Randomised N: 70 Completed N: 70 Drop-outs: 0 Group 1 Randomised N: 35 Completed N: 35 Drop-outs: 0 Group 2 Randomised N: 35 Completed N: 35 Drop-outs: 0 Inclusion criteria: patients in an intensive care setting with a Waterlow Score >10, no existing heel pressure ulcers, >/=18 years or over. Exclusion criteria: not stated	Group 1: Foam body support and standard pressure prevention protocol (half-seated position, water mattress preventative massage 6 times/day) Group 2: Standard pressure ulcer protocol (see above)	Outcome 1: number of participants developing non-blanching pressure ulcer or worse on the heel	Group 1: 3/35 (8.6%) Group 2: 19/35 (55.4%)	Funding: do not know Limitations: Unclear blinding. No a priori sample size calculation and small sample size. Additional outcomes: * Notes: Abstract, with full paper not available in English. Extraction taken from Cochrane Review on support surfaces in the prevention of pressure ulcers.
			Outcome 2: mean time without any pressure ulcer	Group 1: 5.6 days Group 2: 2.8 days P=0.01	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
it is not clear if they were blinded (unclear) Addressing incomplete outcome data: 70 patients were included, 35 in each group. Table presented the principle results and notes that 'n=35' which has been interpreted that data were presented on 35 patients in each group. No mention was found of any withdrawals (yes) Statistical analysis: do not know Baseline differences: translated as at inclusion there was no significant difference between the two groups in the theoretical risk of developing pressure ulcers or any of the main factors known to contribute to the occurrence of bedsores. Study power/sample size: no a priori sample size calculation given Setting: do not know Length of study: maximum follow-up 30					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
days Assessment of PUs: do not know Classification of PUs: not reported Multiple ulcers: N/A					

Table 54: Gilcreast 2005[83]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gilcreast (2005) **Title**: Research comparing three heel ulcer-prevention devices **Journal:** Journal of wound ostomy and continence nursing, 32 (2), 112-120. Type of study: RCT Sequence generation: drawing of cards Allocation concealment: inadequate (non-numbered envelopes) Blinding: no- 1 nurse was performing all research tasks and was	Patient group: patients moderate or high risk of pressure ulcer development (69% of participants were in ICU) All patients Randomised N: 338 (not clear how distributed among the 3 groups). Completed N: 240 Drop-outs: 29% - 53 not included, as did not wear the devices for at least 48 hours; 45 not included as they were non-compliant.	Group 1: Bunny boot (fleece) high cushion heel protector Group 2: Egg crate heel lift positioner Group3: foot waffle The investigators attempted to control for all extraneous variables by monitoring all factors relating to pressure ulcer development.	Outcome 1: incidence of heel pressure ulcers	Group 1: 3/77 (4%) Group 2: 4/87 (5%) Group 3: 5/76 (7%)	Funding: TriService Nursing Research Program Limitations: Inadequate allocation concealment; no blinding; limited details of baseline data; unclear how many patients were randomised to each group and therefore which arms the drop-outs came from but there were 29% of

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not blinded to the device to which the participant was assigned. Addressing incomplete outcome data: gives details of why patients were not followed up but unclear which group they were from. No ITT analysis. Statistical analysis: chi-square , analysis of variance and logistic regression analysis Baseline differences: limited baseline information presented (unclear). Baseline imbalance in sex. Study power/sample size: a priori calculation of 80% power required 550 participants total sample of 338 patients was obtained. Setting: military tertiary-care academic medical centre. Length of study: follow-up period unclear Assessment of PUs: skin	Group 1 Randomised N: unclear Completed N: 77 Drop-outs: unclear Group 2 Randomised N: unclear Completed N: 87 Drop-outs: unclear Group 3 Randomised N: unclear Completed N: 76 Drop-outs: unclear Inclusion criteria: patients with moderate or high risk of pressure ulcer development (Braden score</= 14). Exclusion criteria: Patients with hip surgery; patients anticipated to be admitted for <72 hours; those with pre-existing heel pressure ulcers.				patients who did not have follow-up data. Additional outcomes: * Notes: *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assessed daily Classification of PUs: NPUAP Multiple ulcers: N/A					

Table 55: Tymec 1997[230]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Tymec 1997 **Title**: A comparison of two pressure-relieving devices on the prevention of heel pressure ulcers **Journal:** Advances in wound care, 1997, 10 (1), 39-44. Type of study: factorial design RCT Sequence generation: block randomisation list and the patient's position order was determined by a coin toss Allocation concealment: not reported (unclear) Blinding: not reported	Patient group: patients from nursing units of hospital with a low Braden score (at risk) All patients Randomised N: 52 Completed N: 44 Drop-outs: 8 developed grade 1 pressure ulcers and were removed from the study. f/m: 23/29 Age, mean (range): 66.6 s.d 16.5 years (27-90 years) Mean Braden score at admission: 11.8 Respiratory conditions: 21 Cancer: 6	Group 1: Foot waffle (FDA approved, non-abrasive vinyl boot with built in foot cradle and inflated air chamber Group 2: Hospital pillow under both legs from below knee to the Achilles tendon. In this hospital the standard pillow is a 20-ounce (+/-2 ounces) polyfiber-filled pillow.	Outcome 1: incidence of heel pressure ulcers	Group 1: 0/26 Group 2: 1/26 Logistic regression pillow/foot waffle -1.48, s.e 0.44 , p=0.001, OR 4.38	Funding: not reported Limitations: unclear allocation concealment, blinding, reporting of incomplete outcome data. Additional outcomes: tissue interface pressures. Notes: number of other ulcers eg. Metatarsal, top of foot.
			Outcome 2: time until heel pressure ulcer occurred (mean survival time)	Group 1: 10 days Group 2: 13 days Kaplan Meier – significant difference Log-rank tests p=0.036	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(unclear) Addressing incomplete outcome data: the number/group not reported. 8/52 developed grade 1 pressure ulcers and were removed from the study, so it would appear that the 52 participants were followed-up. Statistical analysis: logistic regression Baseline differences: no details given for characteristics of the groups Study power/sample size: power calculation for 80% power required 52 sample size. Setting: selected nursing units of a large hospital Length of study: 14 days Assessment of PUs: skin inspection Classification of PUs: AHCPR guideline pressure ulcer stages Multiple ulcers: N/A	Stroke: 5 Group 1 Randomised N: not reported Completed N: not reported Drop-outs: not reported Group 2 Randomised N: not reported Completed N: not reported Drop-outs: not reported Inclusion criteria: Braden score of <<16 (risk); intact skin on heels. Exclusion criteria: not reported.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments

Table 56: Vanderwee 2005[237]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Vanderwee 2005 **Title**: Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers **Journal:** Age and Ageing, 2005, 34, 261-267 Type of study: RCT Sequence generation: 'randomisation tables generated with the SPSS 10 software package' (yes) Allocation concealment: 'serially numbered closed envelopes were made for each participating ward' (yes) Blinding: patients and researcher probably not blinded to allocation (unclear) Addressing incomplete outcome data: drop-	Patient group: patients at risk of developing pressure ulcer (Braden score <17) All patients Randomised N: 447 Completed N: unclear Drop-outs: unclear Median age: 82 years (IQR 77-88 years) 93% were older than 65 years and 30%were older than 85 years. No patients had dark skin. Group 1 Randomised N: 222 Completed N: unclear Drop-outs: unclear Age (years): 81 (76-88) Length of stay in hospital (days): 22 (11-39) Mean Braden score (SD) on admission: 14.6 (3.06)	Group 1: APAM (Alpha X-cell, Huntleigh Healthcare); generates alternating high and low interface pressure between the body and support by alternating inflation and deflation. Sitting protocol with air cushion (Airtech, Huntleigh), with no turning protocol. Group 2: Visco-elastic foam mattress (Tempur, Tempur-World). Sitting protocol with air cushion (Airtech, Huntleigh). Turning every 4 h Both groups the heels of the patients were elevated from the mattress with an ordinary cushion beneath the lower legs.	Outcome 1: Incidence of heel pressure ulcers	Group 1: 5/222 (2.25%) Group 2: 16/225 (7.1%) Logistic regression was performed with heel pressure ulcers as outcome to adjust for length of stay, medical speciality, risk assessment method, and prevention protocol variables. There was no interaction between risk assessment method and prevention protocol. In the APAM group, significantly fewer patients developed a heel pressure ulcer compared to the control group: Wald X^2=7.533, df=1, p=0.006	Funding: supported by a grant from Ghent University and from Huntleigh Healthcare Limitations: drop-outs and blinding unclear Additional outcomes: other areas than heels Notes: *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outs/withdrawals not reported. Flow chart showed 447 patients enrolled in total. 297 assessed by Braden and 150 non-blanchable erythema. Number in table match that (unclear). Statistical analysis: logistic regression analysis and Kaplan-Meier survival analysis for the prevention protocol on the incidence of pressure ulcers (grade 2 or above) Baseline differences: well-balanced at baseline. Similar in all characteristics except medical specialty, and this variable was adjusted for in the analysis (yes) Study power/sample size: sample size calculation given, required 223 in each group for a power of 80%. Setting: 19 surgical, internal medicine or	Females (%): 60.6% Medical speciality (%): Surgery: 6.8% Internal: 31.1% Geriatrics: 62.2% Group 2 Randomised N: 225 Completed N: unclear Drop-outs: unclear Age (years): 82 (78-87) Length of stay in hospital (days): 18 (11-31.5) Mean Braden score (SD) on admission: 14.2 (2.93) Females (%): 65.6% Medical speciality (%): Surgery: 2.2% Internal: 25.3% Geriatrics: 72.4% Inclusion criteria: patients at risk of developing pressure ulcer (Braden score <17); or had at least 1 grade 1 ulcer; aged >/=18 years; with expected hospital stay of >3 days; not				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
geriatric hospital wards in Belgium. Length of study: unclear Assessment of PUs: skin inspection and transparent disk. Classification of PUs: EPUAP Multiple ulcers: N/A	contraindicated for turning. Exclusion criteria: if had grade 2 or worse pressure ulcer or weighed >140kg.				

Table 57: Donnelly 2011[70]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Donnelly 2011 **Title**: An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture **Journal:** Journal of wound care, 20 (7), 309-318 Type of study: RCT Sequence generation: computer-generated	Patient group: post-hip fracture patients. All patients Randomised N: 239 Completed N: 227 Drop-outs: 12 f/m: 184/55 age (mean, range): 81 years (65-100) Group 1 Randomised N: 120	Group 1: Heel elevation (Heelift Suspension Boot) plus pressure-redistributing support surface Group 2: standard care plus pressure-redistributing support surface alone). Mattress type determined by ward nurses according to perceived need. Their choice was recorded and analysed as a covariate.	Outcome 2: incidence of heel ulcers (all categories)	Group 1: 0/120 Group 2: 17/119	Funding: research supported by a Special Nursing Research Fellowship funded by the Research and Development Office for Health and Social Care in Northern Ireland. Limitations: No blinding of patient or investigator;
			Outcome 3: comfort (themed analysis)	Group 1: 32% of subjects felt the boots interfered with sleep and 41% felt that they adversely affected movement in bed, 59% rated them as comfortable overall. Poor concordance reasons were the weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%).	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
block randomisation schedule (permuted blocks of 20) Allocation concealment: randomisation schedule was held and managed by a senior research nurse manager not directly involved in the study. Blinding: authors state that it was not possible to blind either the patient or the investigator as the intervention was very distinctive. Outcome assessor was blinded. Addressing incomplete outcome data: yes, flow diagram given. ITT analysis. Statistical analysis: Chi-squared test for association for proportion of patients developing one or more PU. Kaplan-Meier for group survival. Cox Hazards Regressional Model to analyse the potential impact of covariates.	Completed N: 111 Drop-outs: 9 (deteriorating medical condition n=6, lost-to follow-up n=1, adverse event possibly linked to the intervention n=1, patient withdrew consent n=1). Group 2 Randomised N: 119 Completed N: 116 Drop-outs: 3 (lost to follow up n=1, deteriorating medical condition n=1, recruited incorrectly n=1) Inclusion criteria: aged 65 years or over on day of fracture; suffered a hip fracture, including any bony injury to the femoral head or femoral neck, in the previous 48 hours Exclusion criteria: did not give written, informed consent, or indicate willingness to participate through a process of				underpowered. Additional outcomes: Notes: *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: no statistically significant differences at baseline. Study power/sample size: powered for 240 patients per group to give 87.5% power, whereas had half this amount. Setting: fracture trauma unit of a major tertiary referral centre Length of study: 12 days Assessment of PUs: skin risk assessment tool – modified Knoll risk assessment tool Classification of PUs: NPUAP scale. Multiple ulcers: N/A	inclusionary consent; existing heel pressure damage (NPUAP); and/or history of previous pressure ulceration; patients for whom the investigator or medical/nursing team considered unsuitable.				

Table 58: Aronovitch 1999[13]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Aronovitch 1999 **Title**: A comparative study of an alternating air mattress for the prevention of pressure ulcers in surgical patients **Journal:** Wound management, 45 (3), 34-44 Type of study: quasi-randomised trial Sequence generation: quasi-randomised (by week rather than by patient to decrease protocol error) (unclear) Allocation concealment: not reported (unclear) Blinding: not reported (unclear) Addressing incomplete outcome data: all reasons/numbers for attrition/exclusions reported. ITT analysis. Statistical analysis: preoperative skin assessment score analysed using Mantel-	Patient group: elective surgery patients under general anaesthetic. All patients Randomised N: 217 Completed N: 170 Drop-outs: 4 device turned off inadvertently during treatment; 4 patients asked to withdraw for various unreported reasons; 3 patients withdrew due to back pain; 12 patients were placed on another surface postoperatively for reasons unrelated to the surface. Group 1 Randomised N: 112 Completed N: 90 Drop-outs: 22 Group 2 Randomised N: 105 Completed N: 80 Drop-outs: 25	Group 1: AP system intra and postoperatively (micropulse) Group 2: Conventional management (use of a gel pad in the operating room and a replacement mattress postoperatively)	Outcome 1: proportion of people with incidence of heel pressure ulcer	Group 1: 0/112 Group 2: 2/105 (one patient had one on right and left heel (stage 2 pressure ulcers) and another patient had one on left heel (unstageable secondary to eschar)	Funding: sponsored in part by an educational grant from MicroPulse. Limitations: quasi-randomised; unclear allocation concealment, blinding; no power calculation given. The conventional management group were at higher risk of developing a pressure ulcer at baseline (according to the Knoll score). Additional outcomes: * Notes: Vascular surgeries were performed 44.7% of the time in the study group and 73.3% of the time in the control group.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Haenszel (chi-square) test with modified ridit score (which permits the response levels to be scored using ranks). Baseline differences: no significant differences for age, sex, race, weight, height, smoking status but the conventional management group were at greater risk of pressure ulcer development (Knoll score) Study power/sample size: no power calculation given. Setting: operating room, tertiary care facility, USA Length of study: 7 days follow-up Assessment of PUs: skin inspection and then skin risk assessment tool used if change in status (Modified Knoll Risk Assessment Tool) Classification of PUs: NPUAP and the WOCN definitions	Inclusion criteria: > 18 years; free of pressure ulcers; undergoing elective surgery under GA, of 3h operative time Exclusion criteria: if patients had participated in a clinical trial within 30 days of the baseline visit;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: N/A					

Table 59: Sanada 2003[194]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Sanada 2003 **Title**: Randomised controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation **Journal:** J Tissue Viability, 2003, 13 112-114. Type of study: RCT Sequence generation: the subjects were randomly allocated to the groups by sequentially-labelled sealed envelopes (yes) Allocation concealment: following randomisation 'after baseline assessment, the registered nurses	Patient group: acute care patients. All patients Randomised N: 108 Completed N: 82 Drop-outs: 26 Group 1 Randomised N: 37 Completed N: 26 Drop-outs: 2 discontinued, 2 deaths, 7 head elevation </=30 degrees Group 2 Randomised N: 36 Completed N: 29 Drop-outs: 1 mattress malfunction, 2 deaths, 2	Group 1: Single-layer air cell overlay (Air doctor): single layer consisting of 20 round air cells. Group 2: Double-layer air cell overlay (Tricell): two layers consisting of 24 narrow cyclinder air cells. Both overlays had pressure alternating between cells at 5-minute intervals Group 3: standard hospital mattress (Paracare) All groups had change of body position every 2 hours, and special skin care to guard against friction and sheer. Nutritional intervention was given where required.	Outcome 1: incidence of heel pressure ulcers (all stages)	Group 1: 2/26 Group 2: 0/29 Group 3: 2/27 There were only stage 1-2 pressure ulcers	Funding: not reported Limitations: no blinding of nurses, patients were blinded. No a priori sample size calculation. There was a mistake in the numbers reported in the double-layer and the single-layer air-cell groups. Additional outcomes: pressure ulcers on other areas Notes: *
			Outcome 2: incidence of heel pressure ulcers (stage 2)	Group 1: 1/26 Group 2: 0/29 Group 3: 2/27	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
opened the envelopes that indicated which surface each subject would be treated on' Blinding: patients were blinded but nurses were not. Addressing incomplete outcome data: no Analysis: not ITT analysis Statistical analysis: chi-squared test to evaluate incidence of pressure ulcers Baseline differences: no statistically significant differences on prognostic indicators at baseline between groups. Study power/sample size: no power calculation given. Small number of patients in each arm. Setting: a single acute care unit, Japan Length of study: unclear Assessment of PUs: not reported. Classification of PUs: NPUAP	head elevation </=30 degrees Group 3 Randomised N: 35 Completed N: 27 Drop-outs: 1 death, 7 head elevation </=30 degrees. Inclusion criteria: Braden score </=16; bed bound; free of pressure ulcers before the start of the study; required head elevation. Exclusion criteria: not stated.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: N/A					

Table 60: Daechsel 1995[58]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Daechsel1995 **Title**: Special Mattresses: effectiveness in preventing decubitus ulcers in chronic neurologic patients **Journal:** Arch Phys Med Rehabil, 1985, 66, 246-248 Type of study: RCT Sequence generation: 'all qualified subjects were entered in to the trial for a period of three months and all were randomly assigned to one of the two types of mattress'. Method of randomisation not reported (unclear) Allocation concealment:	Patient group: chronic neurological patients in a long-term care hospital All patients Randomised N: 32 Completed N: 32 Drop-outs N: 0 Age: 19-60 years Group 1 Randomised N: 16 Completed N: 16 Drop-outs: 0 Group 2 Randomised N: 16 Completed N: 16 Drop-outs: 0 Inclusion criteria:	Group 1: Alternating-pressure mattress Group 2: Silicore overlay Mattresses were placed on a standard hospital spring mattress or 4-inch foam mattress and were supported by a standard hospital bedframe. The choice of the underlying mattress was dependent on the ease by which attendants could transfer the patient from the bed to wheelchair and back. Both groups received the same standard hospital and nursing care procedure for the prevention of ulcers – turning ¾ hours; daily bed-baths, pericare; weekly full baths or showers; use of absorbent pads; turning sheets and	Outcome 1: incidence of pressure ulcers (Grade 1 ulcers and above)	Group 1: 2/16 (25%) Group 2: 0/16 (25%)	Funding: not reported. Limitations: unclear randomisation method, allocation concealment, blinding; no a priori sample size calculation and small sample size. Additional outcomes: No statistically significant differences were found between the 2 groups with regard to location and severity of pressure ulcers.
			Outcome 2: patient satisfaction	Similar for both devices.	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not reported (unclear) Blinding: not reported (unclear) Addressing incomplete outcome data: all completed trial. ITT analysis. Statistical analysis: x2 test with Yate's correction Baseline differences: no statistically significant differences on the factors associated with the development of pressure ulcers Study power/sample size: no power calculation but very small sample. Setting: long-term care hospital for chronic neurological conditions, Canada Length of study: 3-month follow up Assessment of PUs: skin observations Classification of PUs: Exton-smith scale Multiple ulcers: N/A	between 19 and 60 years of age; free from skin breakdown 2 weeks prior to the study; considered at high risk of pressure ulcers. Exclusion criteria: not reported.	various topical treatments that normally would have been prescribed at the hospital. Additional preventive aids, such as heel and ankle protectors, sheepskins and bed cradles, were used as typically directed by the occupational therapists. Dietary needs were met as necessary. Physical therapy and occupational therapy were continued normally programmed. The skin was observed daily by attendants when dressing and undressing.			Notes: high risk defined as mean score on Norton scale and clinical judgement.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments

Table 61: Gray 2000[86]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gray 2000 **Title**: Comparison of a new foam mattress with the standard hospital mattress **Journal:** Journal of wound care, 2000, 9 (1), 29-31 Type of study: RCT Sequence generation: no randomisation method except 'randomised to a control or trial mattress using an opaque envelope' Allocation concealment: opaque envelope Blinding: mattresses had similar covers. Outcome assessors were unaware of which mattress the subject was using. Addressing incomplete outcome data: no details	Patient group: general hospital patients All patients Randomised N: 100 Completed N: 98 Drop-outs: 2 were withdrawn as the mattress covers were torn Group 1 Randomised N: 50 Completed N: unclear Drop-outs: 2 were withdrawn as the mattress covers were torn – both group 2. M/F: 30 (60%)/20 (40%) Age (years): mean (s.d): 69 (4.5) Waterlow score on admission: mean (s.d): 13 (2.5) 2-6 hours out of bed each day: 45 (90%)	Group 1: Transfoamwave, which were new at the beginning of the trial. Group 2: standard hospital mattress (transfoam), which had been in clinical use for three years. Pressure-reducing seat cushions: 25% in intervention group and 50% in control group.	Outcome 1: heel pressure ulcer incidence	Group 1: 0/50 Group 2: 1/50 (Grade 4)	Funding: not reported Limitations: unclear sequence generation method; no details of incomplete outcome data; Additional outcomes: pressure ulcers (all types) Group 1: 2/50 (1 Grade 2 and 1 non-blanching redness) Group 2: 2/50 (1 Grade 4 and 1 non-blanching redness); baseline difference - provision of pressure-reducing seat cushions (50% in control group and 25% in intervention
			Outcome 2: comfort perception – very uncomfortable	Group 1: 0/47 (0%) Group 2: 0/48 (0%)	
			Outcome 3: comfort perception – uncomfortable	Group 1: 0/47 (0%) Group 2: 1/48 (2%)	
			Outcome 4: comfort perception – adequate	Group 1: 3/47(6%) Group 2: 2/48 (4%)	
			Outcome 5: comfort perception – comfortable	Group 1: 26/47 (55%) Group 2: 34/48 (72%)	
			Outcome 5: comfort perception – very comfortable	Group 1: 18/47 (38%) Group 2: 11/48 (23%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Mann-Whitney U-test to compare groups. Fisher's exact test used for pressure ulcer incidence. Baseline differences: state only difference was in provision of pressure-reducing seat cushions (50% in control group and 25% in intervention group) Study power/sample size: no a priori sample calculation given but small sample size. Setting: general hospital, UK Length of study: data collected on days 1,5 and 10. Assessment of PUs: unclear. Classification of PUs: Torrance scale Multiple ulcers: N/A	Seat cushion provision: 14 (25%) Group 2 Randomised N: 50 Completed N: unclear Drop-outs: unclear M/F: 31 (62%)/19 (38%) Age (years): mean (s.d): 61 (4.1) Waterlow score on admission: mean (s.d): 14 (3.6) 2-6 hours out of bed each day: 49 (98%) Seat cushion provision: 25 (50%) Inclusion criteria: emergency or list admission for bed rest or major surgery; less than 160kg in weight (one of the research wards regularly admitted obese patients for stomach surgery); skin intact; Exclusion criteria: existing skin conditions; terminally				group). Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	ill				

Table 62: Jesurum 1996[108]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Jesurum 1996 **Title**: Balloons, beds, and breakdown. Effects of low-air loss therapy on the development of pressure ulcers in cardiovascular surgical patients with intra-aortic balloon pump support. **Journal:** Crit Care Nurs Clin North Am. 1996 Dec;8(4):423-40. Type of study: Pilot study. Randomized, quasi-experimental design Sequence generation: Patients were placed in either experimental or control group depending on the date of being	Patient group: 36 adult CVS patients requiring IABP for failure to wean from cardiopulmonary bypass surgery All patients Randomised N: 36 Completed N: 36 Drop-outs N: 0 Group 1: Experimental (LAL) Randomised N: 16 Completed N: 16 Drop-outs: 0 Group 2: Controls Randomised N: 20 Completed N: 20	Group 1: Patients who received an IABP in OR on an even day were placed on a low air loss LAL bed (experimental). These beds are designed to maintain low interface tissue pressure of 12 to 45 mm Hg. Group 2: Those who received an IABP in OR on an odd day were placed on a standard bed. The standard bed was fit with extra pressure reduction capabilities for the heel area.	Outcome 1: Incidence of heel pressure ulcers. Early phase	Group 1: LAL bed: 2/16 Patient I – L and R heel ulcer L Heel Stage NA R Heel Stage NA Patient 2 – L and R heel ulcer L Heel Stage I R Heel Stage I Group 2: Standard bed: 1/20 Patient I –L and R heel ulcer L Heel Stage I R Heel Stage I	Funding: None stated Limitations: quasi-experimental; unclear allocation concealment; blinding; no a priori sample size calculation and small sample size; no details on the location of the late phase ulcers
			Outcome 2: Rate of development of new heel pressure ulcers	Group 1: LAL – total of 4 heel ulcers from 2 patients in early stage. 3/4 appeared on day 4 post-op. 1/4 on day 6 post-op Group 2: Standard bed: total of 2 new heel ulcers from 1 patients. 2/2 appeared on day 2 post-op.	Additional outcomes: Number of patients who had single, multiple or no ulcers Number of patients who had stage I or

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
placed on a bed, either even or odd day. Allocation concealment: Unclear Blinding: Unclear Addressing incomplete outcome data: No missing data. ITT analysis. Statistical analysis: Because the sample size was small and had unequal groups, comparison of the two independent samples with respect to dichotomous outcomes was performed using Fishers' exact test. Independent sample t-tests, using either equal or unequal variance as appropriate, were performed. Baseline differences: Control group had higher pre-operative albumin (g/dL). Study power/sample size: Unclear Setting: CV recovery room of 956 bed,	Drop-outs: 0 Inclusion criteria: All Cardiovascular surgery patients who received an Intra-ortic balloon pump in the operating room for failure to wean from cardiopulmonary bypass were eligible to be entered into the study Exclusion criteria: None provided. Patient characteristics: Treatment n=16 Age: 67 (s.d 5.5) Gender M/F: 9/7 Comorbid conditions: 4.75 (s.d 2.11) Skin breakdown (acute phase): 3 (18.8%) Skin breakdown (late): 2 (12.5%) Control n=20 Age: 69 (s.d 2.31) Gender M/F: 17/3			Note. Posterior surfaces were not evaluated until post-op day of presentation 4 due to hemodynamic instability/open sternum.	II vs. III or IV. Characteristics of the patients who did versus those who did not have an ulcer. Notes: *
			Outcome 3: Proportion of participants with new pressure ulcers.	Group 1: LAL n=3/16 Patient I – L and R heel ulcer L Heel Stage NA R Heel Stage NA Sacrum Stage III Patient 2 – L and R heel ulcer L Heel Stage I R Heel Stage I Sacrum Stage NA Patient 3 Sacrum Stage III Group 2: Controls n=3/20 Patient I –L and R heel ulcer L Heel Stage I R Heel Stage I R elbow Stage I Patient 2 Sacrum Stage NA Patient 3 Sacrum Stage I	
			Outcome 4: Rate of	Group 1: LAL – total of 4 heel	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
private, not-for-profit, teaching hospital in USA. Length of study: Unclear. However, total length of stay was NS different between those who developed pressure ulcers and those who did not (p=0.53). This may be skewed by the fact that 5 subjects who had pressure ulcers expired prior to discharge. Assessment of PUs: Pressure ulcers were staged by the enterostomal therapy nurse. Classification of PUs: NPUAP. Multiple ulcers: N/A Number of subjects LAL bed: 2/16 Controls: 1/20	Comorbid conditions: 4.10 (s.d 1.37) Skin breakdown (acute phase): 3 (15%) Skin breakdown (late): 1 (5%)		development of new pressure ulcers	ulcers from 2 patients in early stage. 3/4 appeared on day 4 post-op. 1/4 on day 6 post-op Total of 3 sacrum ulcers – all appeared on day 4* Group 2: Standard bed: total of 2 new heel ulcers from 1 patients. 2/2 appeared on day 2 post-op. Total of 2 sacrum ulcers – 1 appeared day 4 and 1 on day 5. Total of 1 elbow ulcer – appeared on day 2 Note. Posterior surfaces were not evaluated until post-op day of presentation 4 due to hemodynamic instability/open sternum.	

Table 63: Russell 2000A[189]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Russell 2000 **Title**: Randomised controlled trial of two pressure-relieving systems. **Journal:** J Wound Care. 2000 Feb;9(2):52-5. Type of study: RCT Sequence generation: Randomisation was performed blindly, but no details on sequence generation. Allocation concealment: Yes, used a sealed opaque envelope Blinding: Unclear Addressing incomplete outcome data: One analysis included ITT and one included only the evaluable patient sample. Statistical analysis: Skin assessment was compared between treatment groups using Mantel-Haenszel test with modified ridit score.	Patient group: Patients who have had cardiovascular surgery. All patients Randomised N: 198 Completed N: 195 Drop-outs: 3 patients were randomised to Intervention but because of scheduling they were given control treatment and were included in the control group analysis. Group 1 Multi-cell dynamic cell mattress Randomised N: 98 Completed N: 97 Drop-outs: 1 (removed from study because of post-op complications) Group 2 Standard Randomised N: 100 Completed N: 99 Drop-outs: 1 (discontinued because of cardiac arrest + had no	Group 1: Multi-cell pulsating dynamic mattress system Group 2: Conventional management for the prevention of pressure ulcers	Outcome 1: Incidence of heel pressure ulcers Outcome 2: Time to heel pressure ulcers	Group 1: Dynamic mattress n=0/98 Group 2: Conventional n=1/100 Group 1: Dynamic mattress: NA Group 2: Conventional Mattress: day 7	Funding: Dr Russell has been a consultant for MicroPulse. Limitations: No details of sequence generation or a priori power calculation. Unclear if day 7 was the first sign of pressure ulcers. One patient who got an ulcer in Dynamic mattress group spent several hours sitting on a chair on post-op day 4 and 5. Additional outcomes: * Notes: *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Primary outcome of proportion of patients who developed ulcer by day 7 post-surgery, was compared between treatment groups using Fisher's exact test. Baseline differences: no significant differences Study power/sample size: None provided. Setting: Single centre. Canada. Length of study: Patients assigned to multi-cell pulsating mattress were placed on the system in the operating room and in their hospital room until discharge or for a maximum of 7 days post-surgery Maximum follow-up: until discharge Assessment of PUs: Patients were examined immediately post-surgery for pressure ulcers. Patients assessed daily for pressure ulcers. Skin risk assessment was performed on days 1, 4,	pressure ulcer, so was included in analysis) Inclusion criteria: 18 years of age or older and be scheduled for CV surgery with general anaesthesia for at least 4 hours with an actual operative time of 3 hours or more. Exclusion criteria: If they had a pressure ulcer at the baseline visit. Baseline characteristics Experimental Male/Female: 75/23 Age:65.2 (s.d 10.9) Weight (kg):79.1 (s.d 16) Height (cm): 169 (s.d 9) Race: Caucasian: 94% Smoking history: Smoker: 17.5% Ex-Smoker: 45.4% Never: 37% Previous ulcer: 0				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
7 and on other days if a change in status was noted. Classification of Pus: NPUAP classification system. Zero = no ulcer Stage I = nonblanchable erythema of intact skin II – partial thickness skins loss involving epidermis, dermis or both III = full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. IV = full-thickness skin loss with extreme destruction, tissue necrosis, or damage to muscle, bone or supporting structures. Multiple ulcers: Two patients in Conventional had multiple ulcers	Control Male/Female:75/25 Age:65.2 10.6 Weight (kg):80.5 (s.d 150) Height (cm): 170 (s.d 9) Race: Caucasian: 87% Smoking history: Smoker: 15.2% ExSmoker: 51.5% Never: 33.3% Previous ulcer: 1				

Table 64: Gebhardt 1996[80]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gebhardt (1996) **Title**: Pressure-relieving supports in an ICU **Journal:** Journal of wound care, 5 (3), 116-121 Type of study: RCT Sequence generation: Based on the final digit of their hospital number (even to alternating beds, odds to constant) Mattresses were placed in low-, medium, or high cost bands. A mattress was selected by means of a table of random numbers from the cheapest brand suitable for the patients weight according to manufacturer's recommendations Allocation concealment: Unclear Blinding: Unclear Addressing incomplete outcome data: PPA (the results included the patients who died)	Patient group: Patients with a Norton score of <13 who had been in the unit for less than 3 days and had no sores were allocated to alternating pressure or constant-low-pressure supports All patients Randomised N: 52 Completed N: 43 Drop-outs: 9 Data from the first 4 who were allocated to medium-cost brand + 5 who were transferred to other wards or hospitals or died before 2nd assessment were excluded from analysis Group 1 Alternating pressure Randomised N: 26 Completed N: 23 Drop-outs: 3 Group 2 Constant pressure	Group 1: Alternating pressure support – change during a 5-10 minute cycle. Group 2: Constant low-pressure	Outcome 3: Incidence of heel pressure ulcers	Group 1: 0/23 (0%) Group 2: 1/20 (5%)	Funding: manufacturers lent the equipment, and North East Thames Regional Hospital Board provided a grant. Limitations: Quasi-randomised; unclear allocation concealment; Unclear how many patients developed heel sores or pressure ulcers Additional outcomes: Practical problems reported with mattresses UK Costing Notes: *
			Outcome 2: Patient acceptability	Group 1: Alternating pressure – Uncomfortable n=2 Comfortable n=2 Group 2:Unclear.	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: The number of patients developing pressure ulcers and requiring change of support owing to deterioration of their pressure ulcers were compared using the chi square test. Baseline differences: No important differences at baseline. More patients in constant-low-pressure were suffering from cancer and breathlessness and more were receiving nitrates, calcium channel blockers but fewer had infusion pumps Study power/sample size: Owing to lack of previously published data, it was impossible to carry out s meaningful power calculation. However, a total of 30 patients had been recruited, showing an incident rate in the constant-low-pressure group of 53%. For a	Randomised N: 26 Completed N: 20 Drop-outs: 6 Inclusion criteria: patients at risk of developing pressure sores by means of Norton score. Patients with a score of <13 who had been in the unit for less than 3 days and had no sores were allocated to alternating pressure or constant-low-pressure supports Exclusion criteria: None provided. Alternating pressure M/F:12/11 Age:55 (range 23-83) Norton score: >8=5 <8=18 Drugs: Sedatives:21 Muscle relaxants:7 Inotrops:22				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
power of 90% and a significance of p=0.01, 20 subjects were required in each group to show a 48% difference between the groups. Setting: ICU, involving 8-bed ward in a university-affiliated teaching hospital Length of study: time spent in hospital. Patients were taken out of the trial after 3 months, or if their condition improved so that they were no longer at risk of developing sores (a Norton score of >12 and no sore present), if they were discharged or transferred to another ward or hospital, or if they died. Assessment of PUs: The registered nurse: patient ratio was 1:1. Patients were visited 4 times per week by one of two research nurses and at request of ward	Bed bound:23 Died during trial:6 Mean days in trial (SD): 11 (8.7) Controls M/F:13/7 Age:60 (range 21-83) Norton score: >8 = 1 <8 = 19 Drugs: Sedatives:20 Muscle relaxants:6 Inotrops:20 Bed bound:20 Died during trial:6 Mean days in trial (SD):12 (8.3)				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
staff. Progress of any pressure areas were recorded 2xwk. If the pressure areas deteriorated, the mattress was changed for a more sophisticated type in a higher cost-brand within the same group. Classification of PUs: Score were graded according to international accepted systems: Grade I (persistent erythema) Grade 2: epidermal loss; Grade 3: blue-black discolouration or cavity extending dermis: Grade 4 cavity to subcutaneous tissue or deeper. Multiple ulcers: In constant pressure group n=3.					

Table 65: Takala 1996[217]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Takala J; Varmuvuo S: Soppi E **Title**: prevention of pressure sores in acute respiratory failure: a randomised controlled trial **Journal:** Clinical Intensive Care 1996:7: 228-235 Type of study: RCT Sequence generation: Consecutive eligible patients were randomised to one of the two study mattresses. When more than 2 patients were deemed eligible at the same time, patients were entered in decreasing order of actual length of stay at the time of evaluation. Allocation concealment: Unclear Blinding: Unclear Addressing incomplete outcome data: ITT	Patient group: The study sample represents 30% of all patients requiring intensive care for more than 5 days. All patients Randomised N: 40 Completed N: 30 Drop-outs: 10 10 patients were randomised but not treated either due to early discharge or death, but were included in ITT Group 1 Randomised N: 20 Completed N: 11 Drop-outs: 9 Group 2 Randomised N: 20 Completed N: 13 Drop-outs: 7 Inclusion criteria: All patients who, based on	Group 1: Experimental: Pressure relieving mattress (Carital Optima, Carital Ltd, Tuusula, Finland) consists of a series of 21 double air bags (cells) one inside the other and a base. Group 2: Standard hospital mattress (10cm thick foam mattress, density 35 kg/m3)	Outcome 1: Incidence of heel pressure ulcers	Group 1: Pressure relieving mattress: 0/20 Group 2: Controls: 2/20	Funding: grant from Ahstrom Medical Helsinki, Finland Limitations: Unclear allocation concealment and blinding; randomisation; High drop out rate. Additional outcomes: Changes in skin temperature Capillary blood flow Notes: *
			Outcome 2: Category of new heel pressure ulcer	Group 1: Not relevant Group 2: Controls: Patient 1 – Grade 1A Patient 2 – Grade 1A	
			Outcome 3: Time to development of new pressure ulcer	Group 1: Not relevant Group 2: Controls: Patient 1 – day 12 Patient 2 – day 7	
			Outcome 4: Category of heel pressure ulcer over time	Group 1: Not relevant Group 2: Controls: Patient 1 – Grade 1B day 10 Patient 2 – did not progress.	
			Outcome 5: New pressure ulcers	Group 1: Pressure relieving mattress: 0/20 Group 2: Controls n=7/20	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
analysis: 40 patients for ITT; 24 were treated according to protocol Statistical analysis: The primary outcome was analysed using sequential analysis and Fisher's exact test. The sequential analysis allows repeated comparisons between the treatments after each randomised block up to a predefined max number of patients. Differences between the groups for the secondary outcomes were analysed using the unpaired t-test and change within the groups were analysed using the paired t-test. Baseline differences: No differences at baseline Study power/sample size: If a predefined cut-off level for a significant difference was achieved at any point, the study was discontinued. The sample size calculation	clinical evaluation by the attending physicians, had an expected stay in intensive care exceeding five days were eligible. Exclusion criteria: Accidental injuries. Patient characteristics: Pressure relieving mattress: Age:60 ± 16 Sex (M/F): 12/9 Clinically infected: 9 APACHE II in first 24 hrs: 13 ± 8 APACHE II 24 hr preceding admission to study (only those treated): 13 ± 7 TISS score on admission(only those treated): 35 ± 8 Controls Age: 63 ± 12 Sex (M/F): 13/6 Clinically infected: 10 APACHE II in first 24 hrs:15 ± 6				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
was based on the assumption that 65% of patients requiring prolonged intensive care would develop a sore, and that a 50% reduction in the number of patients with sores would be detected. The study was stopped after 40 patients had been randomised. Setting: Dept of Intensive Care, Kuopio University Hospital, Finland) Length of study: Two weeks, or until earlier discharge or death. Assessment of PUs: The status of the skin, interface pressure between skin and mattress, skin capillary blood flow and skin temperatures were measured daily. Each morning any sore was photographed and traced on sterile transparent plastic. The trace was cut off and	APACHE II 24 hr preceding admission to study (only those treated): 17 ± 3 TISS score on admission(only those treated): 34 ± 8				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weighted and the surface area calculated. Classification of PUs: The status of the skin and development of pressure sores were recorded using the grading of Shea. Multiple ulcers: Seven patients on the standard mattress developed a total of 13 pressure sores.					

Table 66: Nixon 2006[163]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Nixon 2006 **Title**: Pressure relieving support surfaces: a randomised evaluation. **Journal:** Health Technology Assessment, 2006, 10(22); iii-101 Type of study: RCT Sequence generation: yes - computer-	Patient group: acute or elective patients from 11 hospitals All patients Randomised N: 1972 Completed N: 1540 Drop-outs: 432 Group 1	Group 1: Alternating-pressure overlay (alternating cell height minimum 8.5cm, max 12.25cm; cell cycle time 7.5-30 minutes Group 2: Alternating-pressure mattress (alternating cell height min 19.6cms, max 29.4cms; cell cycle time 7.5-30minutes) Intervention was allocated within 24 hours of admission.	Outcome 1: no. of participants with incidence of pressure ulcers grade 2 and above	Group 1: 21/989 (13.5%) ITT Group 2: 21/982 (14.1%) ITT	Funding: NHS HTA Limitations: unblinded Additional outcomes: healing of existing pressure ulcers, cost of treatment; high
			Outcome 2: patient acceptability: requests for mattress change:	Group 1: 230/989 (23%) ITT Group 2: 186/982 (19%) ITT	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
generated algorithm Allocation concealment: yes - independent, central, secure, 24-hour randomisation automated telephone service. Blinding: not possible to mask the randomised interventions to patients, ward nursing staff or outcome assessors Addressing incomplete outcome data: yes flow chart provided. ITT Analysis. Statistical analysis: X2 test was used for incidence of pressure ulcers Baseline differences: no important differences. Study power/sample size: for 80% power 3220 and 4870 patients were required but not feasible to recruit so aimed for 2100 so they would have around 1000 per arm. Setting: 11 hospitals	Randomised N: 990 Completed N: 781 Drop-outs: 208 Age mean (s.d): 75.4 (9.7) Male/female: 365 (36.9%)/624 (63.1%) Type of admission: Acute: 363 (46.5%) Elective: 418 (53.5%) Type of speciality: Vascular: 32 (4.1%) Orthopaedic 618 (79.1%) Elderly: 131 (16.8%) Existing grade 2 pressure ulcers - yes/no: 45 (5.8%)/736 (94.2%) Group 2 Randomised N: 982 Completed N: 759 Drop-outs: 223 Age mean (s.d): 75.0 (9.2) Male/female: 346 (35.2%)/636 (64.8%) Type of admission: Acute: 352 (46.4%) Elective: 407 (53.6%) Type of speciality: Vascular: 29 (3.8%)				drop-out. Notes: 1 participant was recruited twice and was excluded from the analysis (group 1).

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 30 day follow-up twice weekly then a further 30 day follow-up once a week Assessment of PUs: tracings Classification of PUs: adapted from EPUAP1999 and Agency for Health Care Policy and Research 1992 Multiple ulcers: largest values used	Orthopaedic: 608 (80.1%) Elderly: 122 (16.1%) Existing grade 2 pressure ulcers - yes/no: 41 (5.4%)/718 (94.6%) Inclusion criteria: >/=55 years; expected to stay for at least 7 days, with either limited activity or mobility (Braden scale activity and mobility score of 1 or 2), or an existing pressure ulcer of grade 2; elective surgical participants without limited activity or mobility were eligible if the mean LOS for surgery was at least 7 days and they were expected to have Braden scale activity and mobility scores of 1 or 2 for at least 3 days postoperatively. Exclusion criteria: grade 3 or worse pressure ulcer at admission; planned admission to ICU after surgery; admitted to hospital more than 4 days				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	before surgery, slept at night in a chair, weighted >140kg or <45kg (as per mattress specifications)				

Table 67: Torra 2009[227]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Torra 2009 **Title**: Preventing pressure ulcers on the heel: a Canadian cost study **Journal:** Dermatology Nursing 2009, 21 (5), 268-272. Type of study: multicentre RCT Sequence generation: no details of method Allocation concealment: no details Blinding: open study Addressing incomplete outcome data: no details by group. Statistical analysis: no details	Patient group: Nursing home patients and home care program patients from primary health care centres. All patients Randomised N: 130 Completed N: 111 Drop-outs: 19 - 6 died, 8 left study (four because of setting change and the other four following clinical decision), 4 abandoned the study (died) Group 1 Randomised N: unclear Completed N: unclear	Group 1: special polyurethane foam hydrocellular dressing for the protection of the heel (Allevyn Heel) and normal measures of preventing pressure ulcers. Dressings were fixed with a socket or a net bandage. Group 2: protective bandage of the heel (Soffban and gauze bandage). The bandage covered all the ankle articulation. Normal measures for preventing pressure ulcers.	Outcome 1: incidence of heel pressure ulcers	Group 1: 3.3% Group 2: 44% RR: 13.42 (95% CI 3.31 to 54.3) P<0.001	Funding: not reported. Limitations: open study. Unclear how many in each group but relative risk reported. No details of allocation concealment and randomisation method. Unclear addressing of incomplete outcome data. Additional outcomes: Notes: The Allevyn heel is said to be a

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: no statistically significant differences Study power/sample size: no a priori power calculation given but 130 entered study Setting: nursing homes and three home care programmes from primary care centres. Length of study: 8 weeks Assessment of PUs: no details Classification of PUs: no details Multiple ulcers: no details	Drop-outs: unclear Group 2 Randomised N: unclear Completed N: unclear Drop-outs: unclear Inclusion criteria: patients at risk of developing pressure ulcers according to Braden Scale; patients who could give consent to participate in the study Exclusion criteria: patients with existing pressure ulcers in heels; patients with diabetes; patients using special prevention surfaces; patients using devices for relieving local pressure at heels				dressing but looks to be also a device for the heel. Another study Torra I Bou et al (2002)[228] was the original study but this was a foreign language paper.

Table 68: Demarre 2012[66]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Demarre 2012	**Patient group:** hospitalised patients. The wards were neurology	**Group 1:** ALPAM with multi-stage inflation and deflation of the air cells. The inflation curve	**Outcome 1:** incidence of patients with heel		**Funding:** Financially sponsored by Ghent University as

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Title: Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: a randomised-controlled clinical trial Journal**:** International Journal of Nursing Studies, 47 (2012), 416-426. **Type of study:** multi-centre RCT **Sequence generation:** randomised on 1:1 ratio by simple randomisation. The sequence was based on computer-generated list of random numbers. **Allocation concealment:** Nurses contacted researcher and received a number for type of allocated mattress (first on computer generated list). **Blinding:** blinding not possible due to differences in external control unit of the	(n=6), rehabilitation (n=3), cardiology (n=2), dermatology (n=1), pneumology (n=1), oncology (n=1) and chronic care (n=1) or a combination of different types of medical conditions (n=2). **All patients** **Randomised N:** 610 **Completed N:** 307 **Drop-outs:** 303 **Group 1** **Randomised N:** 298 **Completed N:** 152 **Drop-outs:** 146 (PU category II-IV (n=17), losses to follow-up because of: technical problems (n=3), discomfort (n=11), reason not defined (n=3), transfer to another ward (n=15), discharge to home (n=40), death (n=15), discharge to another institution (n=42)) **Group 2**	of the air cell was identical to the deflation curve of t air cell. The head zone contained 3 air cells with a continuous low pressure, the heel zone contained 7 cells with a continuous ultra low pressure and the back and sacrum zone contained 10 alternating low pressure cells. A sensor at the sacral zone measured the applied pressure of the body on the mattress. The device consisted of a mattress and a control unit. Cycle times for inflation and deflation were between 10 and 12 minutes. The air cell width was 10cm. **Group 2:** standard ALPAM. An ALPAM with a standard single-stage, steep inflation and deflation of the air cells. All air cells were alternating, the cycle time was 10 minutes and the air cell width was 10cm. An external manual control unit was used to adjust the mattress to the patient's weight. Both mattresses were covered with an identical mattress cover. No standard repositioning protocol was used	pressure ulcers (Heel only) (grade 2 and above) (heel/ankle)(grade 2 and above)	**Group 1**: 4/298 (1.3%) ITT **Group 2:** 5/312 (1.6%) ITT **Group 1:** 4/298 (1.3%) ITT **Group 2:** 6/312 (1.9%) ITT X2 =0.32, df=1, p=0.57	part of a PhD study. Authors state that the mattresses and cushions were provided by Hill-Rom but they did not influence the study. **Limitations:** No blinding of outcome assessors. High drop-out in both groups. Both groups had some patients with patients who had grade I ulcers already (15.4%). **Additional outcomes:** Incidence of grade II, grade III, Grade IV, incontinence-associated dermatitis. Incidence for various areas - pelvic area (sacral; hip); heel area (heel, ankle); other. Probability to

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
mattresses studied. No information was given to the nurses regarding the differences in mattresses. Outcome assessors not blinded. **Addressing incomplete outcome data:** flow chart with detailed reasons for drop-out given. High drop-out (in both groups). ITT analysis used. **Statistical analysis:** data presented in %s and means if normally distributed data and medians of not normally distributed. T-tests used in normally distributed continuous data. Mann-Whitney u-tests for non-normally distributed continuous data. Chi-square and Fisher's exact tests for categorical variables. **Baseline differences:** no significant differences **Study power/sample size:** powered for 600 patients (300 in each group).	**Randomised N:** 312 **Completed N:** 155 **Drop-outs:** 157 (PU category II-IV (n=18), losses to follow-up because of: technical problems (n=3), discomfort (n=16), reason not defined (n=5), transfer to another ward (n=22), discharge to home (n=41), death (n=14), discharge to another institution (n=37), withdrawal of consent (n=1)) **Inclusion criteria:** at risk for pressure ulcer development according to the Braden scale. **Exclusion criteria:** having a pressure ulcer Grade II-IV on admission; the expected admission time in the hospital was < 3 days; aged < 18 years; there was a 'do not resuscitate code' specifying ending all therapeutic interventions; weight was less than 30kg or more than 160kg	in bed. An identical seating protocol was used in both groups. All patients were seated on a static air cushion. The control unit was disconnected during transport of the patient, resulting in an inflated mattress for 2 hours without alternating air cells.			remain pressure free.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: 25 wards from 5 Belgian hospitals. **Length of study:** 14 days follow-up **Assessment of PUs:** Skin assessment daily by nurses. Transparent plastic disc method used to observe non-blanchable erythema (Grade 1). **Classification of PUs:** pressure ulcers classified by EPUAP classification system. **Multiple ulcers:** N/A	(mattress specification); Informed consent could not be obtained from patient or his/her legal representative.				

Table 69: Santa Maria 2013[195]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Santamaria (2013) **Title**: A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and	Patient group: trauma and critically ill patients in the ICU All patients Randomised N: 440 Completed N: 313	Group 1: usual pressure ulcer prevention strategies plus multi-layered (three layers) soft silicone foam heel dressing. Elastic tubular bandages were also used to retain the dressing. Dressings were changed every three days or	Outcome 1: incidence of heel pressure ulcers	Group 1: 5/161 (3.1%) Group 2:19 /152 (12.5%) P=0.002	Funding: no details Limitations: unclear allocation concealment as no mention of the envelopes being opaque

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
heel pressure ulcers in trauma and critically ill patients: the border trial **Journal:** International Wound Journal, 1742-4801 Type of study: RCT Sequence generation: randomised using a computer generated set of random numbers Allocation concealment: pre-prepared series of envelopes Blinding: open-label study Addressing incomplete outcome data: yes CONSORT diagram of patients drop-out. ITT analysis. Statistical analysis: Fishers Exact Test Baseline differences: no differences Study power/sample size: adequate (220 per group for 80% power) Setting: ICU at a teaching hospital in Melbourne, Australia Length of study: 25 days	Drop-outs: 127 Age (years): 55 Group 1 Randomised N: 219 Completed N: 161 Drop-outs: 58 Age (years): 54 Sex (m/f):126/89 Emergency department admission classification: Critical illness: 141 Major trauma: 69 Group 2 Randomised N: 221 Completed N: 152 Drop-outs: 69 Age (years): 56 Sex (m/f): 132/82 Emergency department admission classification: Critical illness: 147 Major trauma:65 Inclusion criteria:	more frequently if they were soiled or dislodged. Group 2: usual pressure ulcer prevention strategies Both groups: Hill-Rom Versa Care low air loss bed and standard hospital ICU prevention strategies which included on-going Braden pressure ulcer risk assessment and regular repositioning.			Additional outcomes: Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
follow-up Assessment of PUs: not reported Classification of PUs: the Australian Wound Management Association (AWMA) Multiple ulcers: N/A	emergency department and ICU admission for critical illness and/or major trauma; over 18 years of age Exclusion criteria: suspected or actual spinal injury precluding the patient being turned; pre-existing sacral or heel pressure ulcer; trauma to sacrum and/or heels				

I.1.7 Barrier creams

Table 70: Bou 2005[32]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Bou, 2005 **Title:** The effectiveness of a hyperoxygenated fatty acid compound in preventing pressure ulcers. Journal**:** Journal of Wound Care.14(3), 117-122. **Type of study:** RCT **Sequence generation:** randomised code **Allocation concealment:** closed envelope **Blinding:** patients and investigators were blinded **Addressing incomplete outcome data:** provides details of how many randomised did not complete study but no	**Patient group:** 380 residents of participating hospitals and residential homes. **All patients** **Randomised N:** 380 **Completed N:** 331 **Drop-outs:** 49 dropouts (details not provided by randomised group) because: died (n=2), transferred to other units or discharged (n=7), general deterioration in condition (n=2), did not complete the questionnaire or staff caring for them did not follow the study protocol (n=38) **Group 1** **Randomised N:** unclear **Completed N:** 164	**Group 1:** Mepentol. Hyperoxygenated fatty acid compound consisting of oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acide, gamma linoleic acid, arachidonic acid, eicosenoic acid. **Group 2:** Placebo cream containing triisostearin and perfume, specially manufactured to have the same appearance and fragrance as the intervention. Both groups: Product was applied twice daily to at least three areas of the body, sacrum, trochanter, heels.	**Outcome 1:** Incidence of new pressure ulcers	**Group 1:** 12/164 **Group 2:** 29/167 **Relative risk:** 0.42 **95% CI:** 0.22-0.82 **P value:** <0.006	**Funding:** Laboatorios Bama-Geve (manufacturer of intervention cream) **Limitations:** The method of assessing pressure ulcers was not recorded in the paper. It was unclear whether the barrier creams described in the patient characteristics were stopped during the trial and what impact this had on the results. It was not clear whether the
			Outcome 2: Time until pressure ulcer developed (days).	Accumulated survival probability at day 30 as read from graph (i.e. probability the patient hasn't developed an ulcer) **Group 1:** 0.93 **Group 2:** 0.83 **p-value:** 0.0054 (from paper) Patients using Mepentol were less likely to develop pressure ulcers for any time period, particularly after day 20.	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
information given by group. Data were excluded from the analysis. **Statistical analysis:** Relative risk, predictable fraction, number needed to treat were estimated. Chi squared test to determine differences in between the groups Survival analysis, using Kaplan-Meier (log rank) test and Cox proportional hazards model to study the effects of treatment over an extended period and the effect on other variables. **Baseline differences:** No significant differences **Study power/sample size:** Powered for 188 patients in each group (based on results of other studies) with a loss of 10% expected. This was achieved	**Dropouts:** unclear **Age:** 84.18 +/- 9.74 **Gender (m/f):** 41/123 **Other relevant patient characteristics:** PU at inclusion: 40/164 No of active pressure ulcers: 0.76 +/- 1.00 Score on Braden Scale: 12.44+/-2.60 Use of barrier products: 99/164 **Group 2** **Randomised N:** unclear **Completed N:** 167 **Dropouts:** unclear **Age:** 83.64+/- 7.37 **Gender (m/f):** 47/120 **Other relevant patient characteristics:** PU at inclusion: 36/167 No of active pressure ulcers: 0.91 +/- 1.01 Score on Braden Scale:				patients who developed pressure ulcers during the study continued with the study and/or what treatment they had. **Additional outcomes:** Cox proportional hazard regression model sound the following variables were significant: Gender, frequency of night-time patient repositioning and the use of barrier products. The relative risk of treatment did not alter after adjusting for the above variables. **Notes:** None

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: 13 different institutions (mainly residential care and some hospitals) all in Spain. **Length of study:** 30 days **Assessment of PUs:** Unclear. Study does not specify a scale for measuring the outcome nor the inter-rater reliability between assessors. **Classification of PUs:** not reported. **Multiple ulcers:** N/A	12.35+/- 2.63 Use of barrier products: 97/167 **Inclusion criteria:** Patients with a medium, high or very high risk of developing pressure ulcers (PU) (Braden scale). Patients able to participate for 30 days. **Exclusion criteria:** Terminally ill or receiving chemotherapy. Had more than 3 pressure ulcers. Were allergic to hyperoxygenated fatty acids or topical fatty products. Had peripheral vascular disease. **Other baseline characteristics recorded:** Other factors evaluated included: use of special support surface to manage pressure, use of local management pressure system, administration of vasosuppressor drugs,				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Administration of anti-inflammatory drugs, diabetes, hours spent lying down/semi recumbent, hours spent sitting, frequency of postural changes, frequency of postural night changes, systolic arterial pressure, diastolic arterial pressure				

Table 71: Cooper 2001[55]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cooper 2001 **Title:** Full Comparison of two skin care regimes for incontinence **Journal:** British Journal of Nursing, 2001, 10(6), S6-S20 **Type of study:** RCT **Sequence generation:** Unclear. First 11 subjects were randomised on an	**Patient group:** Any patient suffering incontinence **All patients** **Randomised N:** 93 **Completed N:** 87 **Drop-outs:** 6 (see results for different groups below)	**Group 1:** Clinisan foam cleanser combining emollients (liquid parafin, Isopropyl mistrate, alkoxylated cetyl alcohol), antibacterial agents (Triclosan) and dimethicone silicone **Group 2:** Standard hospital soap (pH 9.5-10.5) Both groups: No further details on procedures were detailed	**Outcome 1:** Changes in skin integrity at 14 days (for those with healthy skin initially) using Stirling Pressure Sore Severity Scale	**Group 1:** 6/33 **Group 2:** 16/33 **Relative risk:** 0.38 **95% CI:** (0.17-0.84) **P value:** 0.02	**Funding:** Venture Healthcare (now Vernacare) manufacturers of the intervention. **Limitations:** The change in randomisation strategy half-way through the study could have affected the results.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
individual basis. Following participants were recruited on a ward or floor basis to simplify the trial. Randomisation details not provided **Allocation concealment:** First 11 participants: unmarked envelopes Subsequent participants: no information **Blinding:** Interventions were in different forms (foam vs. standard soap) so neither participants nor caregivers were blinded. Photographs taken for assessment were assessed blindly. **Addressing incomplete outcome data:** provides details of how many randomised did not complete study with reasons by group. Data were excluded from the analysis. **Statistical analysis:** Not	**Group 1** **Randomised N:** 44 **Completed N:** 41 **Dropouts:** 3 - wrong treatment (n=2), blistering unrelated to the trial (=1) **Age:** Median 85 (IQR: 73.5, 86.5) **Gender (m/f):** 22/27 **Other relevant patient characteristics:** number with healthy skin at the start of the trial: 33 **Group 2** **Randomised N:** 49 **Completed N:** 46 **Dropouts:** 3 – non-compliance (n=2), transfer (n=1) **Age:** median 85 (IQR: 79.8-89.3) **Gender (m/f):** 9/35				**Additional outcomes:** changes in mobility and changes in patients' type of incontinence. **Notes:** Results for patients with damaged skin at the start of the trial were not included.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
explicitly stated. Proportions of patients with the outcome were detailed along with comparison statistics but no details on tests used. **Baseline differences:** The baseline characteristics of patients with healthy skin were not provided separately. There were differences in the gender and length of stay of patients at baseline, but authors conclude that this is likely to be due to the randomisation by ward/floor with one of the wards being newly opened. There were also differences in the use of incontinence aids again, probably due to randomisation by ward. Authors explored this and concluded it did not impact results	**Other relevant patient characteristics:** number with healthy skin at the start of the trial: 33 **Inclusion criteria:** : All patients suffering from incontinence (all patterns of incontinence were included) **Exclusion criteria:** None were mentioned.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: No sample size calculation reported. **Setting:** 5 different sites providing long-term care for elderly or dependent patients in Scotland. **Length of study:** 14 days **Assessment of PUs:** **Classification of PUs:** Stirling Pressure Sore Severity Scale **Multiple ulcers:** N/A					

Table 72: Green 1974[87]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Green, 1974 **Title:** Prophylaxis of Pressure Sores Using a New Lotion Journal**:** Modern Geriatrics, 376-384 **Type of study:** RCT **Sequence generation:** Not reported in paper **Allocation concealment:** Not reported in paper **Blinding:** Paper is not explicit on how blinding was conducted, except for stating that the trial was double blinded and that the preparations were put into the same type of bottle and were similar in appearance and texture. **Addressing incomplete outcome data:** Authors	**Patient group:** Patients admitted to geriatric department judged to be at clinical risk of developing pressure sores by a clinical score of 14 or less (criteria given in paper) **All patients** **Randomised N:** 354 **Completed N:** 167 **Drop-outs:** excluded before trial started as scores were too high or they had pressure ulcers (n=35), died (n=60), transferred (n=11), clinical score rose i.e. no longer at risk (n=52), developed necrotic pressure sores (n=21) **Age of those completing trial:** 81.5 **Gender of those**	**Group 1:** Lotion containing 'active' ingredients of Hexachlorophane, Saturated hydrocarbons – Squalene (Cosbiol) and Glyoxyle diuride (Allantoin). **Group 2:** Inert 'oil in water' lotion Both groups Inspected two-hourly, turned and changed if wet or soiled. They were washed with water and soap and lotion reapplied after every cleansing. In the absence of cleansing required by incontinence, routine washing and re-application of lotion was carried out six-hourly. No chlorhexidine containing soap was used and all soap used for cleansing was washed off with water before lotion was applied. No topical silicone-containing preparations were used.	**Outcome 1:** Skin deterioration (Erythema and sores)	**Group 1:** 34/141 **Group 2:** 47/178 **Relative risk:** 0.91 **95% CI:** (0.62-1.34) **P value:** Not significant	**Funding:** Dermalex Co Ltd. Who supplied both 'active' and placebo lotions. **Limitations:** Poorly reported study with regards to methodology. **Additional outcomes:** For all patients results for whether the skin condition had deteriorated, was constant or had improved during the trial were given. **Notes:** Poorly reported paper. Outcomes 'skin deterioration'
			Outcome 2: Skin deterioration (Erythema and sores)	**Group 1:** 14/141 **Group 2:** 32/178 **Relative risk:** 0.57 **95% CI:** (0.32-1.03) **P value:** Not significant	
			Outcome 3:	**Group 1:** 9.8 days **Group 2:** 8.7 days No standard deviations given and so not possible to complete comparative analysis	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
gave details for all patients in the trial but analysis of outcomes is only completed for those completing the 3 week trial (47%) **Statistical analysis:** No details provided. **Baseline differences:** Not explicit in paper. Paper reports: *The original randomly distributed dispensing of the two creams had not be disturbed by the exclusions during the trial period as judged by: age , sex, build, month of admission, incontinence, general health, activity and mobility on admission, site of sore, type of bed used and use of incontinence pads'* **Study power/sample size:** No sample size calculation completed. **Setting:** Geriatric departments at 6 hospitals in London.	**completing trial(m/f):** 40/127 **Group 1** **Randomised N:** Unclear from paper **Completed N:** 76 **Dropouts:** died (n=27), clinical score rose i.e. no longer at risk (n=22), developed necrotic pressure sores (n=8) **Other relevant patient characteristics:** none given in paper **Group 2** **Randomised N:** unclear from paper **Completed N:** 91 **Dropouts:** died (n=33), transferred (n=11),clinical score rose i.e. no longer at risk (n=30), developed necrotic pressure sores (n=13)				based on the results of those deteriorating but completing the trial and those who were removed from the trial due to the patient developing sores. Although not mentioned in the paper it is believed the active preparation goes under the trade name 'Dermalex'. See Van der Cammen 1987

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 3 times per week for 3 weeks **Assessment of PUs:** recorded by research nurses using a 5 point scale **Classification of PUs:** not reported. **Multiple ulcers:** N/A	**Other relevant patient characteristics:** none given in paper **Inclusion criteria:** Admission to one of 6 geriatric departments with a clinical score (see paper for scoring system) of 14 or less. (range from 5 -20 [least affected]). Skin erythema did **not** preclude inclusion **Exclusion criteria:** low clinical scores and pressure sores present on admission. Died within 48 hours of initial assessment				

Table 73: Smith 1985[209]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Smith 1985 **Title:** A double blind trial of silocone barrier cream in the prevention of pressure sores in elderly patients Journal**:** Journal of Clinical Experimental Gerontology 7(4): 337-346 **Type of study:** RCT **Sequence generation:** Unclear, paper reports patients were 'randomly allocated' **Allocation concealment:** Not mentioned in paper **Blinding:** Unclear but paper states that the placebo ointment had been suitably scented so that it was indistinguishable from	**Patient group:** Patients with intact skin at one of the 6 participating continuing care institutions. **All patients** **Randomised N:** 258 **Completed N:** 203 **Drop-outs:** 55 (see below for details) **Group 1** **Randomised N:** 129 **Completed N:** 104 **Dropouts:** 25 – redness (n=3), shingles (n=1), deaths (n=21) **Age:** 82 (range: 63-98) **Gender (m/f):** 25/104 **Other relevant patient**	**Group 1:** Conotrane (combination of a silicone cream – 20% dimethicone 350, and a broad spectrum antiseptic – 0.05% hydrargaphen (phenylmercury-dinaphthylmethane-disulphonate) **Group 2:** Placebo (Unguentum) Both groups: All other topical applications were discontinued. The skin was to be washed when required with water and dried thoroughly before applying the ointment. No control was made over the amounts or frequency of application of the creams	**Outcome 1:** Incidence of pressure ulcers (any grade)	**Group 1:** 35/129 **Group 2:** 47/129 **Relative risk:** 0.74 **95% CI:** 0.52-1.07 **P value:** Not significant	**Funding:** W.B Pharmaceuticals (manufacturers of Conotrane) **Limitations:** Poorly reported methodology. **Additional outcomes:** change in continence. **Notes:** Outcome 4 (patient acceptability) was poorly reported as it only records patient satisfaction for those withdrawn from study and not those who were unhappy with treatment but who persisted.
			Outcome 2: Incidence of pressure ulcers (Grade III)	**Group 1:** 5/129 **Group 2:** 4/129 **Relative risk:** 1.25 **95% CI:** 0.34-4.55 **P value:** Not significant	
			Outcome 3: Incidence of pressure ulcers (Grade IV)	**Group 1:** 0/129 **Group 2:** 1/129 **Relative risk:** 0.33 **95% CI:** 0.01-8.11 **P value:** Not significant	
			Outcome 4: Patient acceptability (number who found it	**Group 1:** 4/129 **Group 2:** 3/129 **Relative risk:** 0.75	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
the active preparation, implying patients and healthcare providers were blinded. **Addressing incomplete outcome data:** Authors included all patients in the analysis using the last available data for the patients in the final analysis (i.e. this may underestimate the rate of pressure ulcers) **Statistical analysis:** Chi squared tests with Yates' correction. **Baseline differences:** There was a larger proportion of placebo group who were continent of urine at the start of the trial (19% active group vs. 29% placebo group)and also a larger proportion of placebo group who were continent of faeces at the start of the trial (29% active group vs. 42% placebo group). This did	**characteristics:** urinary continence: 22 Faecal continence: 37 **Group 2** **Randomised N:** 129 **Completed N:** 99 **Dropouts:** 30 – redness (n=1), rash (n=1), non-compliance (n=1), transfer (n=2), death (n=25) **Age:** 83 (range: 69-102) **Gender (m/f):** 23/106 **Other relevant patient characteristics:** urinary continence: 34 Faecal continence: 53 **Inclusion criteria:** Patients with intact skin at one of the 6 participating continuing care		unacceptable)	**95% CI:** 0.30-5.84 **P value:** Not significant	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not reach statistical significance. No other baseline characteristics were included. **Study power/sample size:** No power calculation completed in the paper. **Setting:** patients in one of 6 continuing care facility in Scotland. **Length of study:** patients were assessed every 3rd week for 24 weeks. **Assessment of PUs:** Pressure areas were inspected by a research nurse a **Classification of PUs:** Barbarel scale **Multiple ulcers:** N/A	institutions. **Exclusion criteria:** no criteria given.				

Table 74: Van der Cammen 1987[232]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Van Der Cammen 1987 **Title:** Prevention of pressure sores. A comparison of new and old pressure sore treatments. **Journal:** British Journal of Clinical Practice; 41 (11) **Type of study:** RCT **Sequence generation:** Not reported **Allocation concealment:** Not reported **Blinding:** None reported **Addressing incomplete outcome data:** Data from patients withdrawn from study were not included. **Statistical analysis:** Statistical tests not given in the paper.	**Patient group:** chairbound patients **All patients** **Randomised N:** 120 **Completed N:** 94 **Drop-outs:** 16; Reasons for withdrawal provided but not given per treatment group. Death (n=8), discharged (n=6), transferred (n=1), wet sore developed (n=1) **Group 1- Prevasore** **Randomised N:** 60 **Completed N:** 54 **Dropouts:** 6 **Age:** 82.2 (range: 53-98) **Gender (m/f):** 14/40 **Other relevant patient characteristics:** Condition of skin: 0.5 (range: 0-2) Mean risk Norton Score: 11.4 (range: 8-14) **Group 2 - Dermalex** **Randomised N:** 60 **Completed N:** 50 **Dropouts:** 10 **Age:** 82.9 (range: 64-97)	**Group 1 (Prevasore):** active ingredients through to be hexyl nicotinate, zinc stearate, isopropyl myristate, Dimethicone 350, cetrimide and glycerol. **Group 2 (Dermalex):** lotion containing hexachlorophene squalene (Cosbiol) and allantoin. Both groups: Buttocks and sacral areas were washed and dried and then appropriate lotion applied at least twice daily and after changing, if wet or soiled. Existing routine procedures to prevent pressure sores were continued. The only topical application used was the lotion being tested, and no oral vitamin C or zinc supplements were given.	**Outcome 1:** any skin deterioration (converted from percentages)	**Group 1:** 7/54 **Group 2:** 11/50 **Relative risk:** 0.59 **95% CI:** 0.25-1.40 **P value:** Not significant	**Funding:** Not mentioned but one of the authors was an employee at the manufacturers of Dermalex. **Limitations:** Poorly reported study with little methodological information. No details on randomisation, allocation concealment or blinding. **Additional outcomes:** Norton scores at 1,2 and 3 weeks. **Notes:** None
			Outcome 2: blistering (superficial localised [4 on scale] or deep localised or extensive superficial blistering [5 on scale]	**Group 1:** 0/54 **Group 2:** 3/50 **Relative risk:** 0.13 **95% CI:** 0.01-2.50 **P value:** Not significant	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: No differences in age, gender or initial skin condition. **Study power/sample size:** No details provided in the paper. **Setting:** Geriatric wards in UK hospital. **Length of study:** treatment for 3 weeks. Assessment was weekly for 3 weeks. **Assessment of PUs:** Pressure ulcers measured by research nurse **Classification of PUs:** categorised on a 6 point scale ranging from 0 – normal to 5-deep localised or extensive blistering. **Multiple ulcers:** N/A	**Gender (m/f):** 13/37 **Other relevant patient characteristics:** Condition of skin: 0.5 (range: 0-3) Mean risk Norton Score: 11.5 (range: 9-16) **Inclusion criteria:** Patients scoring between 5 and 14 on the clinical-at-risk score (Norton Score) i.e. predisposed to pressure sores. **Exclusion criteria:** Patients with existing pressure sores were excluded. Other contraindications to entering patients into the study were severe or terminal illness and a likely period of stay in the ward of less than 3 weeks. **Withdrawal:** Patient was withdrawn from the trial if the Norton score rose to more than 17.				

Table 75: Verdu 2012[239]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Verdu, 2012 **Title:** IPARZINE-SKR study: randomized, double-blind clinical trial of a new topical product versus placebo to prevent pressure ulcers **Journal:** International Wound Journal, 9: 557-565 **Type of study:** RCT **Sequence generation:** Randomisation code generated with random numbers by SPSS software package. **Allocation concealment:** Randomised sealed envelopes provided to the sites where the next sequential subject number was picked. **Blinding:** good blinding of patients, clinical practice professionals,	**Patient group:** patients presenting medium, high or very high risk of Pressure Ulcer (PU) development according to the Braden scale (scoring 15 points or lower) without PU at the moment of inclusion and receiving treatment at hospitals or socio-sanitary centres **All patients** **Randomised N:** 194 **Completed N:** 194 **Drop-outs: 0** **Group 1** **Randomised N:** 99 **Completed N:** 99 **Dropouts:** 0 **Age:** 78.16+/-13.85 (Range: 39-101)	**Group 1:** IPARZINE-4A-SKR cream with Iparzine-4A, L-Serine and vegetable oils **Group 2:** Placebo cream Both groups: Application to sacrum, trochanters and heels every 12 hours. The necessary amount of product was administered on each of the application areas and administered with gentle massage until absorbed Other PU prevention methods were also completed and are listed in the full paper	**Outcome 1:** Incidence of category 1 pressure ulcers (non blanching erythema)	**Group 1:** 6/99 **Group 2:** 7/95 **Relative risk:** 0.82 **95% CI:** 0.29-2.36 **P value:** Not significant	**Funding:** Sergio Juan Jordan Foundation for the study and research of chronic wounds and INIBSA laboratorial (manufacturer?) **Limitations:** Well conducted study but underpowered to detect a difference. **Additional outcomes:** none **Notes:** Very low incidence rates compared with other studies. No details on which scale PUs were assessed or their severity It was intended to measure the time to ulcer

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
local researchers and the analysts. **Addressing incomplete outcome data:** Intention to treat analysis was completed. **Statistical analysis:** z-test for difference between two independent proportions. Survival analysis according to Kaplan-Meier (log-rank test) and Cox proportional hazards risk model regression was used. The hypothesis of proportionality of risk was checked with a term in the time interaction model. **Baseline differences:** No differences in baseline characteristics were reported **Study power/sample size:** Sample size calculation was completed (n=239 for each group). Study failed	**Gender (%f):** 61.2% **Other relevant patient characteristics:** Pressure ulcer risk (Braden scale): 12.28 +/- 1.80 Repositioning (where carried out): 4.43 hours **Group 2** **Randomised N:** 95 **Completed N:** 95 **Dropouts:** 0 **Age:** 78.51+/-13.25 (Range: 39-101) **Gender (%f):** 62.1% **Other relevant patient characteristics:** Pressure ulcer risk (Braden scale): 12.65 +/- 1.82 Repositioning (where carried out): 4.66 hours				development but the authors did this but found no significant difference (no further details)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
to reach the required sample size and incidence of pressure ulcers was lower than expected so study is underpowered to detect a difference. **Setting:** 8 hospital and socio-sanitary units in Spain **Length of study:** treatment for a maximum of 2 weeks or until withdrawn. Daily pressure ulcer assessment. **Assessment of PUs:** blind assessment of pressure ulcers. **Classification of PUs:** not reported **Multiple ulcers:** N/A	**Exclusion criteria:** terminally ill patients, patients with active PUs or peripheral vasculopathy, history of allergies to components of the products, patients receiving ongoing treatment with vasopressor or chemotherapy agents, those who were participating in a clinical study or who had participated in one in the past month. **Withdrawal reasons:** death, discharge, transfer, developed a category 1 pressure ulcer. In these cases the last assessment was used.				

I.1.8 Information for patients and carers

Table 76: Akkuzu 2009[6]

Study	**Evaluation by patients and caregivers of the effectiveness of a brochure developed to prevent pressure ulcers.** Journal **of wound, ostomy, and continence nursing: 36: 610-615. Akkuzu G, Arslantas S, Kosker SB, and Sen S**	
Aim	To evaluate the opinions and recommendations of patients at moderate to high risk for pressure ulceration and their caregivers about discharge education and an educational brochure about pressure ulcer prevention	
Population	• 33 hospital patients at moderate or high risk of pressure ulcer and their 33 caregivers; mean age 68 years (range 18-78 years); 54.5% women; 60.5% ≥65 years; 18% had a history of at least 1 pressure ulcer; high risk (Braden score ≤12 points) 39.4%, average risk (Braden score 13 or 14 points) 60.6%	
Setting	Patients admitted to Baskent University Ankara Hospital's medical, surgical, gynaecology, gynaecological oncology, neurology, cardiovascular, general surgery and urology units over a 1-year period	
Methods	• The researchers provided a verbal educational intervention for patients and care providers and gave participants the educational brochure; patients and care providers rated the language level, effectiveness and usefulness of the knowledge in the pamphlet. • Questionnaire on demographic and clinical data and opinions about educational brochure • Both patients and caregivers were allowed to provide specific recommendations about the educational intervention.	
Themes with findings	Patient and caregiver feedback about contents of education	60% or more of respondents found the language used, comprehensiveness of information, adequacy of information, learning environment, clarity of information and usability of information adequate Most of the rest found it partially adequate with a small minority reporting these factors as inadequate
	Patient and caregiver feedback about the written brochure	66% or more of respondents found the language used, information, adequacy of information and beneficial status of information adequate; over 50% of respondents rated the usefulness of information adequate. Most of the rest found it partially adequate with a small minority reporting these factors as inadequate.
		Patients with a lower level of education were less likely to rate the language used in the brochure as adequate
		Five caregivers opined that the number of illustrations in the brochure was inadequate
		Three patients recommended that the pictures should be presented in colour
		One caregiver stated that more information on how to get access to air mattresses and beds was needed.
		One caregiver said the font size was too small.
		Five patients recommended the brochure should be printed in booklet format

Study	**Evaluation by patients and caregivers of the effectiveness of a brochure developed to prevent pressure ulcers.** Journal **of wound, ostomy, and continence nursing: 36: 610-615. Akkuzu G, Arslantas S, Kosker SB, and Sen S**	
		Two patients and one caregiver said the information in the brochure was too complex for comprehension
	Specific recommendations	A minority of caregivers (6.1%) wanted more information about air mattresses but no patients desired additional information
		Two caregivers desired more comprehensive information about pressure ulcers
		One patients and two caregivers stated that content was presented too rapidly
Limitations	Only open questions on questionnaire - no triangulation Little information on analysis so rigour and reliability unclear Data not 'rich': no quotations to illustrate themes	

Table 77: Baharestani 1994[17]

Study	**The lived experience of wives caring for their frail homebound elderly husbands with pressure ulcers: a phenomenological investigation advances in Wound Care 1994; 7 (3): 40-52. Baharestani MM.**		
Aim	To describe and gain understanding of the experience of wives caring for their frail, homebound, elderly husbands with pressure ulcers		
Population	• Six elderly Caucasian women (age 60 or older for inclusion; actual ages ranged from 69 to 82) who provided care at home for their elderly (age 65 or older for inclusion; actual ages ranged from 73 to 88) husbands who had 1 or more stage III or IV pressure ulcers (essentially bed-ridden or chair-fast, requiring complete care with respect to activities of daily living); wives received not more than 20 hours of home health aide assistance per week; duration of care 2-10 years		
Setting	Caregivers' homes, New York		
Methods	• Phenomenological method • Face to face interviews; audiotaped; field notes taken • Transcribed verbatim, data coded, analysed • Validity check by 5 nurses and 5 wife caregivers		
Themes with findings	Difficult caregiving	Physical	Increasing fatigue; difficulty turning, toileting and transferring husbands from bed to chair

Study	The lived experience of wives caring for their frail homebound elderly husbands with pressure ulcers: a phenomenological investigation advances in Wound Care 1994; 7 (3): 40-52. Baharestani MM.		
		Emotional	Difficulty seeing husbands bedridden and becoming more debilitated; depression
		Safety	Falls out of bed for husbands; back problems for wives
		Financial	Financial inability to pay for home health aide assistance which put wives' own health in jeopardy; frustration and confusion regarding Medicare system of reimbursement; Medicare inadequately reimburses for home health aide assistance and does not cover nutritional supplements or dressing supplies needed for pressure ulcers; barely managing on Social Security and pension
	Frailty of caregiver	Physical limitations and multiple medical problems	
	Limited socialisation	Only respite was when husbands hospitalised Keeping in touch with others by phone	
	Limited social support systems	Home health aide assistance very expensive (or used untrained paid assistants as cheaper); inconsistent staff; infrequently met caregiver's needs Adult children not involved Extended family assistance very limited Neighbour/maintenance man called in to help if husband fell out of bed Healthcare clinicians did not understand/were not sensitive to needs; nurses and doctors pushed nursing home placement, ignoring wishes of caregiver	
	Limited caregiving knowledge	Each wife caregiver had learned by experience 5 out of 6 did not know how to place a bedpan or to turn their husbands in bed or transfer them to a chair safely Sought advice from neighbours, dermatologists, doctors on call – husbands inadequately examined; wives told to use various topical agents – educational/referral opportunities missed by physicians contacted; not until husbands became septic and hospitalised that education would begin and community referrals made	

Study	The lived experience of wives caring for their frail homebound elderly husbands with pressure ulcers: a phenomenological investigation advances in Wound Care 1994; 7 (3): 40-52. Baharestani MM.	
	Fear regarding the future	None of respondents able to afford 24 hour assistance Nursing home placement regarded negatively Future uncertain, loss of control regarding welfare of themselves and the husbands
	Symbolic meaning of the pressure ulcer	Bedsores thought to be a normal or expected occurrence among the bedbound Perceived ulcers and a symbol of poor circulation; husband's body breaking down Caregivers blamed by hospital staff for having provided poor care – perceptions of normalcy turned to guilt/inadequacy – reported not knowing husband should be turned every 2 hours; thought sore would heal up
Limitations	Limited number of informants – unclear if data saturation reached	

Table 78: Basta 1991[23]

Study	Pressure sore prevention education with the spinal cord injured. Rehabilitation nursing: 1991; 16: 6-8 Basta SM	
Aim	To explore and describe the various formal and informal pressure sore prevention educational encounters (interaction between client and another person/persons perceived by researcher or client or both as an experience from which the client could learn some aspect of preventive skin care) that occurred with an adolescent spinal cord injured client during his initial admission in an inpatient rehabilitation facility and the client's perceptions of these educational encounters	
Population	• 18 year old single white male admitted for initial rehabilitation following traumatic spinal cord injury; in first week of rehabilitation programme at start of study; T8 paraplegia; sensory and motor impairments; no skin lesions beyond the epidermal layer on admission; no significant learning impairments	
Setting	Inpatient rehabilitation facility	
Methods	• Qualitative single case study: observations (field notes; total duration 33 hours) and client chart review over 9 weeks; at end of study, interview with client on his views of education received and his perceptions of his knowledge and abilities to perform preventive skin care and the measures that were most important for him to perform after discharge (audiotaped and transcribed verbatim). • Codes, charts (to concurrently view the occurrence of educational encounters and significant milestones in rehabilitation) and matrices used to analyse and summarise data	
Themes with findings	Sources of pressure	Medical: "The doctors just talk about it once, where the nurses usually just bug you about it all the time."
		Nursing:

Study	Pressure sore prevention education with the spinal cord injured. Rehabilitation nursing: 1991; 16: 6-8 Basta SM	
	sore prevention education	Nurses in acute care mentioned that he had to roll on his side or he could get "sores" – client did not understand that could mean a "gaping hole in the skin" The primary rehabilitation nurse was the first person to really teach him anything about skin care and pressure sore prevention after his injury. Nurses used the greatest variety of teaching/learning strategies, addressed more content areas and spent the most time on education. Nurses were the only professionals to use planned formal skin care instruction (plus numerous informal sessions including periodic verbal reminders to do lift ups or switch positions in bed) and routine skin care related actions such as skin inspections and back rubs
		Occupational therapy: No data presented
		Other clients: No data presented
		Physical therapy: No data presented
	Teaching strategies	Lecture/ explanation: one-to-one or formal class basis
		Printed handouts
		Audiovisual aids: slides, overhead transparencies, chalkboard
		Demonstrations
		Provision of preventive skin care equipment
		Nursing actions including skin care treatments (e.g. back rubs, turning every 2-4 hours in bed at night) and monitoring of client's skin status; preferred action-oriented learning experiences over lectures/discussions
		"Live client" examples
		Stories about other clients' past experiences
	Types of content addressed	Anatomy and physiology
		Risk factors
		Susceptible skin areas/pressure points
		Detection of early warning signs of skin breakdown
		Preventive actions/ measures

Study	Pressure sore prevention education with the spinal cord injured. Rehabilitation nursing: 1991; 16: 6-8 Basta SM	
		Consequences of skin care neglect
	Subject's perceptions of pressure sore prevention education and self-care	Perception of routine skin-related nursing measures (e.g. back rubs, turning every 2-4 hours in bed at night) as learning experiences
		Remarks about pressure sore prevention-related measures: "just little stuff", "just easy stuff you just gotta remember to do"
		Admission that because he hadn't had any skin problems during rehabilitation, he didn't think he had to worry about performing skin care measures during the day (as opposed to at night when he got into bed) Night time measures were perceived as most important Client equated degree of performance difficulty and extent to which nurses themselves performed measures with the degree of importance of carrying out specific pressure sore prevention measures. But nurses need to clarify which measures are of higher priority when educating them. The nursing staff's consistent performance of particular skin care measures drove the point home to him that these manoeuvres were important for him to carry out. All staff need to b consistent in reinforcing the client's performance of pressure sore prevention measures e.g. wheelchair pressure relief measures, skin inspection, good transfer techniques.
Limitations	Reliability of methods unclear - one researcher only Ethical considerations not stated	

Table 79: Gorecki 2009[84]

Study	**Impact of pressure ulcers on quality of life in older patients: A systematic review: Clinical investigations.** Journal **of the American Geriatrics Society: 2009; 57: 1175-1183. Gorecki C, Brown JM, Nelson EA, Briggs M, Schoonhoven L, Dealey C, Defloor T, and Nixon J**
Aim	To identify the impact of pressure ulcers and pressure ulcer interventions on health-related quality of life
Population	• 31 studies including 2,463 adult participants at least some of whom had existing pressure ulcers grade 1 or higher; age range 17-96 years. 10 were qualitative studies
Setting	Acute, community and long-term caresettings across Europe, the US, Asia and Australia
Methods	• Systematic review and meta-analysis of primary research reporting on the impact of pressure ulcers and pressure ulcer interventions on health-related quality of life according to direct patient reports • 13 databases searched plus hand-searching, cross-referencing, contact with experts and online search, no language, date or methodology restrictions

Study	Impact of pressure ulcers on quality of life in older patients: A systematic review: Clinical investigations. Journal of the American Geriatrics Society: 2009; 57: 1175-1183. Gorecki C, Brown JM, Nelson EA, Briggs M, Schoonhoven L, Dealey C, Defloor T, and Nixon J		
	• Qualitative studies included if there was evidence of at least 6 of the 10 quality statements on the quality appraisal form of the Qualitative assessment and Review Instrument (QARI) including two critical methodological aspects: congruity between i) research methodology and methods used to collect data, and ii) the research methodology and the representation and analysis of the data. • Content analysis to generate categories and themes		
Themes with findings	11 health-related quality of life themes	Physical impact/ limitations	Physical restrictions (e.g. confined to bed or chair for treatment of pressure ulcers), lifestyle changes (to incorporate skin care and pressure ulcer treatment), adapt living arrangements (e.g. having to move to more suitable accommodation, adapting house for wheelchair if heel ulcers made patient wheelchair-dependent)
		Social impact	Restricted social life (including due to hospitalisation), social isolation and loss of interest (e.g. due to pain, odorous exudates), impact on personal life (loss of intimacy)
		Psychological effect	Develop use of coping mechanisms (including avoiding thinking about it), support and help from family and friends, changes to body image and self-concept ('ugly', 'dirty', feeling useless and inadequate), desire and struggle for control and independence (wanting to be involved in decision-making and wanting self-care), emotional problems (impact on mental health and psychological well-being: initially shocked by pressure ulcers, later feelings of dislike and hatred, low mood, anger, frustration, anxiety, depression, hopelessness, powerlessness), preoccupation with pressure ulcer healing and anticipation of pain, acceptance of pressure ulcers and their situation
		Impact of pressure ulcer symptoms	Pain: intense, never-ending, frustrating, annoying, inconvenient, seen as a punishment, disturbed sleep Wound: odour led to poor appetite, embarrassment and distress; exudates led to social isolation and immobility Repositioning could be uncomfortable
		Impact on general health and consequences	Complications (infection, delayed healing) led to hospitalisation and delayed/restricted treatment options for other medical conditions Patient handling difficult
		Impact on others	Pressure ulcers causing other people work and worry (skin inspection, treatment, assistance with ADLs); dependence on others, fear of being a burden
		Financial impact	Poor living circumstances, poor work opportunities, medical and treatment costs, loss of income
		Need for versus effect of	Dressings and pressure-relieving interventions – issues of comfort and whether interventions allowed independence,

Study	Impact of pressure ulcers on quality of life in older patients: A systematic review: Clinical investigations. Journal of the American Geriatrics Society: 2009; 57: 1175-1183. Gorecki C, Brown JM, Nelson EA, Briggs M, Schoonhoven L, Dealey C, Defloor T, and Nixon J		
		interventions	movement, whether it disturbed sleep and whether patient felt safe using equipment. Effective interventions (wound healing/symptom relief/allowing independence and return to work) improved health-related quality of life. Lack of resources leading to ineffective wound care Surgical interventions that restricted activity and mobility contributed to poorer health-related quality of life and frustration. Patients dependent on healthcare professionals for wound care and ADLs; time spent waiting for treatments was an additional burden, disrupting ADLs and social activities. Hospitalisation made patients feel captive, disconnected from the world, confined, alienated and punished. Incongruence between patients' needs (e.g. sleep through the night) and nursing needs (e.g. turning the patient at night); patients feeling needs ignored (e.g. when reporting pain during dressing changes or friction during use of hoists)
		Healthcare professional-client relationships	Positive factors: Skills and expertise of healthcare professional instilled hope and contributed to adherence to treatment; holistic interaction, communication, teaching patients self-care, dialogue and mutual decision-making, positive friendly attitude. Negative aspects: staff having a poor attitude, patients felt blamed for pressure ulcer, felt a nuisance when they asked for help, felt providing healthcare was an effort or a problem for the healthcare professional, failing to draw the curtain during skin inspection or treatment made patients feel exposed and humiliated
		Perceived aetiology	Patients' beliefs about causative factors: some patients blamed themselves (e.g. failure to inspect skin, reduced mobility, not reducing risk factors); some cited intrinsic factors (e.g. incontinence or moisture, inability to move or walk); others extrinsic factors (incompetent healthcare, inadequate use of equipment, delays in noticing or treating patient reports of early signs)
		Need for knowledge	Some patients were aware of risk factors and recognised them as the cause of their pressure ulcers; others lacked knowledge and understanding about pressure ulcer development and prevention. Specifically, patients needed more information about causes, risks, prevention, physiological processes and treatment interventions. Of the patients who demonstrated knowledge of these factors, many had spinal cord injury and had been educated about pressure ulcer risk, or people with previous pressure ulcers.
Limitations	High quality systematic review; no limitations		

Table 80: Jackson 2010[104]

Study	Qualitative study of principles pertaining to lifestyle and pressure ulcer risk in adults with spinal cord injury. Disability & Rehabilitation: 2010; 32: 567-578. Jackson J, Carlson M, Rubayi S, Scott MD, Atkins MS, Blanche EI, Saunders-Newton C, Mielke S, Wolfe MK, and Clark FA		
Aim	To identify overarching principles that explain how daily lifestyle considerations affect pressure ulcer development as perceived by adults with spinal cord injury		
Population	• 19 adults with spinal cord injury and 1 with transverse myelitis, with a history of pressure ulcers; 18 years or older, tetraplegia or paraplegia, at least 1 year post-injury and completion of rehabilitation program, previous treatment at RLANRC for 1 or more pressure ulcers stage 3 or 4, residence within 90 mile radius of downtown Los Angeles • 14 males, 6 females; age range 28 to 77 years		
Setting	Pressure Ulcer Management Clinic at Rancho Los Amigos National Rehabilitation Centre (RLANRC), a leading rehabilitation facility in the US		
Methods	• Qualitative in-depth interviews over an 18-month period (3-23 interviews each participant, ranging from 1-4 hours each interview, monthly or twice-monthly) • Participant observation of daily routines, excursions and therapy sessions • First phase of data collection (4 months): life history, pressure ulcer history, activity patterns, personal strengths and challenges, folk beliefs about development of pressure ulcers, daily routines, environmental facilitators and constraints, social world, pattern of risk • Second phase of data collection (10+ months): explored the manner in which life changes affected daily activities and risk of pressure ulcers; moment-to-moment daily events examined in relation to pressure ulcer risk; interview schedule intensified if relevant unanticipated event occurred (e.g. change of living environment or development of pressure ulcer) • Interviews audiotaped and transcribed verbatim • Thematic analysis (concepts organised into themes) • Narrative analysis (complex and nuanced understanding of the relationship of multiple interconnected lifestyle considerations as they manifest, develop and transform over time in individuals' lives): plot, development of character, crisis moments, transitions in participants' stories; personal activity profile and context; review of the story with the participant • Analytic meetings held between all 6 researchers and meetings with a consumer board of 5 individuals with spinal cord injury		
Themes with findings	8 complexly inter-related daily lifestyle principles that explain pressure ulcer development	Perpetual danger	Threat of a pressure ulcer never subsides – unexpected events (e.g. delays, accidentally sitting on something hard, new shoes, spontaneous outing) can cause ulcers, as can skin changes as the patient ages (e.g. previous methods to prevent ulcers become ineffective due to skin thinning), requiring a change in strategy
		Change/ disruption of routine	Change in carers allows risk of problems Cascade where one problem leads to another (e.g. pressure ulcer in one place leads to redistribution of weight to other areas and second pressure ulcer in the new area of pressure; or moving house leads to change in carers and social isolation, depression, weight gain and pressure ulcers)

Study	Qualitative study of principles pertaining to lifestyle and pressure ulcer risk in adults with spinal cord injury. Disability & Rehabilitation: 2010; 32: 567-578. Jackson J, Carlson M, Rubayi S, Scott MD, Atkins MS, Blanche EI, Saunders-Newton C, Mielke S, Wolfe MK, and Clark FA		
		Decay of prevention behaviours	Performance of preventive behaviours (skin checks, pressure relieving manoeuvres) slowly eroded over time (e.g. due to life distractions, overconfidence, forgetfulness, depression, fatigue, carelessness) but may not be noticed by participant who still thinks they are vigilant. People may require periodic reminders or checks concerning actual prevention practices.
		Lifestyle risk ratio	Some factors always a risk for pressure ulcers (e.g. physical frailty, aging skin, urinary tract infection, lack of adherence to preventive measures, poor nutrition, poor problem solving, unhealthy living environment, unstable attendant care, inadequate finances) while others are a buffer (e.g. solid support system). Other factors could be a help or a hindrance (e.g. engaging in a desired activity could reduce depression but also could increase risk by having to sit for long periods). The balance between risks and buffers is constantly changing.
		Individualisation	Risks are not simply additive in the same way for all individuals but vary between individuals and across time within individuals (e.g. social support may be more meaningful for one person than another or more meaningful at one time than another for a single individual). Some participants individualised their skin care e.g. not relieving pressure every 15 minutes, but taking a half hour break every 4-6 hours
		Simultaneous presence of prevention awareness and motivation	Avoiding pressure ulcers requires prevention awareness (long-term prevention knowledge e.g. need to perform regular pressure reliefs, effective routines, planning, awareness of risk situations in general and short-term attentional considerations e.g. need to perform reliefs in this particular situation just now, the current risk situation) and motivation (commitment to avoid pressure ulcers, sound decision-making) to put practices into action. Initial generalised knowledge about pressure ulcers and prevention techniques in hospital settings during rehabilitation – this could lead to lasting motivational commitment, or the person might only be motivated after they personally experienced a pressure ulcer (see it, smell it, experience the confusion and fear of a pressure ulcer in his own body, experience hospitalisation).
		Lifestyle trade-off	Conflicts between desire to engage in meaningful activities (work/social) and need for rest and caution to prevent pressure ulcers; if people tried to do too much they paid for it with pressure ulcers and extended bed rest so becoming unable to engage in the activities again.
		Access to needed care,	Pressure ulcers can occur in connection with the inability to obtain timely and appropriate services (e.g. delay in

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		services and supports	arrival of equipment, overworked healthcare professionals, language barriers, institutions unequipped or inexperienced in providing care, policies, 'red tape', bureaucracy and gatekeepers to care e.g. Medicare system)
Limitations	Sample included people at high risk of pressure ulcers – may not be generalisable to those with lower risk		

Table 81: King 2008[117]

Study	Preventive skin care beliefs of people with spinal cord injury. Rehabilitation nursing: 2008; 33: 154-162. King RB, Porter SL, and Vertiz KB		
Aim	To identify the skin care beliefs of individuals with spinal cord injury		
Population	• 21 people with spinal cord injury (sampling until data saturation); age 18 or older, with recent or chronic spinal cord injury American Spinal Injury Association classification A, B or C, English-speaking with telephone access, with sensory deficits and using a wheelchair • Mean age 35, range 18-66 years; 81% male; 62% white (including 24% Hispanc), 33% African American and 5% Asian, mean duration of injury 7 years (range 0.08 to 34 years); 4 inpatients with recent injury; 71% had history of one of more pressure ulcers		
Setting	2 free-standing rehabilitation hospitals in the US		
Methods	Semi-structured interviews (face to face or over the phone), recorded and transcribed verbatim Content analysis to develop codes, themes Member checks of themes and codes with 4 participants Memos written during analysis to provide data for decision-making on new codes and themes		
Themes with findings	4 main themes: 1) taking vigilant care	Belief about susceptibility to pressure ulcers	Perception of risk for developing pressure ulcers: most people believed they were at risk; some people believed they were at low risk because they had not yet had a pressure ulcer. Participants internalised information about pressure ulcer susceptibility and severity presented furing acute rehabilitation and retained it for a long time beyond Reducing risk by compensating for lapses in care, taking charge of care, problem solving, adapting or changing lifestyle, eliminating problem, self-discipline, making skin care a high priority, being vigilant and watchful
		Benefits of skin care	Effectiveness/benefits of skin care (e.g. pressure ulcer-free, stay healthy, avoid consequences such as illness and hospitalisation, feel stress-free and good about self, peace of mind, continue activities)
		Self-care motivation	Anything that cues, prompts or motivates participants to perform skin care (e.g. will to stay healthy, fear, avoid consequences of pressure ulcers , family/another person's influence or experience such as burden on caregiver if got a pressure ulcer, learning from own experience, self-love, sensory cues, discipline).

Study	Preventive skin care beliefs of people with spinal cord injury. Rehabilitation nursing: 2008; 33: 154-162. King RB, Porter SL, and Vertiz KB		
			Information given during inpatient rehabilitation motivated people when they returned home.
		Confidence in skin care performance	Confidence in ability to perform or direct skin care and prevent pressure ulcers by being vigilant
		Consequences of a pressure ulcer	Beliefs about severity of consequences for person themselves and family (e.g. medical, financial, employment, lifestyle, loss of time, dependence on others/burden, sickness, hospitalisation, surgery, helplessness, depression); some respondents unsure of impact
		Self-care routines	Description of routines e.g. turning, wheelchair pressure reliefs, constant movement, skin checks, using and checking equipment, lotions, positioning, sit-and-turn tolerance, nutrition, prevention of incontinence, individualised self-care
	2) Taking charge	Benefits of skin care	Effectiveness/benefits of skin care (e.g. pressure ulcer-free, stay healthy, avoid consequences such as illness and hospitalisation, feel stress-free and good about self, peace of mind, continue activities
		Confidence in skin care performance	Confidence in ability to perform or direct skin care, training helpers, using and checking equipment, fitting care into daily life
		Overcoming barriers	e.g. accept need for help with skin care, train help, do what is necessary, use equipment, get a schedule, make skin care a habit, build skin tolerance
		Making healthy decisions	How participants made decisions about skin care
		Taking responsibility for proper skin care	Benefits: staying healthy, avoiding pressure ulcers, leading a more normal life Risks of not taking charge: not adapting care to changing circumstances; performing skin care only when they remembered or when convenient
	3) Maintaining health	Benefits of skin care	Effectiveness/benefits of skin care (e.g. pressure ulcer-free, stay healthy, avoid consequences such as illness and hospitalisation, feel stress-free and good about self, peace of mind, continue activities)
		Decision making about skin care	How participants made decisions about skin care including making it a priority, overcoming hassles and embarrassment (including with support from family members)

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	4) Passing up care	Barriers to care	Cost in energy, time, money; dependence, poor health, fatigue, forgetfulness, inadequate help; embarrassment, hassle, hard to do, socially restrictive, everyday distractions, laziness, discomfort, inadequate lighting for skin checks. Ambivalence towards skin care, need for rigorous routine when faced with other priorities, desire to be free of routines that were a constant reminder of spinal cord injury, tired of being vigilant, inconvenience, interferes with other activities
		Impact of care on life	Need to perform skin care routine gets in the way of other activities (e.g. hard to fit in, reminder of being different) or little impact (e.g. get used to it)
		Self care routines	Description of routines e.g. turning, wheelchair pressure reliefs, constant movement, skin checks, equipment, lotions, positioning, sit-and-turn tolerance, nutrition, prevention of incontinence, individualised self-care
		Misconceptions about care	Erroneous beliefs about aetiology (e.g. not believing that sitting in a wheelchair 12-15 hours a day contributes to pressure ulcers, believing ulcers only occur if you sit on something hard like steps), preventive skin care (checking skin weekly or biweekly sufficient; sceptical about whether skin care routines necessary) or pressure ulcer care
	Other themes	Aetiology, attributions and management of current and prior pressure ulcers	Comments on how and why a pressure ulcer developed
		Advice to others	Suggestions of what rehabilitation nurses can tell patients to help them undertand the need to perform skin care regularly and to motivate them
Limitations	cross-sectional not longitudinal data		

Table 82: Langemo 2000[128]

Study	**The lived experience of having a pressure ulcer: a qualitative analysis. Advances in Skin & Wound Care: 2000; 13: 225-235. Langemo DK, Melland H, Hanson D, Olson B, and Hunter S**		
Aim	To identify themes related to the experience of having a pressure ulcer (what is the lived experience and what meaning is given to this experience?)		
Population	• 8 respondents – 4 with current pressure ulcer (stage IV) and 4 with previous pressure ulcer now healed • 4 respondents had spinal cord injury; 5 had surgical flap reconstruction • 7 men; 1 woman; age range 27 to 52 years		
Setting	Home, hospital or nursing home in the US		
Methods	• Descriptive, qualitative phenomenological study • Unstructured interviews ("Please describe your experience of having a pressure ulcer...share all the thoughts, perceptions and feelings you can recall until you have no more to say about this experience") audiotaped and transcribed verbatim • Field notes of ideas, feelings or responses that emerged during data collection and clarified each interview experience • Content analysis based on phenomenological methodology of themes and meaning • After data analysis, literature reviewed		
Themes with findings	7 themes: 1) perceived aetiology of pressure ulcer	A problem with care received	e.g. lack of or inappropriate equipment, lack of turning
		Patient's own neglect	Neglect of preventive measures, need to take care when transferring
	2) Life impact and changes	Physical	Difficult to accept mandatory bed rest and immobility – need a lot of patience. Sleep disturbance
		Social	Having to stay in their room all the time even for meals meant being alone, confined, isolated, missing family and friends
		Financial	Desire to work not just accept disability benefits
	3) Psycho-spiritual impact	Body image changes	Due to pressure ulcer itself and reconstructive surgeries Lack of privacy, humiliated
		Struggle with stereotypes	Dislike of term "handicapped"

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		Desire/struggle for control and independence	Need to regain control and independence (self-care, daily schedule) Hard to ask for help Confidence they knew how to take care of themselves
		Spiritual issues	Being touched spiritually by the crisis of spinal cord injury and pressure ulcers – beliefs a lot deeper, faith helped people get through, using experiences to help and teach others
	4) Extreme painfulness	Intensity of pain	Stabbing/burning/stinging pain
		Duration of pain	Pain for the majority of the time
		Analgesic use	Tylenol ineffective; taking morphine and other painkillers Fear of addiction
	5) Need for knowledge and understanding	Knowledge of prevention	Patient should be turned every 20 minutes Warning signs are really important – if you see any form of red spot...you have to get off it Use of correct equipment in good repair Vulnerability to pressure ulcers after a time as a paraplegic Angry at themselves for nit using the knowledge they had Importance of ongoing skin assessment – need to check every day
		Knowledge of physiological processes	Knowledge of healing/debridement
		Lack of knowledge	Ignorance of what caused pressure ulcers or the fact there is such a thing as a pressure ulcer Ignorance until experienced an ulcer

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			Confusion regarding the word 'ulcer' (i.e. different from gastric ulcer)
	6) Need for and effect of numerous stressful treatments	Self-care	Having become proficient in self-care
		Treatment regimens and multiple surgeries	Pressure-reducing mattresses confining and prevented even handling the TV remote Need to build yup tolerance to be able to sit for longer periods Need for absolute bed rest for a while to heal ulcers Inability to do things frustrating
		Complications	Complications could be life-threatening e.g. septicaemia, osteomyelitis, depression, kidney failure
		Length of healing time	Long periods spent in bed or hospitalised to heal ulcers
	7) Grieving process	Denial	e.g. not too bothered about possible amputation
		Depression	feeling of wanting to give up
		Anger	e.g. at unnecessary tube feeding
		Acceptance	Don't let depression into the vocabulary – keep upbeat Other people are a lot worse off – just one of those things
Limitations	Results not reviewed by any respondents		

Table 83: Middleton 2008[144]

Study	Issues and Challenges for Development of a Sustainable Service Model for People With Spinal Cord Injury Living in Rural Regions. Archives of physical medicine and rehabilitation: 2008; 89: 1941-1947. Middleton JW, McCormick M, Engel S, Rutkowski SB, Cameron ID, Harradine P, Johnson JL, and Andrews D	
Aim	To develop and implement a service model for people with spinal cord injury living in rural regions	
Population	• People with spinal cord injury (n=80), caregivers and health professionals (n=277)	
Setting	Regional and remote areas of New South Wales, Australia	
Methods	• Service development, pilot evaluation study: phase 1 included needs analysis to identify existing expertise and key contacts, target groups for education and training, educational requirements and strategies; developing specialised educational resources; providing education to rural health professionals, clients with spinal cord injury and care providers; running multidisciplinary outreach clinics in 4 pilot health regions. Phase 2: network development: focused on investigating a local support model for developing sustainable spinal networks between rural health professionals and care providers and metropolitan specialised spinal cord injury units or services. • Focus group discussions, key informant interviews, postal questionnaires • Results of needs analysis grouped thematically, presented to forum of participants from each rural health region to validate and prioritise recommendations. • Resources developed for identified topic areas • Education sessions presented collaboratively by staff of the spinal units and 2 community organisation • Multidisciplinary outreach clinics reviewed clients with spinal cord injury and also provided a way to reinforce education and provide skills training for rural staff and caregivers	
Themes with findings	Education	Respondents sought information on autonomic dysreflexia, bladder and bowel management, skin management, pain management, sexuality and fertility, aging with spinal cord injury, psychosocial issues, equipment and technology. Most health professionals lacked knowledge and self-confidence in most if not all areas of spinal specific practice
	Effective communication	No further details
	Community re-integration and service coordination	Pressure ulcers reported to have a significant impact on quality of life; proved quite challenging to manage serious skin breakdown in rural areas due to lack of availability of specialised pressure-relieving mattresses; difficulty accessing updated equipment in a timely manner to accommodate pressure ulcer management; and limited capacity for service providers to change care regimes to accommodate bed rest. Limited local infrastructure and health workforce capacity Limited availability of specialised services and expertise

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		Difficulty accessing primary care and general practitioners Limited resources and funding for equipment and housing Large geographic distances Lack of transportation
Limitations	Data analysis not described in detail so unable to assess rigour/reliability	

Table 84: Schubart 2008[199]

Study	Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs. Advances in skin and wound care 2008; 21: 322-329. Schubart JR, Hilgart M, and Lyder C	
Aim	To assess the educational needs of adults with spinal cord injury in the prevention and early detection of pressure ulcers	
Population	• Purposeful sampling strategy to select information-rich cases; maximum heterogeneity sampling based on sex (7 females and 9 males), level (3 paraplegia, 13 tetraplegia) and completeness of injury (8 complete, 8 incomplete), time since injury (<1 year to 33 years) and history of pressure ulcers (10 had had a pressure ulcer; 6 had not) • Redundancy reached after 16 interviews	
Setting	Recruited from Rehabilitation Center and local Paralyzed Veterans of America chapters, USA	
Methods	• Environment needs assessment methodology: prospective, exploratory, descriptive design involving individual interviews with patients and caregivers (family and home health assistants) and experienced spinal cord injury medical professionals. • Interviews audio- or video-recorded, coded • Educational needs identified by examining actual performance of adults with spinal cord injury, knowledge about pressure ulcers and what exemplifies success in preventing pressure ulcers at home. Needs are discrepancies between what was desired (optimals, based on "Pressure ulcer prevention and treatment following spinal cord injury" guideline and 8 spinal cord injury clinicians) and what was actually occurring (actual). Participants questioned about feelings about the topic and its priority in their lives. Authors examined institutional drivers and barriers to success, types of solutions that have been implemented and reasons for their success or failure. Needs were rank ordered and possible strategies (educational objectives) considered for each one.	
Themes with findings	Perception of risk	Awareness of risk varied; those who considered themselves at risk were more likely to have experienced a pressure ulcer or to have had a long rehabilitation hospital period after injury. They could describe basic prevention strategies (e.g. pressure shifts or weight releases, appropriate cushioning and skin checks) and recognised that pressure ulcers are potentially very serious.

Study	Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs. Advances in skin and wound care 2008; 21: 322-329. Schubart JR, Hilgart M, and Lyder C	
		Those who had never experienced a pressure ulcer perceived their risks of developing one to be decreasing over time. Those who did not participate in preventive behaviours tended to believe they were not at risk. Those who had had a pressure ulcer in the past were motivated to avoid pressure ulcers in the future and they reported learning the most about pressure ulcers when they actually had one and were trying to stop it progressing to a more serious stage.
	Education	Education about pressure ulcers varied depending on the length and quality of the participant's care after injury. Generally pressure ulcer education was limited to the initial post-injury care and rehabilitation period. Education for family caregivers was lacking, as was education for some paid caregivers and health care providers. Participants injured more than 20 years ago had longer rehabilitation periods that included education about pressure ulcers. This education tended to be fear-orientated and based on negative examples (e.g. photographs of advanced pressure ulcer wounds). These tactics had lasting effects on the individuals who learned from them.
		Participants did not look for information related to keeping their skin healthy. They reported they had opportunities to learn about pressure ulcers when they were being treated for them, and this was delivered by their health care team and was specific to their wound. Participants agreed on the preferred delivery method: they chose reading materials less frequently than video or internet forms of learning.
		Timing of education was a key theme. Some believed that addressing the topic of pressure ulcers too soon when the patient is in shock or denial was not likely to be effective. Others said that learning about the skin would just happen naturally during the course of rehabilitation. Several were concerned about aging skin and wanted current information.
	Environmental considerations	Issues such as being unable to transfer to a chair, bed or toilet or to safely access needed items interfered with participant's ability to keep the skin healthy
		Difficulty keeping an organised clean home; greater difficulty for those with little family support or inconsistent or unreliable paid help
		Family often played an important role in the person's ability to keep the skin healthy: primary caregivers, supplemental caregivers, or provided emotional and/or financial support Need for caregiver training was a recurrent theme. Equipment plays a major role in patients' lives. Varying views on need for ongoing equipment maintenance and obtaining new equipment. In some cases, misperceptions about cushions and the need for proper fitting, e.g. many did not recognise the

Study	Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs. Advances in skin and wound care 2008; 21: 322-329. Schubart JR, Hilgart M, and Lyder C	
		importance of custom-fitting cushions and were not aware of techniques such as pressure mapping. Most did not replace the cushion until it appeared worn out; few kept a maintenance Journal or performed routine checks.
	Access to care	Access to care beyond acute hospital stay and initial rehabilitation varied. Participants who were proactive and more empowered tended to seek the resources they needed. They maintained and upgraded their equipment. They were more successful in navigating the healthcare system and managing the financial costs of their spinal cord injury. For others, finances were a barrier to obtaining care. Several discontinued therapy when their funding ran out. More often they reported frustration in dealing with primary care physicians who did not have awareness of issues typical to people with spinal cord injury, but they did not change physicians or seek a second opinion. Tended to comply with care recommendations even if they did not agree because they saw no other viable choices. Frustration navigating the health insurance and financial aspects of the health care system. Several reported insurance issues around obtaining new equipment. Challenges finding reliable paid home care. A major theme was that the amount of education and nurses' training was insufficient to care for an adult with spinal cord injury among general certified nursing assistants.
Overall interpretation	Need for adults with spinal cord injury to perceive themselves as at lifelong risk for pressure ulcers and to believe that pressure ulcers are preventable. Keeping skin healthy is challenging and requires constant vigilance; adults with spinal cord injury need to feel empowered to find strategies that fit their lifestyles. Some participants acknowledged their skin care regimens get harder with age and that as time passes without a pressure ulcer, they may worry less and be less likely to ask for help when in fact help is most needed	
Limitations	None	

Table 85: Spilsbury 2007

Study	**Pressure ulcers and their treatment and effects on quality of life: hospital inpatient perspectives.** Journal **of advanced nursing: 2007; 57: 494-504. Spilsbury K, Nelson A, Cullum N, Iglesias C, Nixon J, and Mason S** [211]		
Aim	To explore patients' perceptions and experiences of a pressure ulcer and its treatment on their health and quality of life		
Population	• Purposive sample of 23 hospital inpatients with a pressure ulcer (grade 2-5) • 5 men, 18 women; age 33-92 years		
Setting	Hospital inpatients (medical, elderly care, orthopaedic and vascular surgery wards), 4 UK NHS hospitals		
Methods	• Qualitative semi-structured interviews, recorded and transcribed verbatim • Analysed thematically by two researchers		
Themes with findings	Descriptions of health and quality of life	Contextual detail	Age; chronic condition; levels of dependence (care package from social services and help with activities of daily living, or dependence on family member for help with shopping, not wanting to be a burden); living arrangements (some living alone; some adapted houses e.g. with stairlifts or widened doors for wheelchair; some had moved house)
	Experiences of developing a pressure ulcer	Perceived cause of ulcer	Level of mobility (confined to bed, scuffing/rubbing); dependence to move (repositioning not carried out by staff as often as patients would like but more damage if tried to move on their own); bed/chair-bound; skin condition (thin skin); shearing pressure in bed; delay noticing ulcer; delay treating first signs; poor health; poor diet/appetite; lack of knowledge (ignorance or naivety such that they did not seek advice or treatment); actions of 'another' (healthcare professionals failing to attach priority to their reports of ulcer of delays in skin inspection; ill-fitting splint, mis-use of hoist, delay in providing pressure-relieving interventions); 'susceptible'; blamed themselves
		Description of ulcer	Pain (shooting, stabbing, jumping, niggling, red hot poker, carpet burn, tender, raw; constant or worse at night; could vary hour to hour; worse on contact with bedclothes; complaints of pain downplayed or ignored); skin condition (loose, dead, heard); dimensions of ulcer (cavity, hole, shallow, deep); origins of ulcer (underneath, surface); first signs of ulcer (scratch, stinging, irritation, blister); physical appearance (angry, raw, black, nasty); physical sensations; 'poison' in the body; leakage from ulcer; smell from ulcer; unable to see ulcer (did not want to even using mirror)
		Impact of ulcer	Lack of impact (acute – other traumatic injuries more important); further impact for acute patient (setback to recovery); emotional (hating ulcer, not dwelling on it, troublesome, annoying, disruptive, inconvenient); mental (anticipation of pain, worry if ulcer would heal, depression, loss of confidence); physical (effect on positioning and comfort, reduced activities, infections); social (e.g. unable to wear shoes and do normal things like shopping)
	Experiences	Dressings/	Variety; painful especially when dressings changed; staff approach to care; allergies; poorly applied dressings;

Study	Pressure ulcers and their treatment and effects on quality of life: hospital inpatient perspectives. Journal of advanced nursing: 2007; 57: 494-504. Spilsbury K, Nelson A, Cullum N, Iglesias C, Nixon J, and Mason S [211]		
	of pressure ulcer care	treatments	disruptive; time consuming/inconvenient; dressing could ease pain; putting up with treatment
		Pressure equipment	Mattresses (like somebody cares; noisy; restricted movement); cushions (could make people feel unsafe/fear of falling); variable comfort; safety; delay in provision/lack of availability
		Professional attention	Variety involved; reliance on professional; attitude of staff to care (could be negative when asked for help with positioning or could disrupt sleep); poor information; conflicting information; lack of advice (especially about how long ulcer would take to heal)
Limitations	Not possible to differentiate the impact of the pressure ulcer from underlying chronic conditions; patients could not always recall how long they had been diagnosed with a condition or report all comorbidities		

Table 86: Stockton 1994[212]

Study	Preventing pressure sores in wheelchair users. Nursing standard: 1994; 8: 54-56. Stockton L.	
Aim	To develop an educational leaflet to raise awareness into the preventable nature of pressure sores among young wheelchair users in the community including to identify wheelchair users' perspectives and beliefs about pressure sore causation	
Population	• 48 young (age range 24-63 years) wheelchair users in the community	
Setting	Community, UK	
Methods	• Questionnaires, one-to-one and group discussion	
Themes with findings	Beliefs about pressure sore causation	Pressure sores are unavoidable as they were seen as "all part of being a wheelchair user" A the years go by, you become more resilient to pressure sores You build up immunity to pressure sores the longer you sit (like hardening skin on hands by doing manual work) Pressure relief cushions negate the need to perform pressure-relieving movements/lifts Pressure relief cushions provide total pressure relief

Study	Preventing pressure sores in wheelchair users. Nursing standard: 1994; 8: 54-56. Stockton L.	
	Feelings when person has a pressure sore	Unhappy Uncomfortable Irritable Depressed Angry Annoyed when have to go into hospital to get it treated Weak and sick; unable to get out Need for advice and information on pressure sore prevention
Limitations	Data collection and analysis not described in detail so unable to assess rigour/reliability	

I.1.9 Training and education for healthcare professionals

Table 87: Athlin 2010[16]

Study	**Factors of importance to the development of pressure ulcers in the care trajectory: perceptions of hospital and community care nurses.** Journal **of clinical nursing: 19: 2252-2258 Athlin E, Idvall E, Jernfält M, and Johansson I**		
Aim	To describe contributing factors for the progression or regression of pressure ulcers in the care trajectory as they were understood by nurses working in hospitals or community care.		
Population	• Registered nurses (RNs). Inclusion criteria: at least 5 years experience as RNs; experience of patients with pressure ulcers in last 6 months. • 29 women and 1 man agreed to participate; age 34-55 years; hospital 16; community care 14.		
Setting	Two hospitals (different units: medicine 4, surgery 11, intensive care 11) and community care (large, small, urban and rural) in Sweden.		
Methods	• Head nurses in hospital and community selected presumptive informants based on inclusion criteria who were invited to participate • Interview guide based on literature review and researchers' own experience as nurses capturing questions about the discharge process, progress/regress of pressure ulcers and obstacles in pressure ulcer care • Two test interviews carried out and discussed by research team to synchronise the interview style • Interviews lasted about an hour, were tape-recorded and transcribed verbatim. • Data analysed using qualitative content analysis to create an overall view of the informants' perceptions of factors which may contribute to progress or regress of pressure ulcers; units of meaning coded and grouped together; codes and groups compared and challenged; similar ones collapsed into broader groups; sub-categories and categories created and named and compared with original text. Researchers worked in close collaboration discussing meaning units, codes, subcategories and categories until consensus reached.		
Themes with findings	Factors relating to the individual patient	Physical condition	• clean dry skin prevented pressure ulcers and made them regress • risk of pressure ulcers or progression associated with circulatory disturbance, diabetes mellitus, hip fracture, stroke, thinness, pain, obesity, infection, incontinence, fever, poor skin condition, paralyse, terminally ill, bed-ridden patients, nutritional problems, reduced eating ability
		Psychological condition and patient participation	• Psychological well-being, ability and will to participate in their own care lowered risk of pressure ulcers • Increased risk with cognitive impairment (e.g. dementia, confusion, depression), motivation, intrinsic power (inner strength or will – if this was lost, patients were liable to inactivity and immobility), compliance (e.g. did not react to pain, did not follow prescriptions); older patients afraid to ask for help with pressure relief and repositioning or declined these; patients unaware of pressure ulcers at hospital discharge or rejected attempts to inspect and treat them.
		Place of care	• Hospital and community nurses both pointed to the other setting as where patients got pressure ulcers. • Short hospital stays and good mobilisation in hospital seen to decrease risk • Community nurses stated that pressure ulcers seldom appeared in patients' homes when relatives aware of the risks • Hospitalisation decreased general condition and associated with immobilisation which increased risk; emergency

Study	Factors of importance to the development of pressure ulcers in the care trajectory: perceptions of hospital and community care nurses. Journal of clinical nursing: 19: 2252-2258 Athlin E, Idvall E, Jernfält M, and Johansson I		
			unit and operating theatres seen as high risk places
	Factors relating to healthcare personnel	Views and values	• Main focus in hospital was disease and treatment which could lead to development of pressure ulcers • Main focus in community was basic care including pressure ulcers • Pressure ulcers and preventive interventions low status among RNs; pressure ulcer care mainly a concern of less qualified personnel (licensed practical nurses – LPNs). • Early signs of pressure ulcers (erythema) not judged as pressure ulcers and not reported on admission to/discharge from hospital • Pressure ulcers connected with shame and guilt which could lead to neglect and lack of treatment • Pressure ulcers considered by informants to be uncommon which they recognised could mean they were unobservant
		Responsibility and commitment	• Pressure ulcer care mainly a concern of LPNs but RNs responsible (due to higher level of education) for prevention, risk assessment and supervision of LPNs; many nurses did not take on this responsibility due to lack of interest; nurses often not involved until pressure ulcers developed. • Commitment and interest in patient's total care an important factor in avoiding pressure ulcers, e.g. contacting the other setting for more information about patient (personal initiative, only done by some nurses if committed). • Nurses with 'fiery spirits' needed to maintain focus on pressure ulcers; physicians had overall responsibility and authority for pressure ulcer treatment but knowledge about wound care and prevention scarce. • Patient transfer between settings was a risk factor as no-one had responsibility for patient in new setting.
		Knowledge and competence	• Knowledge and competence among healthcare personnel essential to avoid pressure ulcers and heal them. • Most informants had theoretical knowledge about preventing and treating pressure ulcers but a rather unreflective attitude towards pressure ulcer care also found. Incongruity between knowledge and actions of informants and their colleagues. Knowledge could be lacking, out of date or inadequate. Hospital nurses expressed the view that community nurses lacked knowledge about organisation and responsibility in the healthcare system which could cause problems in the care of pressure ulcers. All nurses knew the value of risk assessment but this was seldom used in daily work. • Knowledge about the patient as a person also mentioned as important.
		Co-operation and communication	• Co-operation and communication when patient transferred between settings (home, units in hospital, community settings) important in pressure ulcer care; often stated to be given verbally but lacking in written documentation • LPNs cared to pressure ulcers rather independently; RNs had to rely on their reports of assessment and intervention which could be irrelevant or vague; needed to inspect the sores themselves but difficult without 'stepping on someone's toes'. • In community care, relatives expected to report signs of pressure ulcers to nurses.

Study	**Factors of importance to the development of pressure ulcers in the care trajectory: perceptions of hospital and community care nurses.** Journal **of clinical nursing: 19: 2252-2258 Athlin E, Idvall E, Jernfält M, and Johansson I**		
	Factors relating to the healthcare structure	Organisation and routines in the healthcare system	• Continuity in the organisation important – too many people involved in the care of the patient meant that nobody knew who was responsible for what, which could lead to neglect and failure of care. • Continuity in the caregivers' time-schedule and daily inspection of risk patients' skin allowed early signs of pressure ulcers to be discovered. • Short-time nurses a risk factor due to lack of knowledge and lack of continuity of care. • Importance of regular routines of follow up of pressure ulcers by responsible nurse. • Benefits of primary nurses system where a responsible nurse assigned to each patient. • Lack of routines/agreement about information transfer (what to report, when, to whom, how) regarding pressure ulcers was a serious problem; guidelines differed and were not always complied with. Written and oral reports seen as desirable. Community and hospital care run by different authorities which was a risk factor in itself that could only be overcome by mutual concern between parties involved incare.
		Resources	Lack of personnel and time especially in the evenings and at weekends; being responsible for too many patients meant RNs had no time for pressure ulcer prevention despite personal ambitions and professional demands. To manage they handed over responsibility to LPNs. Well aware of significance of technical equipment, and good availability of equipment and documentation/risk assessment tools, but these not always used due to lack of time.
Limitations	• Findings may not be generalisable to other areas or have captured all possible factors of importance • There were some difficulties in discerning from the interviews when the informants talked about real factors that hindered or increased the development of pressure ulcers versus when they talked about the ideal situation of how to prevent pressure ulcers. • No triangulation with other data or checking with respondents • Interviews only, no field notes • Data not 'rich': no quotations used to illustrate themes		

Table 88: Blanche 2011[31]

Study	Manualization of occupational therapy interventions: illustrations from the pressure ulcer prevention research program. American Journal of occupational therapy: 65: 711-719 Blanche EI, Fogelberg D, Diaz J, Carlson M, and Clark F		
Aim	Manualisation of a complex occupational therapy intervention to ensure treatment fidelity; this paper reviewed the literature on the process of intervention manualisation (not reported here), illustrated by a Pressure Ulcer Prevention Project. Qualitative research provided the initial foundation for manualisation of a multifaceted occupational therapy intervention designed to reduce the incidence of medically serious pressure ulcers in people with spinal cord injury.		
Population	• 20 adults with spinal cord injury and a history of recurring pressure ulcers		
Setting	University of Southern California (USC)/Rancho Los Amigos National Rehabilitation Centre (RLANRC)		
Methods	• A three-year ethnographic (qualitative) study; in-depth interviews and participant observations to gather detailed information on the everyday life circumstances that contribute to the formation of pressure ulcers in adults with spinal cord injury, resulting in a Stage I intervention manual, a manual for rehabilitation professionals and an on-line consumer manual.		
Themes with findings	Input into the Stage I manual	General treatment approach to promote positive health outcomes in older adults (from USC Well Elderly Study)	• significance of the therapist-client relationship • client-centredness • emphasis on social support • application of health-related knowledge • use of resources • focus on daily life activities in multiple settings • attention to existing, anticipated, or unanticipated life circumstances that impact risk • individualisation
		Provisional topics for emphasis identified during the ethnographic study	Factors directly or indirectly affecting the patient's pressure ulcer risk e.g. smoking, attendant care, self-advocacy integrated into the 14 manual units: occupational storytelling and story making; pressure ulcer knowledge; self-advocacy; attendant care; changing body; environment and adaptive equipment; habits and routines; chronic pain; participation and activity; depression and other mental health issues; social support; transportation; spirituality and wrap-up session. Each unit provided a description of the topic, noted suggested treatment activities, provided tips for therapists, and listed additional resources for both interveners and participants.
	Feasibility study of Stage I manual	Redesign of manual to six major units and individualisation	• Six main topics: understanding pressure ulcer risk; taking charge (advocacy); assessing the physical environment; social networks and meaningful relationships; happiness and personal well-being; planning the future. • Individualisation e.g. the equipment module might be used with one patient to identify funding sources to purchase appropriate equipment, for another it might involve exploring reasons for non-use

Study	Manualization of occupational therapy interventions: illustrations from the pressure ulcer prevention research program. American Journal of occupational therapy: 65: 711-719 Blanche EI, Fogelberg D, Diaz J, Carlson M, and Clark F		
			of currently owned working equipment.
	Development of Stage II manual	Modifications based on a literature review	No further details
		Modifications based on further analysis of the data from the ethnographic study	Ethnographic study led to development of a series of models depicting the process through which various risk factors interacted in complex ways in the context of individuals' everyday lives with respect to pressure ulcers (referenced to another paper: Clark 2006) and identification of seven overarching principles that accounted for pressure ulcer development in people with spinal cord injury (referenced to another paper: Jackson 2010 included in the patient information file). These models and principles were incorporated into the manual's units and led to generation of new worksheets and treatment activities (e.g. the model emphasising a balance between buffers and liabilities led to worksheets on problem-solving).
Limitations	Little information presented in this paper on the qualitative part of the study but referenced to Jackson 2010 which is included in the patients information file and is adequate		

Table 89: Jankowsko 2011[106]

Study	**Identifying gaps, barriers, and solutions in implementing pressure ulcer prevention programs. Joint Commission** Journal **on quality and patient safety: 37: 253-264 Jankowski IM and Nadzam DM [106]**		
Aim	To describe a unique partnership that has focused on translating evidence-based best practices to the bedside to prevent pressure ulcers. Aims included developing tools to evaluate pressure ulcer prevention programs and protocol implementation; identify gaps in pressure ulcer prevention programs; identify barriers to consistent application of pressure ulcer prevention protocols; test and promote strategies for achieving consistent and sustained application of protocols; disseminate learning		
Population	• 4 hospitals in the US: each had a project team leader and a multidisciplinary team (nurse managers, staff nurses, nursing assistants, physiotherapists, nutritionists, physicians, risk managers, educators) under the sponsorship of the chief nursing officer.		
Setting	Joint Commission Resources (JCR) and Hill-Rom created the Nurse Safety Scholar-In-Residence program to foster the professional development of expert nurse clinicians to become translators of evidence into practice; 4 hospitals with established pressure ulcer prevention programs participated in the pressure ulcer prevention implementation project		
Methods	• Nurse scholar and project director held joint conference calls with hospitals' team leaders to define roles and responsibilities, review pressure ulcer prevention program information and identify specific challenges and gaps • Site visits including "town hall" meetings to elicit input from front-line bedside caregivers and conference calls for more in-depth analysis to identify and remediate gaps and barriers interfering with efficient implementation of pressure ulcer prevention programs • Interviews with frontline care staff using open-ended questions in patient units; brainstorming perceived barriers to pressure ulcer prevention program implementation; top three issues to be addressed in each hospital; development of action plans		
Themes with findings	Pressure ulcer prevention program assessment (conference calls and review of paperwork)	Positive factors	Program led by executive-level champion (e.g. chief nursing officer, quality director) Had an established team including a certified wound ostomy continence nurse (CWOCN) Pressure ulcer education provided to nurses and nursing assistants during orientation Hospitals had a written pressure ulcer protocol and used teh Braden scale for predicting pressure sore risk Availability of unit-based skin champions All hospitals participating in quarterly national database of nursing quality indicators prevalence surveys methods to ensure patients consistently receiving interventions outlined in pressure ulcer prevention protocols included retrospective and concurrent chart reviews, review of bedside flow sheets, hourly rounding forms; bedside observation of repositioning practices in some units
		Gaps	Nursing assistants (NAs) not included in pressure ulcer teams

Study	Identifying gaps, barriers, and solutions in implementing pressure ulcer prevention programs. Joint Commission Journal on quality and patient safety: 37: 253-264 Jankowski IM and Nadzam DM [106]		
			No follow up education for NAs Patients at risk for pressure ulcers and their family members did not routinely receive instruction about the pressure ulcer prevention program Hospitals did not routinely include the risk score or pressure ulcer prevention care plans in shift-to-shift reports, RN to NA reports, RN to physician reports or other handoffs between hospital staff (e.g. staff nurse to transporters, transporters to imaging staff) Inconsistent description of pressure ulcers by nurses, physicians and wound specialists
	Site visits, "town hall" meetings and conference calls	Nurses	Bedside staff not using/cannot locate wound care manual containing educational material about appropriate product selection and usage
		Nursing assistants	Nursing assistants want more pressure ulcer education and to play a more active role NAs need more training to take more initiative
		Physicians	Some physicians not aware of pressure ulcer prevention program (unavailability? lack of interest?) Others are strong champions
		Teamwork	Lack of teamwork between nurses and NAs Some areas e.g. operating room, post-anaesthesia care unit not involved in pressure ulcer prevention committee meetings Need information about adherence to turning schedules and clarifying roles and responsibilities of RNs, NAs and technicians
		Supplies	Pressure ulcer prevention supplies not always readily available Confusion about supplies and how to use them
		Emergency department	Long hold times in emergency department for high risk patients – need for pressure-redistribution stretcher mattresses, skin care education, ensuring supplies available

Study	Identifying gaps, barriers, and solutions in implementing pressure ulcer prevention programs. Joint Commission Journal on quality and patient safety: 37: 253-264 Jankowski IM and Nadzam DM [106]		
		Patients	Work ongoing to develop and disseminate patient education materials
		Physiotherapy	Nurses should actively mobilise patients without physiotherapy
		Non-nursing staff	Non-nursing staff including transporters, supply or skin care product delivery staff, ancillary staff e.g. in radiology, dialysis and endoscopy departments, expressed interest in participating in pressure ulcer prevention initiatives
	Interviews with frontline care staff, brain-storming, action plans for top three issues	Key barriers included:	Education re skin care supplies and products Physician education
		Top three projects for each site included:	Education re skin care supplies and products Staff education related to pressure ulcer protocol Staff education with a focus on relaunching the wound care manual Increasing participation of operating room, post-anaesthesia care unit, emergency department Increasing participation of NAs Develop and implement a wound education resource manual Identify a physician champion to assist with physician education about pressure ulcer prevention

Study	**Identifying gaps, barriers, and solutions in implementing pressure ulcer prevention programs. Joint Commission** Journal **on quality and patient safety: 37: 253-264 Jankowski IM and Nadzam DM** [106]		
	Improvement actions	Education/ training	Education binder Train-the-trainer nurses for unit-based education RN/NA team approach (team building; pressure ulcer prevention; peer education e.g. correct use of skin care products, life equipment, beds, protective devices; patient advocacy) Multidisciplinary awareness e.g. for physicians, physiotherapists, department heads Structuring handoff processes so risk score is communicated and prevention implemented as the patient moves through the system Education on risk score accuracy Nurses need specific information about available skin care products and equipment (e.g. special beds, lifts, slide sheets, slings, heel protectors and heel lifts, ointments, creams, containment devices) including their indications for specific patient care needs and how to use them. NAs, physiotherapists, transporters and others who move patients form bed to stretcher or chair also need information about indications for special skin care products and equipment to minimise pressure, shear forces and friction Patients education brochures obtained
Limitations	Methods of analysis of qualitative data not reported so rigour and reliability unclear		

Table 90: Justham 2002[109]

Study	**The experience and opinions of teachers of radiography students regarding pressure ulcer prevention and management in x-ray departments.** Journal **of tissue viability: 12: 5-9. Justham D and Rolfe J**		
Aim	To establish the range of views and experience of teachers on pre-registration radiography courses about their experiences of pressure ulcer preventionand management in radiography departments.		
Population	• 14 of the 24 pre-registration radiography course providers in teh UK		
Setting	Pre-registration radiography course providers, UK		
Methods	• Survey about pressure ulcer prevention and management in x-ray departments; qualitative data (open-ended questions) was content analysed		
Themes with findings	Measures respondent had observed being used in radiography department for the prevention of pressure ulcers	Moving and handling	Few measures taken Usually examination time is short so not really a concern of radiographers Care moving and handling patients and inserting cassette under patients
		Changing position	Need for patients to be allowed to change position during long procedures (although not always possible)
		Use of pressure-relieving aids	e.g. sheepskin, mattresses, foam or sponge pads Adaptation of treatment/x-ray couch/table
		Collaboration with colleagues	e.g. nursing and medical colleagues
	Information considered important in relation to pressure ulcer prevention	Choice of technique	Sometimes lying on hard bed unavoidable Sometimes prevention measures possible
		Use of mattresses	Sometimes possible to use mattress Sometimes mattresses not possible due to necessity for accurate positioning/beam direction Mattress needs to be translucent
		Attitudes and education of staff	Not seen as responsibility of radiography staff Low awareness as most procedures pose little threat

Study	The experience and opinions of teachers of radiography students regarding pressure ulcer prevention and management in x-ray departments. Journal of tissue viability: 12: 5-9. Justham D and Rolfe J		
			Prevention and care of pressure ulcers should be given more attention in undergraduate training All radiographers should have regular updates on the importance of pressure ulcers Use of mattresses where possible
		Patient comfort	Patients comfort and image quality not compatible Radiographers/radiologists not always patient orientated Mattresses often not used as most procedures of short duration
Limitations	Open-ended questions on questionnaire only No triangulation with other data or checking with respondents Methods of analysis of qualitative data not reported so rigour and reliability unclear		

Table 91: Meesterberends 2011[143]

Study	**Evaluation of the dissemination and implementation of pressure ulcer guidelines in Dutch nursing homes.** Journal **of evaluation in clinical practice: 2011; 17: 705-712. Meesterberends E, Halfens RJG, Lohrmann C, Schols JMGA, and de Wit R.**	
Aim	To investigate pressure ulcer guideline dissemination and implementation in Dutch nursing homes	
Population	• Eight nursing homes (selected as those who agreed to participate from the 5 with the lowest prevalence rates or pressure ulcers and the 5 with the highest rates); eight people per nursing home: a nurse, 2 nursing assistants, a tissue viability nurse (if present) or if not a member of the pressure ulcer committee, a member of the medical staff, 2 unit managers and a member of the management team	
Setting	Nursing homes in the Netherlands	
Methods	• Semi-structured interviews: awareness of pressure ulcer guidelines, whether respondent had read them, how disseminated in nursing home; attitudes towards guidelines; whether content of guidelines used in daily practice; if guidelines up to date; use of risk assessment and repositioning; barriers to providing pressure ulcer prevention in daily practice; actions taken to help dissemination and implementation of guidelines. Also asked about pressure ulcer policy within the home (e.g. wound rounds) • Interviews transcribed and sent back to interviewees to check content validity • Text analysed by manifest and latent content analysis, selecting meaning units, coded, sorted into structure of categories and subcategories, identified patterns of similarities and differences, themes emerged • 2 additional authors read, reviewed and discussed the data	
Themes with findings	Knowledge	All homes had institutional pressure ulcer prevention and treatment guidelines All interviewees aware of existence of guidelines and had read them Guidelines disseminated by intranet, team discussions on ward rounds
	Attitudes	Pressure ulcer guidelines used in the home confirmed respondents' views on adequate and efficient pressure ulcer prevention and treatment
	Practice	All respondents said they applied contents of guidelines in daily practice however, risk assessment scale not always used routinely Repositioning scheme kept in resident's file or near bed – often not filled in (e.g. lack of time, forgetting), or filled in when repositioning had not actually been done (by colleagues not respondents) – colleagues reported to believe that repositioning was not necessary when a resident was lying on a pressure relieving mattress; or because resident did not want repositioning to be carried out Educating residents and relatives about risk of developing pressure ulcers was done by information leaflet and oral information

Study	Evaluation of the dissemination and implementation of pressure ulcer guidelines in Dutch nursing homes. Journal of evaluation in clinical practice: 2011; 17: 705-712. Meesterberends E, Halfens RJG, Lohrmann C, Schols JMGA, and de Wit R.	
		Barriers identified in applying guidelines included lack of qualified personnel; lack of nurses' /nursing assistants' knowledge; resistance of residents; lack of motivation among staff; stubbornness of staff (people who don't listen to advice/suggestions from others); forgetting to give nutritional support or lifting patients who cannot move themselves; lack of attention to pressure ulcer care; bad communication between different disciplines Guidelines disseminated by pressure ulcer committee, tissue viability nurse, nurses/nursing assistants with special attention for pressure ulcer care (although had not always had special education in wound/ pressure ulcer care), wound rounds, registration of patients with pressure ulcer Education (mostly internal; some external but limited by financial issues) about pressure ulcer prevention and treatment given in most of the homes. In none of the homes was there an obligation for the nursing staff to follow a specific amount of education. Nursing staff free to choose their subjects of interest (may or may not have included pressure ulcer/wound care) so not all staff had specific number of hours of education in this area in the past years. Some nurses/nursing assistants perceived not enough education in pressure ulcer care. Education should be offered more frequently and should be obligatory – some people always sign up for education, most don't. Perception that knowledge of nursing staff regarding pressure ulcer care was lacking; lots of nursing trainees and nursing assistants, few qualified staff. Even in one home where there was a system for providing pressure ulcer education twice a year and it was obligatory for nursing trainees and new personnel to participate, none had been given in the past year due to other priorities and forgetting to organise new education.
Limitations	Only 8 nursing homes represented – may not be representative	

Table 92: Middleton 2008[144]

Study	Issues and Challenges for Development of a Sustainable Service Model for People With Spinal Cord Injury Living in Rural Regions. Archives of physical medicine and rehabilitation: 2008; 89: 1941-1947. Middleton JW, McCormick M, Engel S, Rutkowski SB, Cameron ID, Harradine P, Johnson JL, and Andrews D	
Aim	To develop and implement a service model for people with spinal cord injury living in rural regions	
Population	• People with spinal cord injury (n=80), caregivers and health professionals (n=277)	
Setting	Regional and remote areas of New South Wales, Australia	
Methods	• Service development, pilot evaluation study: phase 1 included needs analysis to identify existing expertise and key contacts, target groups for education and training, educational requirements and strategies; developing specialised educational resources; providing education to rural health professionals, clients with spinal cord injury and care providers; running multidisciplinary outreach clinics in 4 pilot health regions. Phase 2: network development: focused on investigating a local support model for developing sustainable spinal networks between rural health professionals and care providers and metropolitan specialised spinal cord injury units or services. • Focus group discussions, key informant interviews, postal questionnaires • Results of needs analysis grouped thematically, presented to forum of participants from each rural health region to validate and prioritise recommendations. • Resources developed for identified topic areas • Education sessions presented collaboratively by staff of the spinal units and 2 community organisation • Multidisciplinary outreach clinics reviewed clients with spinal cord injury and also provided a way to reinforce education and provide skills training for rural staff and caregivers	
Themes with findings	Education	Respondents sought information on autonomic dysreflexia, bladder and bowel management, skin management, pain management, sexuality and fertility, aging with spinal cord injury, psychosocial issues, equipment and technology. Most health professionals lacked knowledge and self-confidence in most if not all areas of spinal specific practice
	Effective communication	No further details
	Community re-integration and service coordination	Pressure ulcers reported to have a significant impact on quality of life; proved quite challenging to manage serious skin breakdown in rural areas due to lack of availability of specialised pressure-relieving mattresses; difficulty accessing updated equipment in a timely manner to accommodate pressure ulcer management; and limited capacity for service providers to change care regimes to accommodate bed rest. Limited local infrastructure and health workforce capacity Limited availability of specialised services and expertise

Study	Issues and Challenges for Development of a Sustainable Service Model for People With Spinal Cord Injury Living in Rural Regions. Archives of physical medicine and rehabilitation: 2008; 89: 1941-1947. Middleton JW, McCormick M, Engel S, Rutkowski SB, Cameron ID, Harradine P, Johnson JL, and Andrews D	
		Difficulty accessing primary care and general practitioners Limited resources and funding for equipment and housing Large geographic distances Lack of transportation
Limitations	Data analysis not described in detail so unable to assess rigour/reliability	

Table 93: Samuriwo 2010[193]

Study	Effects of education and experience on nurses' value of ulcer prevention. British Journal of nursing: 19: S8-18. Samuriwo R		
Aim	To determine the value that nurses place on pressure ulcer prevention and how this value is formed		
Population	• 16 participants ranging from 2nd year nursing students to senior nurse managers		
Setting	Non-acute adult medical wards of 14 hospitals in one NHS trust, and a university		
Methods	• Semi-structured interviews interpreted through grounded theory • Indirect measure, asking nurses to talk about their experiences of looking after patients with pressure ulcers, then eliciting values form the replies • Simultaneous data collection and analysis (constant comparison) • Open coding, then axial coding, then selective coding • Comparative methods • Memo writing to aid conceptual analysis construction • Sampling to refine the emergent theoretical ideas • Integration of the theoretical framework		
Themes with findings	Value on pressure ulcer prevention had gone from low to	Initial low value	NA participants had not been taught about pressure ulcers Nursing participants had been taught about the importance of pressure ulcer prevention in pre-registration training but had not yet fully appreciated its importance Did what they were told to do to protect the skin (e.g. turn patient, check for redness) but did not understand why they were doing it

Study	Effects of education and experience on nurses' value of ulcer prevention. British Journal of nursing: 19: S8-18. Samuriwo R		
	high	Landmark: the first time they saw a pressure ulcer	Shocked to realise they knew very little about pressure ulcers or how to prevent them
		Catalyst for changing value from low to high	Encountering the patient who had the worse pressure ulcer they had seen – first-hand experience of what could happen if pressure ulcer prevention was not undertaken; consequences including aggressive treatment plans and a multidisciplinary approach to treatment, opportunity to learn from other professionals, seeing how important participants were to improving patients' pressure ulcer-related outcomes, investigations by Social Services
		More proactive than colleagues	More proactive in undertaking interventions to maintain skin integrity than colleagues who had not cared for patients with high-grade pressure ulcers
		Post-registration education invaluable	Post-registration pressure sore courses equipped them for current role Desire to keep updated Education appeared to affect the participants only after they had had personal experience of a patient with a pressure ulcer
Limitations	No triangulation with other data or checking with respondents little information presented in this paper on the data collection and analysis but referenced to another Samuriwo 2010 paper		

I.2 Pressure ulcer management

I.2.1 Ulcer measurement

Table 94: O'Meara 2012[166]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Reference
Author and year: O'Meara (2012) **Title**: A systematic review of the performance of instruments designed to measure the dimensions of pressure ulcers. **Journal:** Wound Repair and Regeneration (2012), 20, 263-276.	No. and type of studies: 12 cross-sectional studies. Inclusion criteria: studies of any design reporting an evaluation of a wound measurement instrument as the main focus of the investigation. Participants: studies recruiting people with pressure ulcers, managed in any care setting. Evaluations involving patients with various wound etiologies were included if there was separate data available for those with pressure ulcers. Assessors: reports involving any health professional(s) who are described as being involved in the measurement of pressure ulcers. Exclusion criteria: evaluations of assessment checklists which are designed to evaluate a range of wound variables and	Evaluations of any method of estimating the diameter, depth, surface area or volume of pressure ulcers.	Intra-rater reliability or inter-rater reliability of at least one method of wound measurement; agreement between at least two methods of wound measurement; comparison of at least one method of wound measurement against a defined reference standard; or comparison of the feasibility of at least two methods of wound measurement.	Does the review address an appropriate question relevant to the guideline review question? yes Does the review collect the type of studies you consider relevant to the guideline review question? yes Was the literature search sufficiently rigorous to identify all relevant studies? yes Was study quality assessed reported? yes Was an adequate description of the methodology used and included, and the methods used are appropriate to the question? yes	Quality grade: very low risk of bias

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Reference
	focus on the performance of the tool overall rather than on individual components such as measurement of ulcer dimensions.				

Table 95: Terris 2011[220]

Reference	Patient characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Author and year: Terris 2011 **Title**: Comparison of in-person and digital photograph assessment of stage III and IV pressure ulcers among veterans with spinal cord injuries **Journal:** Journal of Rehabilitation Research and Development, 2011, 48 (3), 215-224. Study design: Statistical analysis: kappa coefficient Setting:Spinal cord Inury and Disorders unit of a Veterans affairs Medical Centre	Patient group: patients with stage III and IV pressure ulcers with spinal cord injuries N measured: 15 patients (with 31 pressure ulcers) N withdrawals: Reasons for withdrawal: Male, n (%): 15 (100%) Age (year), mean (s.d): 65.5 (8.6) Pressure ulcers location: Ankle: 2 Foot and heel: 8 Ischium: 8 Knee: 1 Sacrum and Buttock: 8 Thigh: 1	14 cm disposable ruler placed adjacent to pressure ulcer to measure length and width of wound. Digital photographs taken with camera.	Number of assessors: 2 wound-care nurses with similar training and length of experience Third study team member scheduled the in-person assessments and took the digital photographs. In-person assessments within 24 hours from when photographs taken. Number of repetitions (reliability studies):	Outcome 1 Wound diameter – intra-rater reliability Length Width	0.075 (p=0.003) slight 0.103 (<0.001) slight	Funding: based on work supported by a Veterans Integrated Service Network 10 Clinical Care Council Emerging Technologies grant. Limitations: unclear if the rater's knew the other rater's values and whether order of measurement
				Outcome 2 Wound diameter – inter-rater reliability Length Width	0.075 (p=0.003) slight 0.103 (<0.001) slight	
				Outcome 3 Wound diameter – in-person		

Reference	Patient characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Multiple ulcers: accepted in study.	Trochanter: 3 Inclusion criteria: all patients with a stage III or IV pressure ulcer in the pelvic region or on a lower limb who could be positioned and remain motionless for photography. Exclusion criteria: not stated.		Frequency of measurement (reliability studies):	Intramethod comparison Length Width	 0.072 (0.07) 0.149 (0.02)	s was random. Notes:
				Outcome 4 Wound diameter – digital photograph intramethod comparison Length Width	 0.062 (0.12) 0.0625 (0.13)	

I.2.2 Categorisation

Table 96: Alvey 2012[10]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Alvey B et al. Improving accuracy of pressure ulcer staging and documentation using a computerised clinical decision support system. J Wound Ostomy continence Nurs 2012; 39: 607-612 **Study design:** Accuracy study **Statistical analysis:** % of correct stagings were presented **Setting:** 500 bed regional referral hospital in USA.	**Patient group:** Not applicable. 5 photographs of PUs used, at the following stagings (in order): stage II, suspected deep tissue injury (SDTI), stage I, unstageable, stage III. Stage IV not used as depth perception difficult with photographs. **Evaluator group:** Student and qualified nurses, 52% with BNurs and 74% with > 10 years' experience. Not specified as PU specialists. **Pressure ulcers location:** NA (pictures and location unspecified) **Inclusion criteria:** Nurses employed at the specified medical centre **Exclusion criteria:** None stated	Computerised clinical decision support (CCDS) program, based on the NPUAP classification. This uses drop-down menus to assist accurate staging. Nurses could over-ride the computer's staging if they wished. Each participant was allowed to do a 1 hour simulation practice session beforehand.	**Number of assessors:** 31 **Gold standard (accuracy studies):** staging carried out by a WOC (wound, osteotomy and continence) nurse	% of accurate stagings overall	79/123 (64.2%)	**Funding:** None stated **Limitations:** Unclear if the study participants were representative of nurses who would normally assess staging of PUs. **Notes:** See above. Contamination avoided by asking nurses not to discuss stagings with others. Error in computer algorithm for stage II – hence the stage II results not included.
				% of accurate stagings for STDI	24/30 (80%)	
				% of accurate stagings for stage I	23/31 (74%)	
				% of accurate stagings for stage III	20/31 (65%)	
				% of accurate stagings for unstageable	12/31 (39%)	
				Correlation (spearman rho) of nurse characteristics and accuracy	Age group/stageI: 0.25 Age group/stageIII:-0.07 Age group/unstageable:0.16 Age group/DTI:0.05 Nurse ed/stageI: -0.32 Nurse ed/stageIII: 0.10 Nurse ed/unstageable:-0.21 Nurse ed/DTI:-0.35	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
					Years exp/stageI: 0.24 Years exp/stageIII: 0.05 Years exp/unstageable:0.30 Years exp/DTI:0.28 All NS (p<0.05)	

Table 97: Kottner 2009[122]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Kottner J et al. An interrater reliability study of the assessment of pressure ulcer risk using the Braden scale and the classification of pressure ulcers in a home care setting. Int J Nurs Stud 46: 1307-1312 **Study design:** Inter-rater reliability study of the EPUAP. Braden risk scale was assessed as well but outside scope of this review question.	**Patient group:** Patients from care homes in Holland. No overall demographic data as split into the two years that data were collected – but age around 77 yrs, BMI around 27 and about 65% were female **Evaluator group:** first evaluation by trained nurses. Second evaluation (1-3 days later) by nurses specially qualified in wound management [thus we are not just assessing normal systematic error between raters – instead	EPUAP, including evaluator training, involving instruction manuals and 1:1 instruction.	**Number of assessors: Not stated** **Number of repetitions (reliability studies):** 1 initially and 1 repetition **Frequency of measurement (reliability studies):** 1-3 day interval	Inter-rater agreement of absence or presence of PUs in 2007 (n=352)	Exactly agreed in 338/352 Inter-rater agreement P_0=0.96 (=338/352) Inter-rater reliability π=0.87(95% CI: 0.77-0.93)	**Funding:** **Limitations:** Poor reporting of assessors, their number, and their level of expertise. Results separated into 2 separate year cohorts, although no reason given why this should be so. Training given to raters – thus reliability may not be representative of the standard PU 'grader'. Included large numbers of sites with
				Inter-rater agreement of absence or presence of PUs in 2008 (n=332)	Exactly agreed in 318/332 Inter-rater agreement P_0=0.96 (=318/332) Inter-rater reliability π=0.89(95% CI: 0.79-0.95)	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Statistical analysis: P_0 and Scott's π **Setting**: Home care institutions in Holland.	we are looking at normal systematic error plus the systematic effect of expertise. Is this clinically relevant?]. **N measured:** 691 started the study, but 684 patients took part in both assessments (each assessment involved grading by a different rater) separated by 1-3 days). This was a random sample from 12,979 people who had been assessed once by the trained nurses. **N withdrawals:** 7 – omitted from analysis. **Reasons for withdrawal:** Not given **Pressure ulcers location:** No restriction **Inclusion criteria:** None given **Exclusion criteria:** None given			Inter-rater agreement across all 5 categories of PUs in 2007 (n=352)	Inter-rater reliability π=0.81(95% CI: 0.73-0.88)	no ulcers so this will have greatly magnified accuracy (agreement) as most people will be able to agree on no ulcer!! **Notes:** 1-3 day delay between readings – appears very acceptable in such a chronic condition; second raters blinded to the results of the first, and first raters unaware who they measured would be assessed by another rater. P_o and π were calculated including non-PUs (the vast majority were not PUs). Thus this is not a true measure of grading *per se*, but also a measure of differentiating between PU/no PU.
				Inter-rater agreement across all 5 categories of PUs in 2008 (n=332)	Inter-rater reliability π=0.79(95% CI: 0.72-0.87)	

Table 98: Yarkony et al. 1990[247]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Yarkony GM et al. Classification of pressure ulcers. Arch Dermatol 126; 1218-1219 **Study design:** Cross-sectional reliability study **Statistical analysis:** use of 'correlations' to evaluate the inter-rater reliability between pairs of testers for72 PUs on 10 patients for TWO evaluation tools. It is unclear what kind of correlations these were. Also use of % agreement – this is the % of rater pairs that agreed across the 72 PUs. **Setting:** Rehabilitation institute in USA. No other details given.	**Patient group:** Unclear, apart from the fact that they must have had PUs **Evaluator group:** 10 registered rehabilitation nurses of unspecified expertise**.** Any PU was evaluated by a <u>single</u> pair of raters, not all 10. **N measured:** 72 PUs were graded **N withdrawals:** Unknown **Reasons for withdrawal:** NA **Pressure ulcers location:** Unclear **Inclusion criteria:** Not stated **Exclusion criteria:** Not stated	Yarkony-Kirk classification (6 levels) Shea classification (5 levels)	**Number of assessors:** 10 **Number of repetitions (reliability studies):** 2 (1 by each rater) **Frequency of measurement (reliability studies):** 'simultaneous' (but independent)	Inter-rater 'correlation' for Yarkony-Kirk scale	0.90(P<0.001)	**Funding:** None stated **Limitations:** use of 'correlations' to evaluate the inter-rater reliability between pairs of testers for72 PUs on 10 patients for TWO evaluation tools. It is unclear what kind of correlations these were. If ICCs for agreement, then this is acceptable; if Pearson's product correlations then completely inappropriate. Unclear how the 10 nurses made up the testing pairs. Potential for bias as one testing technique may have had pairs who were randomly similar and the other tool may have had pairs who were not. Only by ensuring the same pairs were used across tools can we have a useful comparison.
				Inter-rater 'correlation' for Shea scale	0.86(p<0.001)	
				Inter-rater 'agreement' for Yarkony-Kirk scale [in terms of identical results]	85%	
				Inter-rater 'agreement' for Shea scale[in terms of identical results]	68%	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
						Nurses trained and experienced with Shea, but not Yarkony. No information on patients at all.

Table 99: Healey 1995[97]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Healey F. The reliability and utility of pressure sore grading scales. Journal of Tissue Viability. 1995; 5: 111-114. **Study design:** inter-rater reliability study of 3 PU scales. **Statistical analysis:** Cohen's kappa for inter-rater reliability. This was based on the agreement between the 37 (or 35) raters grading each of the 10 photographs. Each rater also asked to rate	**Patient group:** None. 10 photographs of different skin areas were used. **Evaluator group:** 109 qualified nurses. 75% were RGNs. This was an **opportunity** sample. **N measured:** 10 photos **N withdrawals:** NA **Reasons for withdrawal:** NA **Pressure ulcers location:** unclear but one on buttocks **Inclusion criteria:** none stated **Exclusion criteria:** none	• Surrey • Torrance • Stirling (without 3rd and 4th digits) • Stirling (without 2nd, 3rd and 4th digits)	**Number of assessors:** 109 (each were meant to grade all 10 photos using just one scale – unclear how the choice of scale was made*. Only 79 actually graded all 10, for the remaining 30 only the first 6 were graded due to a clerical error). *37 graded the Torrance, 37 used the Stirling and 35 used the Surrey. The 'groups' appeared	Surrey scale Cohen's kappa (inter-rater reliability) – overall result over the 10 photos.	0.37 (NB: simple % agreement was 206/309 = 67%)	**Funding:** None stated. **Limitations:** No assessment of confounding by experience which could be as important as qualifications. Use of photographs rather than real patients. Time between assessments by each rater
				Torrance scale Cohen's kappa (inter-rater reliability) – overall result over the 10 photos.	0.29 (NB: simple % agreement was 197/330 = 60%)	
				Stirling scale, without 3rd and 4th digits Cohen's kappa (inter-rater reliability) – overall result over the 10	0.15 (NB: simple % agreement was 125/330 = 39%**) **sig lower than the other 3	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
each grading system according to ease of use. **Setting:** Seven trusts in north-east of England	stated		well-matched for distribution of nursing qualifications, which could have been a serious confounder. **Number of repetitions (reliability studies):** 2 **Frequency of measurement (reliability studies):** Not stated**.**	photos.		not given. No information on prior expertise in the grading scales.
				Stirling scale (only first digit, without second, third or fourth) Cohen's kappa (inter-rater reliability) – overall result over the 10 photos.	0.22 (NB: simple % agreement was 194/330 = 59%)	
				Inter-rater reliability was worse for the less severe sores in all three grades.		
				Ease of use for Surrey*** ***sig easier than other 2	57% easy to use, 6% difficult to use	
				Ease of use for Torrance	16% easy to use, 35% difficult to use	
				Ease of use for Stirling (without 3rd and 4th digits)	11% easy to use, 57% difficult to use	

Table 100: Nixon 2005A[164]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Nixon J et al. Reliability of pressure ulcer classification and diagnosis. Issues and innovations in nursing practice 2005; 50: 613-623 **Study design:** Accuracy study **Statistical analysis:** Kappa statistic for diagnosis (PU v no PU) – this is not relevant to the review and so not reported. % agreement for the PU gradings (including grade 0: no PU). **This was done in two separate conditions:** 1) one lead research nurse paired with 4 other research nurses (16 paired assessments) and 2) 6 research nurses paired with 109 ward nurses (362 paired assessments; ie not all possible [654] pairings were used). At least 4 sites were aimed to be	**Patient group:** >18, bed-fast or chair-fast on day of assessment. Number of patients not reported. **Evaluator group:** 1) 1 lead research nurse and 4 research nurses; 2) 6 research nurses and 109 ward nurses) **N measured:** 1) 107 site comparisons between lead research nurse and 4 research nurses [could have been 112 as each of the 4 pairs could see up to 4 patients, each of whom had 7 sites, but clearly not all sites were seen] 2) 2396 site comparisons between 6 research nurses and 109 ward nurses [could have been 3052 as each of the 109 pairs could see up to 4 patients, each of whom had 7 sites, but clearly not all sites were seen] **N withdrawals:** unclear **Reasons for withdrawal:** NA **Pressure ulcers location:** Skin assessed on 7 body	Modified AHCPA/EPUAP scale – in addition to standard EPUAP scale had grade 0 (no PU), grade 5 (black eschar) and Grade 1 was subdivided to 1a and 1b (blanching and non-blanching respectively). All nurses prepared with information about the scale.	**Number of assessors:** 120 (or 116 if the same research nurses used for both arms) **Frequency of measurement (gold standard and evaluator):** observations made simultaneously, but recorded separately. **Gold standard (accuracy studies):** the gradings of the research nurses, who had almost complete consensus.	Agreement on gradings between lead research nurse and 4 other research nurses Accuracy - Agreement on gradings between 6 research nurse and 109 ward nurses.	98.1% [2/107 grades disagreed – both one grade different. One 1a was assessed as a 0 and one 1b was assessed as a 1a]. This confirms this group as having gold standard status (see below) **Overall:** **78.8% [508/2396 grades disagreed – 419 were one grade different, 68 2 grades different, 21 >2 grades different** Break down of different sites: Sacrum: 76% Left buttock: 75% Right buttock: 75% Right hip: 94% Left hip: 95% Left heel: 69% Right heel: 71%	**Funding:** None stated **Limitations:** All nurses received instruction on the scales thus potentially reducing the external validity of these results. Number of patients not reported. Simultaneous observation of PUs – therefore possible that some verbal or other cues were shared due to asking patient questions, making comments about what was observed etc. Included large

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
examined per pair. **Setting:** Four NHS trusts	sites including sacrum, left and right buttocks, left and right hips and left and right heels. **Inclusion criteria: :** >18, bed-fast or chair-fast on day of assessment. **Exclusion criteria:** not stated.					numbers of sites with no ulcers so this will have greatly magnified accuracy (agreement) as most people will be able to agree on no ulcer!! **Notes:** patients only tested by a pair of in study on one occasion (though most were assessed at 7 potential ulcer points that were included as separate data points)

Table 101: Sarhan 2010[196]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Sarhan F et al. Use of digital images in the assessment and treatment of pressure ulcers in patients with spinal injuries in community settings. Journal of Telemedicine and Telecare 2010; 16: 207-210 **Study design:** Agreement (?Accuracy) of staging of PUs based on a retrospective review of digital images from 50 patients with PUs, compared with the gold standard face to face result recorded in patient notes. Each of the 10 nurses carried out one assessment in 50 photos (thus should have been 500 assessments in total – in the end there were 414 (81% response rate). **Statistical analysis:** Per	**Patient group:** digital images from 50 patients of mean age 69 years (range 30-90). 32 male; all had SCI; 35 tetraplegic **Evaluator group:** Nurses at a national spinal injury centre **N measured:** 50 **N withdrawals:** NA **Reasons for withdrawal: NA** **Pressure ulcers location:** sacrum, ischium, foot, ankle, trochanter, hip, knee or back	EPUAP used on digital images compared to a retrospective rating using EPUAP in a real-life setting by trained staff.	**Number of assessors: 10** **Number of repetitions (reliability studies):** 1 (compared to result in notes) **Frequency of measurement (reliability studies):** NA (photo taken at same time as the face to face evaluation) **Gold standard (accuracy studies):** Original face-to-face evaluation of staging. BUT see limitations section in final column.	Overall agreement about stage Agreement for: Sacrum stage 4 Ischium stage 3 Foot stage 1 Foot stage 2 Ankle stage 1 Ankle stage 2 Trochanter stage 3 Trochanter stage 4 Hip stage 3 Hip stage 4 Knee stage 3 Knee stage 4 Back stage 1 Back stage 2	85% Number of ulcers can be derived by dividing denominator by the 10 assessors 102/150 [68%] 77/80 [96%] 20/20 [100%] 20/20 [100%] 20/20 [100%] 20/20 [100%] 35/40 [88%] 20/30 [67%] 34/40 [85%] 23/30 [77%] 8/10 [80%] 15/20 [75%] 10/10 [100%] 10/10 [100%]	**Funding:** Not stated **Limitations:** use of photographs rather than real patients. Was the prior face to face assessment by a 'trained nursing staff' member truly a gold standard? If not, this is more a study of agreement than accuracy. An accuracy study makes good sense. However, there seems little to be gained from assessing agreement between non-expert real-life stagings and photo-based stagings, except to show that photos can be used clinically (or not). **Notes:**

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
cent agreement **Setting:** Spinal injury centre in UK						

Table 102: Marrie 2003[137]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Marrie RA et al. Pressure ulcers: prevalence, staging and assessment of risk. Geriatrics today 2003; 6: 134-140 **Study design:** inter-rater reliability study. This study also included prevalence measurement, and the evaluation of the Braden risk assessment tool – these areas are not covered in this review. **Statistical analysis:** Intra-class correlation co-efficient **Setting:** Canada	**Patient group:** 164 patients in whole study but not all used in the reliability study. The 46 used for reliability study had a mean time from admission to ulcer development of 7 days (range 1-22). 14/46 had >1 ulcer **Evaluator group:** unclear. Appears to be two assessors **N measured:** unclear, possibly 46 **N withdrawals:** not stated **Reasons for withdrawal:** NA **Pressure ulcers location:** coccyx/sacrum, buttocks, ankle and foot, greater	NPUAP	**Number of assessors: probably** 2, but unclear **Number of repetitions (reliability studies): probably** one by each assessor but unclear **Frequency of measurement (reliability studies):** unclear – ie duration between assessments not reported	ICC of NPUAP	0.91	**Funding:** None stated. **Limitations:** Very poorly reported. Expertise of raters not reported. **Notes:**

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
	trochanter **Inclusion criteria:** NA **Exclusion criteria:** NA					

Table 103: Russell and Reynolds 2001[191]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Russel LJ, Reynolds TM. How accurate are pressure ulcer grades? An image-based survey of nurse performance. Journal of Tissue Viability 2001; 11: 67-75 **Study design:** cross-sectional survey. **Statistical analysis:** accuracy [mean of all differences (-ve and +ve) from all 97 participants from gold standard] and precision of measures [mean of all absolute differences (all converted to +ve) from all 97 participants from gold standard]. Done for both Stirling and	**Patient group:** No actual patients used. 12 photographs of PUs, graded by consensus panel of experts [gold standard] were used. These were selected from an original selection of 30 photos that had been graded by the experts. **Evaluator group:** 97 nurses (from pool of 200) sent a questionnaire and the 12 images – 27 clinical nurse specialists, 21 pressure ulcer advisory panel members, 25 acute nurses and 24 community nurses. All > 3 years' experience and all working in community and acute sectors. **N measured:** 12	• Stirling • EPUAP	**Number of assessors:** 97 **Gold standard (accuracy studies):** 12 photographs of PUs, graded by consensus panel of experts with no eventual disagreement [gold standard] in both scales.	Stirling accuracy – all nurses mean(sd)[n]	-0.045 (0.21) [85]	**Funding:** None reported **Limitations:** use of photographs rather than real patients. Use of continuous scales for a clearly ordinal measure. Categorical analysis would have been more appropriate. **Notes:** Did not use kappa on the basis that kappa is sensitive to
				Stirling precision – all nurses mean(sd)[n]	0.36 (0.15) [85]	
				EPUAP accuracy – all nurses mean(sd)[n]	0.15 (0.21) [86]	
				EPUAP precision – all nurses mean(sd)[n]	0.49 (0.15) [86]	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
EPUAP scales **Setting:** 5 acute trusts and 5 community trusts in England and Wales	photographs – each assessor graded each photograph according to both scales. **N withdrawals:** NA **Reasons for withdrawal:** NA **Pressure ulcers location:** **Inclusion criteria:** NA **Exclusion criteria:** NA					the increments of the scales and so kappa would not be a fair comparison between the scales.

Table 104: Defloor 2006[64]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Defloor T et al. Reliability of the European Pressure Ulcer Advisory Panel classification system. Issues and innovation in Nursing practice 2006; 54:189-198 **Study design:** intra-rater reliability study. Also accuracy (compared to gold standard by expert raters). This was erroneously reported as inter-rater reliability, which would	**Patient group:** No patients used. 56 photographs used, some of which were not of PUs (ie incontinence lesions). If erythema was visible on a photograph, a second photograph was also shown, where a transparent disc was pressed into the erythema to assess blanchability. **Evaluator group:** Phase 1: 473 nurses. Phase 2:86 nurses. In phase 1, 76% in practice, 9.1% in education. 21% had done	EPUAP. No prior training given.	**Number of assessors:** 473 nurses and 86 nurses. **Number of repetitions** (reliability studies): 2 for intra-rater reliability **Frequency of measurement (reliability studies):** For sequential intra-rater separated by 1 month. For concurrent intra-rater separated by negligible time	Multi-rater kappa* phase I for 473 nurses [accuracy] *summary of agreement across all raters, adjusted for the level of agreement that would be expected to occur solely by chance.	Multi-rater Kappa 0.37 (p<0.001) Not affected by training level	**Funding:** None stated **Limitations:** use of photos rather than real patients. The 473 nurses participating in phase 1 were all participating in a wound care conference – hence they may not have
				kappa phase I for 473 nurses [accuracy]	Kappa 0.50 (0.49-0.52)	
				Multi-rater kappa phase II for 86	Multi-rater Kappa 0.38	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
not be against a gold standard. Phase 1 looked at accuracy and concurrent intra-rater reliability. The 56 photos were mixed with nine different duplicates of these (thus 9 pairs within 65 photos) to allow **concurrent** intra-rater reliability to be measured. These were all shown to 473 nurses (participating in a wound care conference) once. Phase 2: accuracy and s**equential** intra-rater reliability measured by showing the 56 single photos to 86 new nurses twice, with an interval of 1 month. Both types of intra-rater reliability estimated by comparing the 2 readings by each rater regardless of its accuracy; for accuracy all relative to the	an external course, 31% an internal course and 42% educated via a Journal. In phase 2, all from a university hospital. **Pressure ulcers location:** unclear		period (ie within the same testing session) **Gold standard (accuracy studies):** The 56 photographs were classified by 9 EPUAP trustees, 7 PU researchers, 20 staff nurses responsible for the PU policy in their hospital and 17 PU nurses. The inter-rater reliability was high (kappa=0.8; 94.1% agreement). Not reported how differing classifications were derived.	nurses [accuracy]		been representative of all nurses – reduced external validity. Expertise of nurses unclearly reported. **Notes:** No prior training given means that external validity may have been higher than if training had been given. However note point in limitations above.
				kappa phase II for 86 nurses [accuracy]. First session only given.	Kappa 0.51 (0.49-0.54)	
				Concurrent intra-rater kappa phase 1 for 473 nurses	Kappa 0.38 (0.26-0.50)	
				Sequential intra-rater kappa phase II for 86 nurses	Kappa 0.52 (0.50 – 0.55)	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
expert's gold standard. **Statistical analysis:** kappa **Setting:** Belgium and Netherlands						

Table 105: Beeckman 2010[26]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Beeckman D et al. Pressure ulcers and incontinence-associated dermatitis: effectiveness of the Pressure Ulcer Classification education tool on classification by nurses. Qual Saf health care 2010; 19: e3. Doi 10.1136/qshc.2008.028415 **Study design:** RCT, including accuracy study. The PUCLAS intervention was designed to improve accuracy and was randomly allocated to half the participants. However, only the	**Patient group:** NA. One of 2 sets of 20 photographs were used. Each set contained one photo of normal skin, one photo of blanchable erythema, 3 photos of each PU grade, three photos of incontinence associated dermatitis (IAD) and 3 of a combination of PUs and IAD. **Evaluator group:** 1217 Belgian, Dutch, British and Portuguese nurses. Approximately 70% had >10 yrs of experience, and 30.3% worked as a nurse for >20 years. All were familiar with the EPUAP. About a third considered themselves expert at the	EPUAP. Images projected onto a white background.	**Number of assessors:** 1217 **Gold standard (diagnostic accuracy studies):** 12 trustees of EPUAP with an extensive experience in PU research. They all agreed on the gold standard classifications for the 20 photographs using a double Delphi procedure.	Accuracy overall – including the IAD photos (PRETEST ONLY)	10498/23595 (44.5%). Note that in the RCT the control group (559 nurses) got a better result than the one by all at baseline, maybe due to practice effects, on a fresh set of 20 photographs: 53%% (5804/10944)	**Funding:** None reported **Limitations:** Some nurses were attending a wound care conference so may have been more proficient in PU classification than the average nurse – thus less representative. Use of photographs rather than real patients. **Notes:** Some information on expertise (1/3
				Accuracy – normal skin and PU grades only (not including the IAD and IAD/PU photos) (PRETEST ONLY)	8266/16520 (50.0%)	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
initial baseline accuracy aspect of the study is described here. **Statistical analysis:** Accuracy (% of photographs classified correctly) **Setting:** Belgium and the Netherlands	EPUAP. **N measured:** 23,595 photographs [1217 nurses x average number of photos observed (19.39) **N withdrawals:** Not stated **Reasons for withdrawal:** NA **Pressure ulcers location:** Not stated					experts) of assessors. Gold standard very rigorous.

Table 106: Hart 2006[94]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Hart S et al. Reliability testing of the national database of nursing quality indicators pressure ulcer indicator. J Nurs care Qual 2006; 21: 256-265 **Study design:** Reliability study. This was a three part study, involving 1) identifying if wound was PU, venous, arterial or diabetic 2) the staging of PUs and 3) deciding	**Patient group:** NA – 18 photographs used, accessed online. Pictures were derived from NPUAP and other sources. The 18 pictures included 4 stage I, 3 stage II, 5 stage III, 5 stage IV and 1 unstageable. **Evaluator group:** People from the 55 institutions who participated in PU staging were invited to participate. Nearly half were staff nurses, and 16% were wound/skin	NPUAP, accessed online, including the photos (with or without verbal descriptions). Only one log in was allowed to ensure the activity was done only once per person and in one sitting.	**Number of assessors:** 256 raters from 48 hospitals **Number of repetitions (reliability studies):** 256 (all raters evaluated each picture) **Frequency of measurement (reliability studies):** Not relevant, as photos.	Kappa for inter-rater reliability of pressure ulcer grading	Overall: 0.65 (0.21) For photos + descriptors: 0.72(0.22). **For photos alone; 0.56(0.17)**	**Funding:** Not stated **Limitations:** Use of photographs rather than real patients. A highly trained group of evaluators (78% had had staging training at their hospital, 82% had a skin inspector
				HLM for PU staging, showing effect of wound, continence and/or ostomy care certification	B = 0.12, SE = 0.03, p<0.001. In other words, presence of certification leads to increase kappa. <u>No wound descriptors</u> After adjustment for	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
if it was nosocomial or community acquired. Only the results of part 2 are relevant to this review and so information recorded here is restricted to that part. Stage 2 consisted of two parts: a) photos with wound descriptors and b) photos alone. **Statistical analysis:** kappa for agreement. Hierarchical linear modelling (HLM) to estimate effects of rater characteristics on agreement **Setting:** 48 randomly sampled National Database of Nursing Quality Indicators (NDNQI) Hospitals. Plus Seven more non-NDNQI hospitals. USA	care nurses. 67% had a bachelor's degree and 17% were certified in wound, continence or ostomy care. 78% reported PU staging training in their hospitals. **N withdrawals:** 7 hospitals dropped out, leaving just 48 hospitals (and 256 raters) participating				this effect, kappa for certified nurses is 0.66 (SE 0.04) compared to 0.54 (SE 0.03) for noncertified nurses. <u>With wound descriptors</u> After adjustment for this effect, kappa for certified nurses is 0.83 (SE 0.03) compared to 0.71 (SE 0.02) for noncertified nurses.	role in ulcer prevalence studies). However only 12% had completed the NDNQI tutorial.

Table 107: Buckley 2005[39]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Buckley KM. The use of digital images in evaluating homecare nurses' knowledge of wound assessment. Journal of wound, ostomy and continence nurses society 2005; 307-316 **Study design:** Accuracy study. This study also involved evaluation of accuracy in aspects other than PU staging, but these are not relevant to this review and so not reported here. **Statistical analysis:** % accuracy **Setting:** Homecare agency, Washington DC, USA.	**Patient group:** NA, as 10 photographs of PUs used. The photographs were colour and projected onto a screen and viewed from a distance of 12 feet. The photos covered surgical wounds, venous stasis ulcers, diabetic foot ulcers and arterial ulcers, as well as PUs. Only 5 covered PUs, so only results pertaining to these are included here. **Evaluator group:** Home health nurses, aged in 40s/50s, with mean experience of 22.2(9.9) years as an RN, and 10.6(5.5) years in homecare. All had at least a diploma in nursing and 21.2% had Masters or doctoral degrees.79.8% saw at least 2 wounds per week clinically, and 36.4% saw 5-10 wounds per week. **Pressure ulcers location:** Not stated	NPUAP.	**Number of assessors:** 33 **Gold standard (diagnostic accuracy studies):** 4 WOC nurses provided the correct gradings, by consensus	Accuracy of staging across all 5 PU photographs amongst the 33 home health nurses <u>Separate results per image</u> Photo 1 of Stage IV Photo 2 of Stage IV Photo of Stage II Pressure ulcer covered with necrotic tissue Pressure ulcer covered with eschar	67.8% 39% 100% 82% 30% 88%	**Funding:** Not reported **Limitations:** Use of photographs rather than real patients. **Notes:** During image viewing the nurses were given a brief case history, read aloud. This may have led to higher accuracy than otherwise.

Table 108: Kelly and Isted 2011[112]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Kelly J, Isted M. Assessing nurses' ability to classify pressure ulcers correctly. **Study design:** Accuracy study. This study also included an intervention carried out after the initial accuracy study, followed by a final assessment of accuracy. However the final accuracy of accuracy is not described here. **Statistical analysis:** % agreement and kappa **Setting:** NHS Trust, Norfolk.	**Patient group:** NA; 3 photographs of PUs (3 out of 5 randomly chosen per assessor) **Evaluator group:** Randomly chosen nurses at NHS trust in Norfolk, working at bands 2-8. Did not include paediatric and maternity nurses.	EPUAP	**Number of assessors:** 93 **Number of repetitions (reliability studies):**93 (each evaluator graded each picture) **Frequency of measurement (reliability studies):** NA **Gold standard (diagnostic accuracy studies):** Not reported who and how the correct gradings were decided, but gold standard grading were used..	PU staging accuracy - overall	93 nurses gave 156 correct answers out of a possible 279 correct answers: 56%. Kappa was 0.48	**Funding:** **Limitations:** No description of how the gold standard answers were derived. Use of photographs rather than real patients. **Notes:**
				PU staging accuracy – category 1 (% correct)	86%	
				PU staging accuracy – category 2 (% correct)	56%	
				PU staging accuracy – category 3 (% correct)	43%	
				PU staging accuracy – category 4 (% correct)	89%	
				PU staging accuracy – unstageable (% correct)	6%	
				Effect of seniority of job role in accuracy	Band 2-4 nurses had accuracy of 57%; Band 5-7 nurses had accuracy of 55%. Chi square with Yates correction was 0.005 (p=1)	

Table 109: Beeckman 2007[25]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Beeckman D et al. EPUAP classification system for pressure ulcers: European reliability study 2007; Journal of Advanced Nursing 60: 682-691 **Study design:** Diagnostic accuracy. 2 sets of 20 photographs used, and the 1452 evaluators were given one of the sets via random selection. **Statistical analysis:** % agreement with gold standard and kappa. Gold standard staging decided by 12 trustees of the EPUAP, and all these were experts with extensive experience of PU staging. **Setting:** Five European countries	**Patient group:** NA. 20 photographs, including normal skin, blanchable erythema, pressure ulcers (4 grades), moisture lesions and combined lesions. However only results pertaining to correct staging of the PU are included in this review. **Evaluator group:** Nurses from 5 countries (Belgium n=666; Netherlands n=411; UK n=221; Sweden n=107; Portugal n=47). 70% of nurses had 10 years of experience and 30.1% had been active in nursing practice for >20 years. All were familiar with the EPUAP scale. 55% worked in a hospital, 18.5% in a nursing home, 21.7% in home care and 4.8% in education. 4% considered their expertise as 'expert', 26.4% 'extensive', 56.1% 'basic' and 13.5% 'limited'. Mean age 38.7(10.1).	EPUAP	**Number of assessors:** 1452 **Gold standard (diagnostic accuracy studies):** Gold standard staging decided by 12 trustees of the EPUAP, and all these were experts with extensive experience of PU staging.	Median (IQR) kappa for all for staging of PU	0.29 (0.14-0.47)	**Funding:** **Limitations:** convenience sampling. Use of photographs rather than real patients.
				Interactions of overall kappa with: Country	Chi square 83.9 (p<0.001). Best for Netherlands (kappa 0.37(0.23-0.48), worst for Sweden (kappa 0.19(0.09-0.29)	
				Experience	No clear relationship	
				Education	No clear relationship	
				Expertise	Chi square 36.2 (p<0.001) Best for 'expert', [kappa 0.47(0.32-0.56)] lowest for 'limited' [kappa 0.25 (0.089-0.38)]	
				Work location	No clear relationship	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
	Pressure ulcers location: Not reported					

Table 110: Beeckman 2008[24]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Beeckman D et al. Pressure ulcers: e-learning to improve classification by nurses and nursing students. Journal of Clinical Nursing 2008; 17: 1697-1707 **Study design:** This was an RCT study comparing accuracy with and without the PUCLAS2 e-learning programme. However the results of the intervention study are not relevant to this review and **this review only contains details of the baseline diagnostic accuracy.** 2 sets of 20 photographs used, and the 426 evaluators were given one of the sets via	**Patient group:** NA. 20 photographs, including normal skin, blanchable erythema, pressure ulcers (4 grades), moisture lesions and combined lesions. It was not possible to extricate the non PU data to calculate overall PU grading accuracy (because accuracy data in figures given as percentages without any indication of actual numbers with each gold standard grade). However it was possible to extract % accuracy for each grade of PU. **Evaluator group:** Student (n=214) and qualified (n=212) nurses from Belgium. Qualified nurses came from 7 general hospitals, 7 homes for	EPUAP	**Number of assessors:** 426 **Gold standard (diagnostic accuracy studies):** Gold standard staging decided by 12 trustees of the PUCLAS workgroup, and all these were experts with extensive experience of PU staging.	Median (IQR) kappa overall for accuracy (including also photographs that were not PUs)	0.24 (in both groups at baseline) [% agreement was 35% in both groups]	**Funding:** **Limitations:** convenience sampling. Use of photographs rather than real patients. Analysis included non PUs, and not possible to extricate these to gain an overall PU grading accuracy.
				<u>Specific grades % agreement</u> Normal skin Blanchable erythema Grade 1 Grade 2 Grade 3 Grade4	 92.9% 68.7% 38.2% 29.1% 24.6% 47.9%	
				Interactions of overall kappa with: Student/qualified	STUDENTS: 0.23 for the experimental group and 0.19 for the control group. QUALIFIED: 0.25 for the experimental group and 0.30 for the control group. Thus a possible trend for qualified to have	

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
random selection. **Statistical analysis:** % agreement with gold standard and kappa. Gold standard staging decided by 12 trustees of the PUCLAS workgroup, and all these were experts with extensive experience of PU staging. **Setting:** Belgium.	older people, one home care organisation and 5 nursing schools. Student nurses came from 2 schools with an undergraduate education and 4 colleges with non-degree qualifications. All students were in the first semester of their final year. **N measured:** NA **N withdrawals:** NA **Reasons for withdrawal:** NA **Pressure ulcers location:** Not reported **Inclusion criteria:** NA **Exclusion criteria:** NA				better accuracy but not rigorously tested.	

Table 111: Vanderwee et al. 2007A[238]

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
Vanderwee K et al. Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. Journal of Advanced Nursing 2007; 57: 59-68 **Study design:** Reliability study within RCT. Only 'reliability' results given here. However possible that these results should instead be interpreted as accuracy (see limitations section in comments column). **Statistical analysis:** kappa **Setting:** Elder care nursing homes, Belgium.	**Patient group:** random selection of patients from the overall RCT samples. Number and characteristics of those selected for the reliability study not reported. The RCT sample were nursing home residents of median 84 years, and median length of stay in the care home was 42 months (IQR 37-45). They had all been PU-free at the start of the study but clearly some had PUs at the time of the reliability study. **Evaluator group** the researcher, the study nurse and the nursing staff. **N measured:** unclear **N withdrawals:** NA **Reasons for withdrawal:** **Pressure ulcers location:** **Inclusion criteria:** **Exclusion criteria:**	EPUAP	**Number of assessors:** 1868 nursing staff and possibly 1 researcher and 1 study nurse. **Number of repetitions (reliability studies):**1 by nursing staff and another independently by the researcher and study nurse. **Frequency of measurement (reliability studies):** Time interval not stated **Gold standard (diagnostic accuracy studies):** The study nurse and researcher could be regarded as the gold standard.	Kappa 'IRR' between study nurse and nursing staff: Kappa 'IRR' between researcher and nursing staff:	0.88(95% CIs: 0.85-0.91). 0.89(95% CIs: 0.87-0.92).	**Funding:** **Limitations:** Why weren't the nursing staff compared to each other? They were the ones that should have been compared as they were those that did the measurements in the RCT. Instead 'reliability' was assessed by comparing the nursing staff to 'experts' – thus making this effectively an accuracy study. Certainly, in the context of this study, the 'IRR' values

Reference	Participant characteristics	Instrument	Method	Outcome measures	Evaluations	Comments
						are meaningless. Time interval not stated between measures (confounding by time effects).

I.2.3 Nutritional supplementation and hydration strategies

Table 112: Ter Riet 1995[219]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ter Riet (1995)[219] **Title:** Randomised clinical trial of ascorbic acid in the treatment of pressure ulcers Journal**:** J. Clinical Epidemiol, 1995, 48(12), 1453-1460 **Type of study:** multi-centre blinded randomised controlled trial – factorial design **Sequence generation:** randomisation in stratum, using random permuted blocks size 4, prepared with help of a computer program. **Allocation concealment:** unclear **Blinding:** tablets were identical; investigators, nursing staff (and physiotherapists), and patients were blinded to treatment allocation. Success of blinding checked at 2 and 12	**Patient group**: patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse). Most patients had nutritional deficiencies on admission. **All patients** **Randomised N:**88 **Completed N**:63 **Drop-outs:** 25 There were 3 deaths and 1 withdrawal in the intervention group and 5 deaths and 2 withdrawals in the control group. 7 patients died and 2 withdrew before effect measurement at 6 weeks. One died and 1 withdrew after 6 weeks follow-up. Three patients were excluded from the analyses pertaining to wound surface areas. One patient was found to be	**Group 1:** ascorbic acid supplementation (500mg twice daily), effervescent tables. **Group 2:** identical placebo containing 10mg of ascorbic acid Factorial design study and ultrasound was the second intervention under study. Randomly allocated to one of the four treatment groups (high Asorbic Acid – ultrasound; high Asorbic Acid – sham ultrasound; low Ascorbic Acid – ultrasound; low Ascorbic Acid – sham ultrasound) after pre-stratification on nursing home and muscle involvement (yes/no). The results of the ultrasound were reported elsewhere and the trial was designed on the assumption that the effect of AA supplementation was not modified by ultrasound.	**Outcome 1:** wound closure probability per unit time (closure rate)	Cox proportional hazards analysis: HR 0.78 (90% precision interval 0.44 to 1.39) ITT	**Funding:** Grant from the Netherlands Organisation for Scientific Research (NWO). **Limitations:** unclear allocation concealment. The control group had a greater number of large ulcers at baseline and a high drop-out. **Additional outcomes:** overall visual mark, wound survival time,
			Outcome 2: mean surface reduction (cm2/wk) [mean absolute healing rate]	**Group 1:** 0.21 cm2/week **Group 2:** 0.27 cm2/week Difference: -0.06cm2/week No standard deviations reported	
			Outcome 3: mean surface reduction (%/wk)	**Group 1**: 13.88 **Group 2:** 22.85 Intervention minus control -8.97 Adjusted difference (PI 90% precision interval): -3.13 (-13.66 to 7.39) ITT	
			Outcome 4: proportion healed at 84 days	**Group 1:** 17/43 **Group 2:** 22/45 Relative risk: 0.81 95% CI: 0.50 to 1.30 This was calculated by Cochrane Reviewer's from a graph (Langer 2003)	
			Outcome 4: mean volume reduction (ml/week)	Group 1: 0 ml/week Group 2: 0.20 ml/week	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weeks. **Addressing incomplete outcome data:** They mention drop-outs and reasons for it but do not say which group had missing data. ITT and per protocol. The authors state that they did a sensitivity analysis where trend of each drop out was extrapolated using the same group **Statistical analysis:** Kaplan-Meier to calculate wound survival times and Cox proportional hazards analysis to calculate the ratio of the wound closure probabilities per unit time. **Baseline differences:** the control group had a greater proportion of patients with very large ulcers which might be a prognostic disadvantage in survival analysis. Prognostic baseline covariates grouped in cogent clusters and used	ineligible. **Group 1** **Randomised N:** 43 **Completed N:** 35 **Dropouts:** 8 Wound status: bad 34.9%, normal 58.1%, good 7.0%. Nutritional status: bad 69.8%, normal 30.2% Vitamin C: </=2mg/l 25.6%, 2-4mg/l 37.2%, >4mg/l 37.2%. Mobility: bad 16.3%, normal 60.5%. Subcutaneous cushioning: bad 16.3%, normal 83.7%. Care level: bad 37.2%, normal 62.8% Concomitant diseases: bad 20.9%, normal 79.1%, overall pressure ulcer status 65.1%, normal 34.9% **Group 2** **Randomised N:** 45 **Completed N:** 28 **Dropouts:** 17 Wound status: bad 33.3%, normal 48.9%, good	Patients were on water beds and repositioned once every 3 hours. Flotation pads were provided if patients were sat up. Patients received wound care once (or exceptionally twice) daily. Debridement was performed when indicated. Ulcers were covered with paraffin and hydrophilic gauze. Topical antibiotics were left to the treating physician but discouraged by authors of study.		Difference: -0.20ml/week	
			Outcome 4: mean volume reduction (%/wk)	Group 1: -3.39 Group 2: 16.71 Intervention minus control -20.10 Adjusted difference (PI 90% precision interval): 35.33 (-74.58 to 3.91)	
			Outcome 5: mean healing velocity (cm/wk)	Group 1: 0.12 Group 2: 0.19 Intervention minus control -0.08 Adjusted difference (PI 90% precision interval): -0.05 (-0.13 to 0.03)	
			Outcome 6: mean clinical change where improvements (surface reduction, healing velocity, volume reduction) scored on a scale from 100 to +100%:	Group 1: 17.89%/week Group 2: 26.08%/week Difference: -8.19%/week	
			Outcome 7: all cause mortality	Group 1: 3/43 (6.98%) Group 2: 5/45 (11.1%) RR: 0.63 95% CI: 0.16 to 2.47	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
in the analysis to control for confounders. Baseline similarity for these cluster variables was good for five of eight clusters, leaving some room for confounding. The authors used the clusters in a multivariate analysis to correct for potential confounding and found that the adjusted differences were close to the crude ones. **Study power/sample size:** n=88, no sample size calculations given **Setting:** 11 nursing homes and 1 hospital in the South of the Netherlands **Length of study:** 12 weeks **Assessment of PUs:** Slides were made and projected and wound contours drawn and scanned into computer, where surface area was calculated by computer programme. If possible	17.8% Nutritional status: bad 69.8%, normal 30.2%. Vitamin C: </=2mg/l 26.7%, 2-4mg/l 24.4%, >4mg/l 48.9% Mobility: bad 42.2%, normal 57.8% Subcutaneous cushioning: bad 22.2%, normal 77.8% Care level: bad 33.3%, normal 66.7%. Concomitant diseases: bad 20.0%, normal 80.0%. Overall pressure ulcer status: bad 77.8%, normal 22.2% **Inclusion criteria:** pressure ulcers with partial thickness skin loss or worse. If there were multiple ulcers they preferred ulcers located on the trunk and then chose the most serious one. **Exclusion criteria:** difficulties with swallowing or frequent vomiting, osteomyelitis in				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ulcer volumes were measured by Berg et al (1990)'s method. **Classification of PUs:** not stated, says that recruited patients with pressure ulcers with partial thickness skin loss or worse. **Multiple ulcers:** would use ulcers located on the trunk first and second would choose most serious PU.	the ulcer area, idiopathic hemochromatosis, thalassemia major, sideroblastic anemia, Cushing's syndrome or disease, pregnancy, radiotherapy in the ulcer area, and the use of antineoplastic agents or systemic glucocorticosteroids. A high probability to drop out within the 12-week follow-up period (terminally ill patients, patients for whom surgical treatment of the ulcer – other than debridement – had been planned) also led to exclusion; patients who were already taking vitamin C supplements in excess of 50mg/day; patients with grade II ulcers (partial thickness skin loss) could participate only if de-epithelialisation had persisted for at least 7 days without interruption; patients with leg ulcers had to have a positive history of pressure on that site to be				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	eligible.				

Table 113: Norris 1971[165]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Norris 1971[165] **Title:** The effect of oral zinc sulphate therapy on decubitus ulcers Journal**:** J. Am Geriatr. Soc. 1971, 19(9), 793-797 **Type of study**: double-blinded crossover RCT. **Sequence generation:** no details of how generated **Allocation concealment:** tablets were packaged in separate containers by the hospital pharmacy and labelled Zincate A and Zincate B. The physicians and the nursing staff did not know the exact contents of these capsules until completion. **Blinding:** identical appearing capsules	**Patient group:** patients with decubitus ulcers **All patients** **Randomised N:** 14 **Completed N:** 3 **Drop-outs:** 11 - ulcer healed (2); died (7); transferred to surgery (1); discharged home (1). 6 of these 11 patients were in the study for 12-16 weeks. 10/14 received zinc sulphate for 4-12 weeks and 8 received only placebo for 4-12 weeks. Patients who received placebo for less than 4 weeks following 12 weeks of zinc sulphate were not included in the calculations for the control group due to 'probably spillover effect from the zinc therapy. Age range: 26-88 years	**Group 1:** oral zinc sulphate (200mg) capsules 3 times per day. **Group 2:** placebo	**Outcome 1:** mean net change of ulcer volume	**Group 1:** 10.1ml (s.d 9ml) (10 patients) **Group 2:** 6.0ml (s.d 17.5ml) (10 patients) T value in comparing the means: NS (0.7</=p</=0.8) Weighted Mean Difference: 4.1ml 95%CI: -8.10 to 16.30, p=0.5	**Funding:** C.R Canfield and Company (supplied the zinc sulphate and defraying incidental costs). **Limitations:** Very small study. No details of sequence generation and a high drop-out rate. Many patients died (7) but do not know which arm of the crossover this occurred. Crossover study but no washout period. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: gives details of reasons patients dropped out but unclear which arm of trial when discontinued. Did not use ITT analysis, but assessed volume in 10 patients receiving oral zinc sulfate therapy for 4-12 weeks and in 8 receiving placebo for 4-12 weeks. **Statistical analysis:** no tests mentioned **Baseline differences:** N/A **Study power/sample size**: very small (14 patients) **Setting:** The Chronic Disease Hospital of Baltimore City Hospitals (a 320 bed unit for the care of patients with chronic disease and those with geriatric problems) **Length of study:** 24 weeks (12 weeks then crossed over for another 12 weeks)	M/F: 9/5 **Group 1** **Randomised N:** 7 **Completed N:** unclear **Dropouts:** unclear **Group 2** **Randomised N:** 7 **Completed N:** unclear **Dropouts:** unclear **Inclusion criteria:** all hospital patients with decubitus ulcers **Exclusion criteria:** those with neoplastic disease or those in the terminal phase of their illness; case with superficial ulcers or deep sinus tracts excluded because the authors thought that the volume measurements would be inaccurate. Patients had: brain damage after head injury (1), senile dementia (1), subdural hematoma (1),				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of ulcers: Volume assessed by filling ulcers with a rapidly-setting alginate hydrocolloid (Jeltrate). After solidification ulcer volume determined by immersing Jeltrate impression in a graduated cylinder and measuring the displacement of water in millimeters (adaptation of Pories et al method) **Classification of ulcers:** not reported **Multiple ulcers:** not reported	paraplegia (4), multiple sclerosis (2), cerebral thrombosis (1), poliomyelitis (1), quadriplegia (1), brain damage after cardiac arrest (1), rheumatoid arthritis; amputee (1).				

Table 114: Taylor 1974[218]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Taylor 1974[218] **Title:** Ascorbic acid supplementation in the treatment of pressure sores Journal**:** Lancet, 1974, 2(7880), 544-546. **Type of study:** double-blind quasi-randomised controlled trial **Sequence generation:** allocated to treatment groups A or B according to their year of birth. **Allocation concealment:** no details **Blinding:** identical white tablets were used. The data were analysed by an independent blinded observer. **Addressing incomplete outcome data:** no details given on drop-outs. **Statistical analysis:** no mention of statistical tests. **Baseline differences:** no differences	**Patient group:** surgical patients with a pressure sore. **All patients** **Randomised N:** 20 **Completed N:** 18 **Drop-outs:** 2 (patients died – one in each group) Diagnosis: 9 had fractured neck of femur, 2 had rheumatoid arthritis or cerebrovascular accident, and one patient had fractured pelvis, peripheral vascular disease, paraplegia, gastric ulcer, benign prostatic hypertrophy, diverticular disease and aortic aneurysm. Gender: 8 males and 12 females. Age mean (range): 74.5 years (54-88 years). **Group 1** **Randomised N:** 10 **Completed N:** 9 **Dropouts:** 1 Age (mean): not reported	**Group 1:** basic hospital diet plus 500mg ascorbic acid (twice daily). **Group 2:** basic hospital diet plus placebo.	**Outcome 1:** mean % (SE) reduction in area at one month	**Group 1:** 84% (SE 7.60) **Group 2**: 42.7% (SE 7.41) Relative risk: Weighted Mean Difference 41.30 95% CI: 34.72 to 47.88 p<0.005	**Funding:** Joint Research Board of the Institute of Child Health and the Hospital for Sick Children, and the Department of Health and Social Security. **Limitations:** quasi-randomised using year of birth. No details allocation concealment. **Additional outcomes:**
			Outcome 2: completely healed pressure sores	**Group 1:** 6/9 (66.67%) ACA, 6/10 ITT **Group 2:** 3/9 (33.33%) ACA, 3/10 ITT Relative risk: 2.00 95% CI: 0.68 to 5.85	
			Outcome 3: mean rates of healing	**Group 1:** 2.47 cm2 per week **Group 2:** 1.45 cm2 per week Relative risk: 95% CI:	
			Outcome 4: all cause mortality	**Group 1:** 1/10 **Group 2:** 1/10 Relative risk: 1.00 95% CI: 0.07 to 13.87	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: very small (20 patients), no sample size calculation. **Setting:** Surgical ward UK **Length of study:** one month **Assessment of PUs**: areas assessed by one of the researchers clinically, by pressure-area tracings and by weekly photographic assessment. **Classification of PUs:** not reported **Multiple ulcers:** not reported	separately Other baseline data: not reported separately Group 2 Randomised N: 10 Completed N: 9 Dropouts: 1 Age (mean): not reported separately Other baseline data: not reported separately **Inclusion criteria:** surgical patients with a pressure sore. **Exclusion criteria:** not stated.				

Table 115: Desneves 2005[68]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Desneves 2005[68] **Title:** Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomised controlled trial Journal**:** Clin. Nutr. 2005, 24(6), 979-987. **Type of study:** randomised controlled trial **Sequence generation:** randomly assigned into one of 3 groups sequentially by order recruited. Sequence determined before trial by list of random numbers generated by a computer program) in numerical order. **Allocation concealment:** no details **Blinding:** No details of blinding of patients and those administering treatments. Pressure ulcer assessors blinded. **Addressing incomplete**	Patient group: Inpatients from aged care or spinal injury wards with either stage 2,3 or 4 pressure ulcer. All patients Randomised N: 16 Completed N: 13 Drop-outs: 3 Age (range): 37-92 years. BMI (range): 16.4-28.1kg/m2 Group 1 Randomised N: 6 Completed N:5 Dropouts: 1 (died after completion of assessment at week 2) Age (mean and SEM): 6.30 (SEM 9.9) BMI (kg/m2 and SEM): 24.4 (1.0) Weight (kg and SEM): 63.0 (2.6) Males/females: 4/2 Diagnosis: Dementia: 0	Group 1: Standard hospital diet plus 2 tetrapaks of a defined arginine-containing supplement (providing an additional 500kcal, 21g protein, 0g fat, 500mg vitamin C, 30mg zinc and 9g arginine. (diet C). Group 2: Standard hospital diet plus 2 tetrapaks of high-protein, high-energy supplement (providing additional 500kcal, 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc) (diet B). Group 3: Standard hospital diet (diet A) Pressure ulcer care including turning schedules, bed and mattress type and dressings were kept constant during the study period.	Outcome 1: improvement in pressure ulcer healing (change in PUSH tool scores from baseline)	Group 1: -1.7 (baseline: 8.7 (1.0) and week 3: 7.0 (1.5) Group 2: -2.0 (baseline 8.0 (0.5) and week 3: 6.0 (1.2) Group 3: -6.8 (baseline: 9.4 (1.2) and week 3: 2.6 (0.6) P<0.05 (diet C compared to diet A or B)	Funding: Research grant from the Windermere Foundation Ltd. Limitations: Very small study. No details of allocation concealment or blinding of patients or those administering treatment. Did not screen for malnutrition at start of study but transthyretin levels were normal which the authors say suggest they were not severely malnourished. Additional outcomes: actual dietary intake, changes in body weight, blood biochemistry, dietary compliance.
			Outcome 2:	Group 1: Group 2: Relative risk: 95% CI:	
			Outcome 3:	Group 1: Group 2: Relative risk: 95% CI:	
			Outcome 4:	Group 1: Group 2: Relative risk: 95% CI:	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: adequate. **Statistical analysis:** within-group changes using the Friedman test with between-group comparisons using the Mann-Whitney U-test. Differences in baseline measures tested by one-way ANOVA. Repeated-measures ANOVA testing used to calculated differences in weight changes and biochemical parameters Baseline differences: BMI significantly lower for Diet C compared to Diet A or B. **Study power/sample size:** small. No sample size calculation given. **Setting:** Inpatients in Australia **Length of study:** 3 weeks **Assessment of PUs:** PUSH tool. **Classification of PUs:** Staging according to the Australian Wound	Cerebrovascular accident:3 Spinal cord injury:1 Parkinson's disease:0 Chronic cardiac failure:0 Fractured bones: 1 Pressure ulcers (alone):1 Initial stage of pressure ulcer: Stage 2: 4 Stage 3:2 Stage 4:0 Pressure ulcer location: Heel: 2 Sacrum:1 Perineal:1 Ischium:0 Ankle:1 Toe:1 Group 2 Randomised N: 5 Completed N:5 Dropouts:1 (died after completion of assessment at week 2) Age (mean and SEM): 75.6 (5.9) BMI (kg/m2 and SEM):25.6 (0.8)				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Management Association Clinical Practice Guidelines. Assessment of diary intake: daily food and fluid record **Multiple ulcers:** not reported	Weight (kg and SEM): 68.8 (5.8) Males/females: 3/2 Diagnosis: Dementia: 1 Cerebrovascular accident:1 Spinal cord injury:0 Parkinson's disease:0 Chronic cardiac failure:2 Fractured bones: 1 Pressure ulcers (alone):0 Initial stage of pressure ulcer: Stage 2: 5 Stage 3:0 Stage 4:0 Pressure ulcer location: Heel: 2 Sacrum:1 Perineal:0 Ischium:1 Ankle:1 Toe:0 Group 3: Randomised N: 5 Completed N:5 Dropouts:1 (discharged				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	after completion of assessment at week 2) Age (mean and SEM): 83.2 (1.1) BMI (kg/m2 and SEM): 20.6(1.5) Weight (kg and SEM): 59.5 (8.7) Males/females: 3/2 Diagnosis: Dementia:0 Cerebrovascular accident:2 Spinal cord injury:1 Parkinson's disease:1 Chronic cardiac failure:0 Fractured bones: 1 Pressure ulcers (alone):0 Initial stage of pressure ulcer: Stage 2: 3 Stage 3:1 Stage 4:1 Pressure ulcer location: Heel: 1 Sacrum:3 Perineal:0 Ischium:1 Ankle:0 Toe:0				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Inclusion criteria: Inpatients on aged care or spinal injury wards with stage 2, 3 or 4 pressure ulcer. Exclusion criteria: Clinical suspicion or diagnosis of osteomyelitis as it can cause skin ulcers with a different aetiology to pressure ulcers; patients with diabetes mellitus, individuals receiving enteral or parenteral nutrition support or individuals prescribed hydroxyurea or greater than 10mg of steroids/day as these factors inhibit wound healing.				

Table 116: Cereda 2009[45]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cereda 2009[45] **Title**: Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalised older adults: a randomised controlled trial **Journal:** J. Am. Geriatr. Soc, 2009, 57(8), 1395-1402. Type of study: multicentre RCT Sequence generation: computer-generated randomisation list. Allocation concealment: no details. Blinding: nurse and pressure ulcer assessor were blinded to the interventions. Addressing incomplete outcome data: adequate, 2 patients in the treatment group died and the final analysis consisted of 28 patients which did not	Patient group: elderly participants with stage II, III and IV pressure ulcers of recent onset (<1 month history). All patients Randomised N: 30 Completed N: 28 Drop-outs: 2 patients Group 1 Randomised N: 15 Completed N=13 Dropouts: 2 patients died within first 4 weeks of follow-up period (days 15 and 22) Age (mean+/-sd):82.2+/-9.6 BMI g/m2 (mean+/-sd):20.8+/-3.2 Oral feeding:tube feeding: 4:9 Diagnoses, n: Vascular dementia: 4 Alzheimer's disease: 3 Cerebrovascular accident: 4	Group 1: Disease-specific nutritional treatment - standard hospital diet plus 400mL oral supplement (500kcal, 34g protein, 6g arginine, 500mg vitamin C, 18mg zinc or tube fed 1000mL high-protein formula (20% energy from protein, enriched with arginine, zinc and vitamin c). Group 2: standard hospital diet (16% energy from protein) without any additional supplement or tube fed standard formula (standard formula satisfied protein requirements) Both groups received nutritional support of at least 30kcal/kg per day regardless of feeding method – no modification was made for patients receiving above this prior to the study. Additional wound care for both groups: reduction in pressure, turning and repositioning program (dynamic air mattress or gel cushion). Topical	Outcome 1: pressure ulcer healing (mean reduction in pressure ulcer area) at week 12 (mean +/- s.d) mm2	Group 1: -1450 +/- 803 Group 2: -841 +/- 559 MD: p<0.005	Funding: No direct funding, Nutricia provided the supplements. Limitations: study is very small. No details of allocation concealment of the randomisation list. Additional outcomes: Change score for PUSH. Notes: nutritional intervention can only be considered effective if it produces a reduction of 20% to 40% in the PPU in the first 4 weeks (Frias 2004) Have taken results for week 12 but was reported at different time points.
			Outcome 2: pressure ulcer healing (PUSH score) at week 12 (mean+/-s.d)	Group 1: 7.4+/-3.4 Group 2: 10.7+/-3.4 Relative risk: 95% CI: P<0.05	
			Outcome 3: complete healing	Group 1: 1/13 (7.7%) ACA Group 2: 0/15 (0%) ACA Relative risk (Peto odds ratio): 8.62 95% CI: 0.17 to 438.70	
			Outcome 4: % reduction in pressure ulcer area at 12 weeks	Group 1: 72% Group 2: 45% P=0.05	
			Outcome 5: all-cause mortality	Group 1: 2/15 Group 2: 0/15 Peto OR 7.94 (0.47 to 133.26)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
include these 2 patients. ACA. Statistical analysis: Differences in proportions were assessed with the Chi-square or fisher exact test; Comparisons of between–group and within–groups were performed using unpaired and paired student t-tests. Mann-Whitney U-test was used for nonhomogenous ANOVA. Baseline differences: no significant differences except 10 in the treatment group and 5 in the control group had more than one lesion (p=0.03) Study power/sample size: very small sample size (28 patients), no sample size calculation given. Setting: long-term facilities in Como, Italy Length of study:12 weeks follow-up	Psychiatric disorders: 2 MS: 0 Pressure ulcers, n: Stage II:2 Stage III:4 Stage IV:7 Group 2 Randomised N: 15 Completed N:15 Dropouts: 0 Age (mean+/-sd):81.4+/-9.9 BMI g/m2 (mean+/-sd):23.1+/-5.0 Oral feeding:tube feeding: 6:9 Diagnoses, n: Vascular dementia: 5 Alzheimer's disease: 2 Cerebrovascular accident: 5 Psychiatric disorders: 2 MS: 1 Pressure ulcers: Stage II:3 Stage III:4 Stage IV:8	treatments, antibiotic therapy, systemic therapy. Total dietary adherence: Treatment group: 94.7% Control group: 94.3% All patients reached 85% or greater proposed cut-off.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Pressure Ulcer Scale for Healing (PUSH) tool and area measurement Classification of PUs: NPUAP staging system Multiple ulcers: the most severe pressure ulcer was included	Inclusion criteria: residents in long-term care aged 65 and older; stage II, III or IV lesions as assessed according to NPUAP staging system; patients fed orally and by feeding tubes. Exclusion criteria: presence of acute illness (e.g infection) or chronic disease (eg diabetes mellitus, peripheral vascular disease, autoimmune or neoplastic disorders) possibly affecting the nutritional intervention and healing process, positive culture from pressure ulcer swab sampling, use of immunosuppressive therapies, development of the lesion more than 1 month before evaluation, and lack of dietary adherence (<85% of prescription).				

Table 117: Meaume 2009[140]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Meaume 2009[140] **Title**: Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomised controlled trial Type of study: multi-centre double-blinded RCT Sequence generation: randomised in blocks of four, randomisation codes generated by using computer. A randomisation no. attributed to chronological order of entry of patients into the double-blind period within each investigational site. Allocation concealment: adequate Blinding: placebo had similar aspect and taste. Investigators and assessors were blinded.	Patient group: hospitalised or outpatient elderly patients All patients Randomised N: 165 Completed N: 93 Drop-outs: 72 Group 1 Randomised N: 89 Completed N: 45 Dropouts:44 Age (mean):80.8+/-8.8 years (ITT) Sex (m/f): 34.1/65.9 BMI: 27.1+6.5 Ulcer area (cm2): mean 8.7+/-6.7 Median: 6.6 Min-Max: 0.71-39.05 Log-transformed ulcer area: 0.816+/-0.349 >8 area </=12cm2: 18.8% Group 2 Randomised N: 76 Completed N:43	Group 1: one 10g sachet of ornithine alpha-ketoglutarate Group 2: one sachet of placebo Both sachets given during or after lunch, preferably in 200ml of water or mixed with food. Other ulcer management included mechanical debridement, cleaning, heel elevation, dressings, heel offloading with a suspension boot, management of pain with analgesics and topical corticosteroids and topical antibacterials for excessive granulation tissue. Compliance tested with by collecting treatment kits.	Outcome 1: wound area changes at week 6	Group 1: -2.3+/-4.2cm2 Group 2: -1.7+/-1.cm2 p=0.006	Funding: grant from CHIESI France and Italy. Limitations: well-reported trial with clear details of methodology. Study powered for 70 in each arm which was met for studies randomised but there was a very high drop-out rate in both arms. Due to difficulties in patient recruitment the study was opened to many more centres than initially planned and 2 or 3 of the centres recruited no more than 2 patients while randomisation was balanced by blocks of four. Randomisation did not balance
			Outcome 2:% regression in wound area	Group 1:-59.5+/-71.4% Group 2:-54.0+/-69% Relative risk: p=0.477	
			Outcome 3: >90% regression by week 6	Group 1:23.4% Group 2:13.0% OR: 0.49 95% CI: 0.16/1.46	
			Outcome 4: adverse events in patients	Group 1: 13/85 Group 2: 7/75	
			Outcome 5: severe adverse events in patients (all were considered unrelated to study treatment by investigators)	Group 1: 13/85 Group 2: 15/75	
			Outcome 6: Mortality (unrelated to drug):	Group 1: 5/89 (5.6%) Group 2: 3/76 (3.9%) Relative risk: 1.42 95% CI: 0.35 to 5.76	
			Outcome 7: Rate of complete healing at week 6	Group 1: -0.07 +/-0.11cm2/day Group 2: - 0.04 +/- 0.08 cm2/day	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: adequate Type of analysis: ITT on efficacy analyses – who take at least one dose of study medication and who had at least one post-treatment evaluation. LOCF applied to deal with missing efficacy time-points. Statistical analysis: ANCOVA (age, history of lesion and patients weight as covariates). Baseline differences: more males in OKG than placebo group; significant difference in ulcer area. Study power/sample size: power calculations 70 patients per group based on previous studies of OKG in pressure ulcer treatment. Setting: 67 investigational centres in six European countries.	Dropouts: 33 Age (mean):80.5+/-9.6 Sex (m/f): 52.6/47.4, p=0.017 BMI: 26.7+5.9 Ulcer area (cm2): mean 8.2+/-8.9 Median: 3.9, p=0.044 Min-Max: 0.23-48.14 Log-transformed ulcer area: p=0.027 >8 area </=12cm2, p=0.001 Inclusion criteria: males or females over age of 60 years; heel pressure ulcer (NPUAP stage II or III) occurring after accidental immobilisation; ulcer in process of recovery with early signs of granulation tissue (at least 10% of red tissue on colour scale). Exclusion criteria: patients confined to bed 24 hours a day before the episode triggering development of the pressure ulcer; pressure ulcer entirely covered by necrosis or		(cm2/day)	P=0.007	baseline pressure ulcer characteristics and ulcer area distribution deviated from normal distribution as healing is strongly related to baseline ulcer are the abnormal distribution was a major bias so was subgrouped. Additional outcomes: particular adverse events.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 6 weeks Assessment of PUs: assessed once a week for 6 weeks. Classification of PUs: NPUAP Multiple ulcers: not reported	fibrin, infected ulcer; poorly controlled type I or II diabetes, dialysed patient, active neoplastic disease; parenteral nutrition; serum albumin <22g/l; advanced peripheral arterial occlusive disease [[ABPI (ankle brachial pressure index)ranging between 0.80 and 1.3 with presence of distal pulses]				

Table 118: Ohura 2011[167]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ohura 2011[167] **Title**: Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomised controlled trial) **Journal:** Wound Repair Regen, 2011, 19(3), 330-336. Type of study: open randomised controlled	Patient group: tube-fed patients with stage III-IV pressure ulcers (NPUAP classification) in the sacral, occygeal, trochanteric or calcaneal region. All patients Randomised N: 60 Completed N: 50 Drop-outs: 10	Group 1: received calories according to the range of Basal Energy Expenditure (BEE, calculated from the Harris-Benedict equation) x active factor 1.1 x stress factor 1.3-1.5. Group 2: same nutrition management as before trial. Both groups prior to study underwent a preparation period of 10 days or less to	Outcome 1: Number of pressure ulcers healed within 12 weeks	Group 1: 7/21 (33.3%) Group 2: 4/29 (13.8%) Relative risk: 2.42 95% CI: 0.81 to 7.21	Funding:The Health and Labor Sciences Research Grants (Comprehensive Research on Aging and Health) Limitations: no blinding. High differential drop-out . Additional outcomes (list
			Outcome 2: changes in size of pressure ulcers over time (at 12 weeks)	Group 1: 1.32 (0.24) Group 2: 0.32 (0.2) MD 0.99 95% CI: 0.86 to 1.12	
			Outcome 3: study-related adverse events	Group 1:8/29 ITT minus one who did not have treatment. Group 2:5/30 ITT Relative risk: 1.66	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
trial Sequence generation: Minimisation used Allocation concealment: minimisation method in the central enrolment centre. Blinding: none (open) Addressing incomplete outcome data: authors specified which group and the reason for exclusion. These were not included in the analysis. Statistical analysis: Wilcoxon's rank sum test (0.15 significance level, two-sided). ANOVA for efficacy parameters. Fisher's exact test for adverse events. For size of pressure ulcers analyses were performed on log-transformed data. Baseline differences: no significant differences Study power/sample size: small, no sample size calculation Setting: Japan	Group 1 Randomised N: 30 Completed N: 21 Dropouts: 9 Age (mean and range): 81.4+/-8.13 (62-95) Sex (m/f): 6/15 BMI (mean +/-SD) and range: 18.60+/-4.04 (14.0-32.3) Group 2 Randomised N: 30 Completed N: 29 Dropouts: 1 Age (mean and range): 80.6+/-8.91 (58-95) Sex (m/f): 10/19 BMI (mean +/-SD) and range:17.11+/-2.56 (10.9-20.9) Inclusion criteria: albumin (Alb) 2.5-3.5g/dL, OH scale 8.5 or lower and Braden scale 9-17. Exclusion criteria: current condition or history of serious liver or renal disorder, severe diabetes mellitus, arteriosclerosis	adjust to a switch in their feeding formula to Racol - this formula contained protein 4.38g, fat 2.23g, and carbohydrate 15.62g, all per 100mL of product. The ratio of omega 3 to omega 6 essential fatty acids is 1:3 in this formula, which also includes Cu 125ug, and Zn 0.64mg. The day when the calories supplied by the feeding formula reached the pre-specified value was defined as the start of the intervention period. Patients treated according to the Guidelines for Local Treatment of Pressure Ulcers. Only wound dressing materials in general were used in this study. Use of therapeutic ointments limited to agents such as bucladesine sodium or alprostadil alfadex, antibacterial agents. Use of trafermin was prohibited. All patients used the ADVAN pressure release mattress and body position was changed every 2 hours daily. Study representative and nursing staff went round all		95% CI: 0.61 to 4.47	additional outcomes reported in paper but not recorded in this table): changes in size of pressure ulcers at 8 weeks and at ten weeks. Also changes in size of pressure ulcers over time (stratified by median)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 10 days preparation, 12 weeks intervention period. When pressure ulcer resolved patient was removed from the study. Assessment of PUs: diagnosis and healing process determined based on NPUAP classification and DESIGN tool for evaluation (Japanese evaluation tool for pressure ulcers: depth, exudates, size, inflammation/infection, granulation tissue, necrotic tissue and undermining) as well as the size (length x width) and depth of pressure ulcers. The Braden scale and the OH scale were also used for observation Classification of PUs: NPUAP staging system Multiple ulcers: not reported	obliterans, or a malignant tumor (within the past 5 years); patients with unmanageable severe general condition or unevaluable pressure ulcer wounds (existence of necrotic tissue in 20% or more of the wound surface, wound before sharp debridement, 2cm or more in depth of the undermining, multiple pressure ulcers and wound infection).	wards to ensure consistency of nursing and care. Nursing staff were trained in how to eliminate body pressure and shear force for each patient using the 'Hand touching method'.			

Table 119: Lee 2006[131]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Lee 2006[131] **Title**: Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomised controlled trial **Journal:** Advances in skin and wound care, 19 (2), 92-96. Type of study: double-blinded multicentre RCT Sequence generation: the first patient in each building was randomised to red or white group by research assistant using the flip of a coin. Following assignments were made by alternating between the two groups. Allocation concealment: no details of who held the randomisation schedule. Blinding: Placebo was a non-caloric liquid indistinguishable from	Patient group: residents of long-term care facilities with stage II, III or IV pressure ulcers All patients Randomised N: 89 Completed N: 71 Drop-outs: 18 (11 had AEs including 2 deaths), 5 left facilities before end of trial, 2 died from causes unrelated to the study) Group 1 Randomised N: 56 Completed N: 44 Dropouts: 12/56 (21.5%) Age (mean): no details Weight (lbs) mean (SD): 157 (39.2) BMI (kg/m2) mean (SD): 27 (8.8) Kilocalories (kcal): 1381 (484.1) Protein (g): 55 (18) BUN (mg/dL): 25.2 (15.81) Creatinine (mg/dL): 0.94	Group 1: standard care plus a concentrated, fortified, collagen protein hydolysate supplement Group 2: standard care plus placebo.	Outcome 1: PUSH tool scores at 8 weeks (a measurement of pressure ulcer healing) mean +/- s.d	Group 1: 3.55 +/-4.66 Group 2: 3.22 +/-4.11 MD 0.33 95% CI: -1.74 to 2.4 P<0.05	Funding: medical nutrition USA and one of authors is consultant for this company. Limitations: small sample size. Not clear which group had adverse events and drop-outs. Additional outcomes: wound healing over time (mean push tool score) at weeks 0,2,4 and 6.
			Outcome 2: % reduction in PUSH tool score (change scores)	Group 1: 60% Group 2: 48% MD 12% P<0.05	
			Outcome 3: all cause mortality	Group 1: 1/56 (1.8%) Group 2: 1/33 (3%) Relative risk: 0.59 95% CI: 0.04 to 9.11	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
the study produce in colour, taste and texture. The placebo and intervention packaged in identical opaque white, unit-dose bottles differentiated by a numeric code and a red dot or no dot on the label. Staff were unaware of the numeric code or the meaning of the colours. Addressing incomplete outcome data: analysed all who completed study. Authors state how many discontinued and reason but do not state from which group they dropped out from. Statistical analysis: Chi-square was conducted to compare frequency of PU stage by groups. T-test to compare mean supplement intake per group. ANOVA with repeated measures calculated to compare PU healing in the treatment and control groups.	(0.469) Group 2 Randomised N: 33 Completed N: 27 Dropouts: 6/33 (18%) Age (mean): no details Weight (lbs) mean (SD): 160 (55.4) BMI (kg/m2) mean (SD): 27 (7.9) Kilocalories (kcal): 1279 (520.9) Protein (g): 47 (29.4) BUN (mg/dL): 21 (16.36) Creatinine (mg/dL): 0.88 (0.498) Authors state that there were no significant differences between the 2 groups on the baseline characteristics (weight, BMI, kilocalories, protein, blood urea nitrogen and creatinine). Inclusion criteria: patients from long term care facilities with stage II, III or IV pressure ulcers. They				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: no significant differences. Study power/sample size: small, no sample size calculation given. Setting: LTC facilities, New York, New Jersey, Ohio and Indiana Length of study: 8 weeks Assessment of pressure ulcer healing – PUSH tool used by nurses trained in the use of the tool Classification of PUs: NPUAP staging system Multiple ulcers: not reported	were selected from a convenience sample from 23 LTC facilities in New York, New Jersey, Ohio and Indiana; Exclusion criteria: terminal diagnosis, hospice care, a protein-restricted diet due to renal insufficiency, active metabolic or gastrointestinal diseases that might interfere with nutrient absorption, distribution, metabolism, or excretion (eg Crohn's disease, bowel resection, ileus, or dumping syndrome), food allergies, use of corticosteroids or antibiotics for wound infection.				

Table 120: Van Anholt 2010[231]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Van Anholt 2010A[231] **Title**: Specific nutritional support accelerates pressure ulcer healing and reduces wound care intensity in non-malnourished patients **Journal:** Nutrition, 2010, 26(9), 867-872 Type of study: multicountry, randomised, controlled, double-blind, parallel group trial Sequence generation: no details, states randomly allocated. Allocation concealment: no details. Blinding: placebo was similar in taste and appearance. Addressing incomplete outcome data: In case of drop-outs the parameters of the remaining time-points were set at 'missing'. ITT analysis. Statistical analysis:	Patient group: non-malnourished patients with stage III or IV pressure ulcers All patients Randomised N:47 Drop-outs: 4 before consuming anything but does not say from which group, so ITT number 43. Group 1 Randomised N: 22 Completed N: 17 Dropouts: 5 Age (mean): 76.2+/-3.2 Males/females: 8/14 Body weight (kg):66.3+/-4.5 BMI (kg/m2): 23.7+/-1.0 Ulcer location: Heel:8 Ischium:2 Sacrum:8 Trochanter:4 Ulcer size (cm2):10l5+/-2.3 Ulcer stage:	Group 1: 200ml of the specific ONS (200mL high energy supplement (250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, 238mg vitamin A, 250 mg vitamin C, 38mg vitamin E, 1.5mg carotenoids, 9mg zinc, 64ug selenium, 1.35mg copper, 200ug folic acid) three times per day plus regular diet and standard wound care Group 2: non-caloric control product three times per day plus regular diet and standard wound care Standard nutrition diets and wound care were maintained according to the locally used protocols.	Outcome 1: reduction in pressure ulcers size by time (8 weeks – study period)	Group 1: 8.4 cm2/week Group 2: 8.75 cm2/week Treatment by time: P=0.006 RMMM treatment by time2: p=0.016	Funding:Nutricia Advanced Medical Nutrition Limitations: inclusion to study stopped early due to limited availability of patients who fulfilled the inclusion criteria. It was underpowered (100 subjects was originally required). Additional outcomes (list additional outcomes reported in paper but not recorded in this table): compliance, total number of dressings applied; Average time spent per week applying dressings; Tissue types (granulated, necrotic, closed, epithelial); gastrointestinal
			Outcome 2:PUSH scores by time (8 weeks – study period)	Group 1: 6 Group 2: 5.4 MD: 0.6 Treatment by time: P=0.011 RMMM treatment by time2: p=0.033	
			Outcome 3: adverse events related to the product	Group 1: 9/22 (40.9%) Group 2: 4/21 (19%) RR 2.15 95% CI: 0.78 to 5.92	
			Outcome 4: incidence of diarrhoea	Group 1: 6/22 (27.3%) Group 2: 2/21 (9.5%) RR 2.86 95% CI: 0.65 to 12.64	
			Outcome 5: incidence of nausea	Group 1: 1/22 (4.5%) Group 2: 1/21 (4.8%) RR 0.95 95% CI: 0.06 to 14.3	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Repeated-measures mixed models (RMMM) used to compare changes in time between treatments. Data adjusted for center and baseline by including these as covariates in analysis. Baseline measurements and blood parameters analysed by ANOVA. Fisher's exact test for categorical variables. Baseline differences: no statistically significant differences Study power/sample size: small (47 randomised) Setting: 8 health care centres, hospitals and long-term care facilities in four countries (Czech Republic, Belgium, The Netherlands, and Curacao). Length of study: 8 weeks Assessment of PUs: healing: measured maximum length and width of ulcer with a ruler. Assuming surface	Stage 3:17 Stage 4:5 PUSH tool (total score):11.5+/-0.7 Group 2 Randomised N: 21 Completed N: 15 Dropouts: 6 Age (mean): 73.0+/-3.3 Males/females:11/10 Body weight (kg):75.6+/-5.3 BMI (kg/m2): 25.8+/-1.1 Ulcer location: Heel:8 Ischium:0 Sacrum:8 Trochanter:5 Ulcer size (cm2):11.5+/-2.5 Ulcer stage: Stage 3: 14 Stage 4:7 PUSH tool (total score):11.4+/-0.7 Inclusion criteria: aged 18 to 90 years; at least one				tolerance (varied from zero to four per time point in the study).

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
area had an ellipse form they calculated the formula: length/2x width/2 x 3.14 [15.24]. The Pressure Ulcer Scale for Healing (PUSH tool) was used as a secondary parameter. Assessment of other parameters: volume consumed recorded in a diary. Tolerance (gastrointestinal) was assessed weekly by standardised questionnaires. Classification of PUs: EPUAP and NPUAP 2009 classification Multiple ulcers: If multiple pressure ulcers the local investigator selected one representative ulcer to be assessed throughout the study.	stage III to IV pressure ulcer according to the revised EPUAP classification system; receiving standard care and a standard (institutional) diet without nutritional supplements for at least 2 weeks before the study; Exclusion criteria : malnourished patients as indicated by a BMI below 18.5kg/m2 for patients 18 to 70 years old or a BMI below 21kg/m2 for those older than 70 years; severe medical conditions, non-pressure-related ulcers (e.g diabetic ulcers), life expectancy shorter than 6 months; receiving palliative care; use of corticosteroids and/or dietary restrictions e.g a protein-restricted diet. 4 drop-outs before consuming anything (1 death, 1 hospitalisation, 1 exceeding inclusion criteria for BMI, 1				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	withdrawal of informed consent). A further 11 dropped out (5 from ONS arm and 6 from CTRL arm – 1 withdrew consent, 1 due to exclusion criteria, 2 diarrhoea and or dyspepsia; 1 IHD, 3 lost to follow-up /discharged; 2 stroke recurrence, 1 taste of control). There were no details on which group the dropouts came from except 2 diarrhoea/diarrhoea and dyspepsia were in the ONS group and were judged to be related to the study product. In the control group 2 subjects discontinued due to serious (non-related) AEs (death due to cerebral vascular accident and stroke recurrence).				

Table 121: Chernoff 1990[48]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Chernoff 1990[48] **Title**: The effect of a high protein formula (replete) on decubitus ulcer healing in long term fed institutionalised patients. **Journal:** J. Am Diet Assoc. 1990, 90, A-130. Type of study: Randomised controlled trial - abstract Sequence generation: no details Allocation concealment: no details Blinding: no details Addressing incomplete outcome data: no details Statistical analysis: no details Baseline differences: no details Study power/sample size: very small sample size Length of study: 8 weeks	Patient group: institutionalised tube feeding dependent patients with decubitus ulcers. All patients Randomised N: 12 Completed N: not reported Drop-outs: not reported Males/females: 5/7 Mean age: 7 1.5 years (range 6-88) Group 1 Randomised N: 6 Completed N: not reported Dropouts: not reported Ulcer size at baseline (range): 1.0cm2 to 46.4cm2 Group 2 Randomised N: 6 Completed N: not reported Dropouts: not reported	Group 1: very high protein (25% of calories) commercially available polymeric dietary formula. Group 2: high protein (16% of calories) commercially available polymeric dietary formula.	Outcome 1: ulcer completely healed	Group 1: 4/6 (66.7%) Group 2: 0/6 (0%) Relative risk: 9 95% CI: 0.59 to 137.65	Funding: no details Limitations: abstract. Pilot study of only 12 patients. No details on randomisation, allocation concealment or blinding. Additional outcomes:
			Outcome 2: decrease in ulcer size (%)	Group 1: 73% Group 2: 42% MD: 31%	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
monitoring Assessment of PUs: no details Classification of PUs: no details Multiple ulcers: not reported	Ulcer size at baseline (range): 1.6cm2 to 63.8cm2 Inclusion criteria: no details Exclusion criteria: no details				

Table 122: Benati 2001[29]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Benati 2001[29] **Title**: Impact on pressure ulcer healing of an arginine-enriched nutritional solution **Journal:** Archives of gerontology and geriatrics, suppl 7, 43-47. Type of study: randomised controlled trial Sequence generation: no details Allocation concealment: no details	Patient group: inpatients with severe cognitive impairment and pressure ulcers. They also had a reduced oral food intake. All patients Randomised N: 16 Completed N: 16 Drop-outs: 0 Age (range): 72 to 91 Activities of daily living (ADL) scores (range): 0 to 3. Group 1 (group B):	Group 1: normal hospital diet plus oral supplementation 2x200ml aliquots/day of a high protein calorie supplementary feeding (providing an extra 500Kcal and approximately 37g of protein each day) (group B) Group 2: normal hospital diet plus an oral supplementation 2x200ml aliquots/day of a high protein calorie supplementary feeding (providing an extra 500Kcal and approximately 37g of protein each day) plus arginine (7.5g/day), zinc (25mg) and antioxidants. (group C)	Outcome 1: Individual PSST scores	GRAPH of PSST score but no further outcome reporting	Funding: no details Limitations: no details of sequence generation, allocation concealment or blinding. No details of baseline differences. Short study duration. Incomplete outcome reporting of the only outcome reported. Very small sample size.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: no details Addressing incomplete outcome data: no drop outs. Statistical analysis: no details Baseline differences: no details except gender Study power/sample size: very small sample size, no power calculation Setting: hospital Length of study: 15 days Assessment of PUs: Pressure sore status tool (PSST) at 0,5,10 and 15 days Classification of PUs: Multiple ulcers: not reported	Randomised N: 5 Completed N: 5 Dropouts: 0 Age (mean): not reported Sex (m/f): 3/2 Group 2 (group C) Randomised N: 6 Completed N: 6 Dropouts: 0 Age (mean): not reported Sex (m/f): 2/4 Group 3 (group A) Randomised N: 5 Completed N: 5 Dropouts: 0 Age (mean): NR Sex (m/f): 4/1 Inclusion criteria: severe cognitive impairment (mini mental state examination, MMSE, Folstein et al, 1975) score </=15 out of 30; pressure ulcers. Exclusion criteria: patients who were unlikely to	Group 3: normal hospital diet (group A) Other treatments: all patients lay on an alternating pressure air mattress. Pressure ulcer treatment was standardized with advanced protocols.			Additional outcomes (list additional outcomes reported in paper but not recorded in this table): none.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	benefit from nutritional supplementation.				

Table 123: Brewer 1967[35]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Brewer 1967[35] **Title**: The effect of oral zinc sulphate on the healing of decubitus ulcers in spinal cord injured patients **Journal:** Proceedings of the annual clinical spinal cord injury conference, 16, 70-72. Type of study: randomised controlled trial Sequence generation: selection of capsule was made on a random basis. Allocation concealment: two types of capsules prepared by the Pharmacy but no more details. Blinding: double-blinded but no details.	Patient group: patients with spinal cord injuries and poorly healing pressure ulcers of various size, types, locations and duration (5 months to over 2 years). All patients Randomised N: 14 Completed N: 13 Drop-outs: 1 Group 1 Randomised N: 7 Completed N: 6 Dropouts: 1 Group 2 Randomised N: 7 Completed N: 7 Dropouts: 0 Inclusion criteria: not	Group 1: oral zinc sulphate 220mgs (50mg zinc) t.i.d Group 2: inert substance (Lactose) t.i.d.	Outcome 1: proportion of patients completely healed	Group 1: 1/6 (16.7%) Group 2: 2/7 (28.6%) RR 0.58 95% CI: 0.07 to 4.95	Funding: no details Limitations: Very small study. No details of sequence generation and unclear allocation concealment. No details of baseline values. Additional outcomes: there was an equal number of transient gastrointestinal upsets (nausea and loose stools) – but no figures given. No significant changes in white blood counts, hemoglobins, hematocrits, total proteins, albumins,
			Outcome 2: side effects – discontinued due to upper gastrointestinal distress (although the patient was noted to have x-ray evidence of a pre-existing prolapse of gastric mucosa into the duodenum)	Group 1: 1/7 Group 2: 0/7	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: one patient was not able to remain on zinc sulphate. Statistical analysis: none Baseline differences: no details except that ulcers were various sizes, types, locations and durations (5 months to over 2 years). Study power/sample size: very small. No power calculation Setting: no details Length of study: 2-3 months Assessment of PUs: not reported Classification of PUs: not reported Multiple ulcers: not reported	stated Exclusion criteria: not stated				BUN, or creatinine before, during and after zinc sulphate. NB the authors state that when dealing with trace elements in micrograms there are multiple sources of contamination and therefore error. Therefore the figures are much higher than the laboratory controlled normal range of values.

Table 124: Leigh 2012[132]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Leigh 2012[132] **Title**: The effect of different doses of an arginine-containing supplement on the healing of pressure ulcers **Journal:** Journal of wound care 2012, 21 (3). Type of study: randomised controlled trial Sequence generation: computer-generated block randomisation schedule (in permuted blocks of 4). Allocation concealment: researchers involved with patient recruitment were blinded to the allocation sequence Blinding: blinded assessor Addressing incomplete outcome data: ACA Statistical analysis: differences in PUSH tool scores were evaluated	Patient group: inpatients with category II, III or IV pressure ulcers All patients Randomised N: 29 Completed N: 22 Drop-outs: 2 died, 1 withdrew due to side effects, 2 were non-concordant, 2 discharged shortly after starting the study. Data collection completed up to one but last data collection for one of the patients who died and so was included in the analysis. Mean age (years): 68.65(range 31-92 years) M/F: 14/9 Group 1 Randomised N: 14 Completed N: 12 Dropouts: 1 died, 1 nonconcordant. Age (years): 69.8 M/F: 8/4	Group 1: hospital diet plus 4.5g arginine supplement (one sachet of Arginaid, Nestle Medical Nutrition Group 2: hospital diet plus 9g arginine supplement (two sachets of Arginaid). The sachets were in powder form and weighed 9.1g, containing 4.5g arginine, 4g carbohydrate, 155mg vitamin C and 40.5mg vitamin E. The powder was then mixed thoroughly with 200ml water before swallowing, as per manufacturers' directions.	Outcome 1: Reduction in mean PUSH tool scores (change scores) Figures taken from change from baseline and graph figures	Group 1: 3.4 Group 2: 3.1 P=0.991	Funding: no details Limitations: no details of blinding of patient or HCP; >10% differential drop-out. Additional outcomes:
			Outcome 2: Reduction in mean PUSH tool scores by nutritional status (change scores) Figures taken from change from baseline and graph figures	Group 1 (4.5g arginine +well nourished): 2.7 Group 2 (9.0g arginine + well nourished: 3 Group 3 (4.5g arginine + malnourished): 0.90 Group 4 (9.0g arginine + malnourished: 2.9	
			Outcome 3: concordance	Group 1: 90.3% Group 2: 93.3% P=0.429	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
with repeated measures ANOVA. Baseline differences: Study power/sample size: small sample size, underpowered Setting: Acute inpatient and rehabilitation services in Melbourne, Australia, at 3 campuses. Length of study: 3 weeks Assessment of PUs: nurse assessed using PUSH tool. Classification of PUs: NPUAP Multiple ulcers: all pressure ulcers were included	BMI (kg/m2): 26.9 (SD 2.5) Pressure ulcers: 17 PU category II: 13 PU category III: 3 PU category IV: 1 Cause of admission: Pressure ulcer: 2 Injury from falls: 2 Neoplasms: 3 Cardiac failure: 1 Infection: 3 Aneurysm/stroke: 1 PU location: Sacrum: 4 Heel: 6 Ischium: 5 Knee: 2 PUSH tool scores: 8.9 (SD 0.7) Group 2 Randomised N: 15 Completed N: 11 Dropouts: 1 died, 1 withdrew due to side effects, 1 nonconcordant, 2 discharged shortly after starting the study. Data collection completed up to one but last data				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	collection for one of the patients who died and so was included in the analysis. Age (years) : 69.8 (SD 5.2) M/F: 6/5 BMI (kg/m2): 26.7 (SD 2.0) Pressure ulcers: 14 PU category II: 10 PU category III: 3 PU category IV: 1 Cause of admission: Pressure ulcer: 2 Injury from falls: 4 Cardiac failure: 2 Infection: 1 Aneurysm/stroke: 1 Parkinson's: 1 PU location: Sacrum: 6 Heel: 3 Ischium: 2 Ankle/elbow: 2 Trochanter: 1 PUSH tool scores: 8.1 (SD 1.0) Inclusion criteria: Category II, III or IV				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	pressure ulcer not showing signs of healing (from reviewing nursing and medical notes, if not improved over 2 weeks considered non-healing); consuming an oral diet and had not yet started taking an arginine-containing supplement. Exclusion criteria: patients with evidence of sepsis; acute gastrointestinal surgery; those receiving dialysis; individuals receiving hydroxyurea or >10mg of prednisolone or 1.5mg dexamethasone per day.				

Table 125: Theilla 2012[222]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Theilla (2012)[222] **Title**: Impact of a nutritional formula enriched in fish oil and micronutrients on pressure ulcers in critical care patients. **Journal:** American Journal of Critical Care 2012, 21 (4) **Author and year**: Theilla (2012)[223] **Title**: Enteral n-3 fatty acids and micronutrients enhance percentage of positive neutrophil and lymphocyte adhesion molecules: a potential mediator of pressure ulcer healing in critically ill patients. **Journal:** British Journal of Nutrition 2012, 107, 1056-1061. Type of study: randomised controlled trial Sequence generation: computer-generated random list.	Patient group: ICU patients with grade II or higher pressure ulcers All patients Randomised N: 40 Completed N: 40 Drop-outs: 0 Group 1 Randomised N: 20 Completed N: 20 Drop-outs: 0 Age (years): 49.3 (SD 20.7) M/F: 14/6 BMI: 28.3 (SD 4.8) Hours in ICU: 627.2 (SD 340.9) Diagnostic category: medical 5; trauma 11; surgery 4. Severity of pressure ulcers: 9.10 (SD 2.84) Group 2 Randomised N: 20 Completed N: 20 Drop-outs: 0	Group 1: Enteral nutritional formula enriched in fish oil and antioxidants. Group 2: Isonitrogenous nutritional formula. Those who could not tolerate enteral nutrition (gastric residual volume >500mL0 received parenteral nutrition in the form of OliClinomel N6-900 (Baxter Healthcare Ltd). Patients in the study group who required parenteral nutrition also received Omegaven (Fresenius Kabi AG) as the source of fish oil. Treatment protocols for grade II pressure ulcers: hydrogel dressings when secretions were minimal, alginates, when secretions were moderate and specialty absorptives when secretions were excessive. Treatment protocols for grade III pressure ulcers consisted of composite dressings.	Outcome 1: Increase in PUSH tool score (derived from graph)	Group 1: 1.50 Group 2: 0.30	Funding: no funding received Limitations: no details of allocation concealment. No blinding of ICU staff, patients or assessor of ulcer severity. Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Allocation concealment: not reported. Blinding: treatment allocation was concealed from the study statistician but not from ICU staff, patients, or the assessor of the ulcer severity. Addressing incomplete outcome data: ITT Statistical analysis: repeated-measures analysis of variance. Baseline differences: no significant differences. Study power/sample size: small sample size Setting: general ICU of medical centre Israel University –affiliated hospital Length of study: 28 days Assessment of PUs: PUSH tool Classification of PUs: NPUAP classification Multiple ulcers: not reported	Age (years): 53.1 (19.3) M/F: 13/7 BMI: 32.1 (SD 9.9) Hours in ICU: 507 (SD 217.8) Diagnostic category: medical 9; trauma 8; surgery 3. Severity of pressure ulcers: 9.25 (SD 2.12) Inclusion criteria: adult patients admitted to the ICU who were expected to require nutritional support for at least 5 days and who had evidence of grade II or higher pressure ulcers (ie damage of the epidermis extending at least into the dermis), according to the NPUAP categorisation. Exclusion criteria: Conditions associated with markedly impaired immunity and/or wound healing, such as AIDS, autoimmune disorders and treatment with immunosuppressive				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	medications.				

I.2.4 Pressure redistributing devices

Table 126: Allman 1987[7]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Allman 1987 **Title**: Air-fluidized beds or conventional therapy for pressure sores. A randomised trial **Journal:** Annals of Internal Medicine 1987; 107 (5); 641-8 Type of study: RCT Sequence generation: random number table (low risk) Allocation concealment: sealed envelopes numbered sequentially – no mention if they were opaque (unclear risk) Blinding: masked assessment included review of serial photographs of all pressure sores (low risk)	Patient group: surgical patients with pressure ulcers All patients Randomised N: 72 were randomised but do not know which groups. Completed N: 65 Drop-outs: 90% follow-up; Group 1 Randomised N: 35 Completed N: 31 Drop-outs: 4 patients withdrew because of difficulty transferring in and out of the air-fluidised bed Group 2 Randomised N: 37	Group 1: Air-fluidised therapy (CLINITRON) repositioned every 4 hours Group 2: Conventional treatment (including 2-hourly turns, heel and elbow protectors, alternating-pressure mattresses)	Outcome 1: Change in total surface area of ulcers – median (range) (cm2)	Group 1: -1.2 (-38.0 to +15.5) Group 2: +0.5 (-55.1 to +94.7) Difference: -1.7cm2 (95%CI: -9.2cm2 to -0.6cm2) P=0.01 Insufficient data available to calculate the difference in effects between the two interventions using Revman	Funding: Grant in part from Support Systems International Inc. Limitations: unclear allocation concealment; baseline difference and size of ulcer at baseline not reported. Study underpowered. Additional outcomes: N/A
			Outcome 2: Proportion with improvement in condition of pressure ulcer (judged from photographs by blinded assessors)	Group 1: 22/31 Group 2: 16/34 Difference: 24% (95% CI 1% to 47%) P=0.05	
			Outcome 3: Proportion with 50% reduction in total surface area	Group 1: 9/31 Group 2: 8/34 Difference: 5% (95% CI -16% to 26%) P=0.64	
			Median length of	Group 1: 16 days	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: yes, 7 withdrew and details of when and where. Patients were not included in the analysis. ITT analysis specified in study report (low risk) Statistical analysis: two-tailed chi-square or Fisher exact tests for categorical variables. Wilcoxon rank sum test used for continuous and ordinal data; stepwise logistic regression analysis to determine factors associated with a masked assessment of improvement after adjustment. Nonparametric methods used for CIs for median change in total surface area and normal approximation used for CIs for differences in % of patients showing improvement or 50% reduction in surface area. Baseline differences: patients on air-fluidised	Completed N: 34 Drop-outs: 3 were withdrawn because pressure sore getting worse; one withdrew because of noise of the bedside pump used to inflate the air mattress. Inclusion criteria: aged 18 or over, with pressure ulcers of all stages; patients expected to be limited to bed/chair and in hospital for a minimum of 1 week. Exclusion criteria: if been in trial previously; skin graft or flap was planned for the pressure sore within one week.		stay in hospital after randomisation	Group 2: 15 days	
			Mortality	Group 1: 8/31 Group 2: 7/34	
			Outcome 4: Change in pain intensity from baseline: from asking patients to score 0 to 5 on words to describe pain (none, mild, discomforting, distressing, horrible or excruciating) Decreased No change Increased	 Group 1: 8/13 Group 2: 4/14 Group 1: 5/13 Group 2: 7/14 Group 1: 0/13 Group 2: 3/14 P=0.01	
			Outcome 5: Change in comfort from baseline:		

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
beds had a more limited activity level. Size of baseline ulcers not measured. (high risk) Study power/sample size: a priori sample size calculation. Study was underpowered. Setting: hospital, USA Length of study: mean 13 days follow-up (range 4-77 days) Assessment of PUs: surface area was obtained by tracing borders of pressure sores on clear, plastic transparencies then using a computerised digitiser and summing all areas from various areas. Photographs taken. Classification of PUs: Shea classification Multiple ulcers: NR			Increased No change Decreased	Group 1: 8/13 Group 2: 3/14 Group 1: 4/13 Group 2: 4/14 Group 1: 1/13 Group 2: 6/14 P=0.04	

Table 127: Branom 2001[34]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Branom 2001 **Title**: 'Constant force therapy' versus low-air-loss therapy in the treatment of pressure ulcers. **Journal:** Ostomy Wound Management 2001; 46 (9); 38-46 **Type of study:** RCT Sequence generation: patients who met the inclusion criteria were randomly assigned to one of the two groups, the study mattress or the LAL, in an alternating pattern as they were admitted (high risk) Allocation concealment: inadequate information given (unclear risk) Blinding: unstated (unclear risk) Addressing incomplete outcome data: unstated (unclear risk) Statistical analysis: not reported	Patient group: inpatients from long-term and subacute care centre specialising in ventilator-dependent patients and those with extensive wound care needs. All patients Randomised N: 20 Completed N: not reported Drop-outs: not reported Group 1 Randomised N: 10 Completed N: not reported Drop-outs: not reported Group 2 Randomised N: 10 Completed N: not reported Drop-outs: not reported Inclusion criteria: bedridden patients had a pressure ulcer at grade 3	Group 1: PressureGuard CTF (Constant Force Therapy) (non-powered mattress) Group 2: LAL mattress	Outcome 1: Mean % of closure per week (at week 8)	Group 1: 9% (s.d 4.8) Group 2: 5% (s.d 3.7)	Funding: not reported Limitations: randomisation inadequate; unclear allocation concealment and blinding; no details of incomplete outcome data, type of analysis, ulcer sizes at baseline and classification of pressure ulcers. Very small sample size. Two of the ten patients in the LAL group at randomisation were switched from the LAL to the study mattress. Additional outcomes: N/A Notes: each facility used the LAL mattress brand most familiar to

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: very small Setting: Long term and subacute care centre specialising in ventilator-dependent patients and those with extensive wound care needs Length of study: 8-week follow-up Assessment of PUs: not specified Classification of PUs: not specified. Multiple ulcers: not reported	or 4 on trunk or pelvis. Exclusion criteria: not stated 2 groups were matched in age, nutritional deficiency and use of g-tubes.				them

Table 128: Caley 1994[43]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Caley 1994 **Title**: Randomised prospective trial of two types of low air loss therapy. **Journal:** Personal communication 1994 Type of study: RCT Sequence generation: method of randomisation not stated. Authors state subjects were randomised to either the low-air-loss bed or the low-air-loss overlay (unclear risk) Allocation concealment: allocation concealment not stated (high risk) Blinding: No blinding (high risk) - unclear (and unlikely) that outcome assessment was blind to treatment group. Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk)	Patient group: Acute care patients with existing pressure ulcers, for whom an Enterostomal Therapy Nurse had recommended low-air-loss therapy. All patients Randomised N: 93 Completed N: 55 Drop-outs: 38 (those discharged before 3rd week of study were not included in analysis ie those who improved quickest). Gender (f/m): 60%/40% Age, mean (range): 76 (42-98 years) Group 1 Randomised N: unclear Completed N: 23 Drop-outs: not reported Group 2 Randomised N: unclear Completed N: 32 Drop-outs: not reported	Group 1: LAL bed (Mondarch, Mediscus) Group 2: LAL overlay (SPR Plus, Gaymar) Skincare protocol applied to both groups.	Outcome 1: Median change in ulcer area (measured by multiplying ulcer length by ulcer width)	Group 1: 3.9cm2 Group 2: 1.9cm2 Very little data provided P=0.060 Perimeter 0.171	Funding: not reported Limitations: very little data provided (median change in area and range); unclear (and unlikely) that the outcome assessment was blind to treatment group. No description of co-interventions except skincare protocol applied to both groups; insufficient reporting of incomplete outcome data; high drop-out; Additional outcomes: healing progress over time
			Outcome 3: mean changes in pressure ulcer surface area	Group 1: 10.2cm2 Group 2: 3.8cm2 Insufficient data to calculate the mean difference between the two interventions.	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: not reported Baseline differences: not reported Study power/sample size: small sample size Setting: acute care ward Length of study: average 24-day follow-up Assessment of PUs: not reported Classification of PUs: not reported Multiple ulcers: not reported	Inclusion criteria: acute care patients with existing pressure ulcers and for whom an enterostomal therapy nurse had recommended low air loss therapy Exclusion criteria: not reported				

Table 129: Clark 1998[50]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Clark 1998 **Title**: A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat cushions. **Journal:** Proceedings of the 7th European Conference on Advances in Wound Management; 1997, 18-20 November; Harrogate, UK. 1998: 122-5. Type of study: RCT Sequence generation: all eligible subjects were allocated to a cushion according to a pre-determined randomisation protocol (unclear risk) Allocation concealment: allocation using sequential, sealed, opaque envelopes (low risk) Blinding: a single unblinded observer	Patient group: Elderly patients in 2 acute care hospitals and 2 nursing homes. All patients Randomised N: 33 Completed N: 25 Drop-outs: 8 Group 1 Randomised N: 17 Completed N: 14 Drop-outs: 2 withdrawn due to enzymatic debridement of sores; 1 withdrawn due to deteriorating medical condition prompting confinement to bed Group 2 Randomised N: 16 Completed N: 11 Drop-outs: 1 died within 7 days of recruitment; 2 were withdrawn due to enzymatic debridement of sores, 2 withdrawn due to deteriorating medical	Group 1: ProActive 2 cushion (Pegasus). Cushion for day chairs and wheelchairs. Seating automatically adjusts to patient's weight. Cycle time 12 minutes. Group 2: ROHO cushion. Dry flotation system. All patients had a Pegasus Airwave system in bed.	Outcome 1: Number of ulcers healed completely	Group 1: 3/14 Group 2: 5/11 RR 0.47 (0.14 to 1.56)	Funding: Pegasus Airwave Ltd. Limitations: unclear details of randomisation; unblinded observer; grading system of ulcers not specified; high drop-out Additional outcomes: N/A Author used data from subjects with more than one assessment completed.
			Outcome 2: rate of healing (cm2/day)	Group 1: 0.13 (SEM 0.10) Group 2: 0.27 (SEM 0.17)	
			Outcome 3: rate of healing (cm3/day)	Group 1: 0.56 (SEM 0.23) Group 2: 0.49 (SEM 0.26)	
			Outcome 4: % change in area per day	Group 1: 2.56 (SEM 2.10) Group 2: 5.71 (SEM 1.68)	
			Outcome 5: % change in volume per day	Group 1: 1.00 (SEM 0.49) Group 2: 0.68 (SEM 0.26)	
			Mortality	Group 1: 3/14 Group 2: 1/11 RR 2.36 (95% CI 0.28 to 19.66)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
collected all data (low risk) All data were analysed blinded. Addressing incomplete outcome data: no missing outcome data (low risk); data analysis was based on the remaining 25 subjects (high risk) Statistical analysis: SPSS no mention of statistical tests. Baseline differences: groups well matched at baseline for important variables such as Waterlow score, mobility, nutritional status, continence. Baseline comparability for initial area of ulcer also reported (low risk). Study power/sample size: although a priori sample size calculation was done, projected sample size not achieved. Setting: 2 acute care hospitals and 2 nursing homes. Length of study: average	condition prompting confinement to bed Inclusion criteria: predicted to remain in the trial for at least 7 days; with established pressure ulcers grade 2 or above; Exclusion criteria: patients with pressure sores with a surface are of greater than 15cm2.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
58.6 days (Proactive) and 43.73 days (ROHO) Assessment of PUs: wound area calculated using the formula length x width x 0.785 while wound volume was calculated by the formula (length x width x 0.785) x depth. Classification of PUs: grading system not specified Multiple ulcers: not reported					

Table 130: Day 1993[61]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Day 1993 **Title**: Seeking quality care for patients with pressure ulcers. **Journal:** Decubitus 1993; 6(1); 32-43 Type of study: RCT Sequence generation: patients were randomised to either the air-suspension bed or the foam mattress overlay (unclear risk) Allocation concealment: allocated by sealed envelopes. No other details (unclear risk) Blinding: not state (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Statistical analysis: ancova; logarithmic transformation was used due to highly skewed ulcer size. Baseline differences:	Patient group: hospitalised, adult patients with existing grade 2-4 pressure ulcers (NPUAP) All patients Randomised N: 83 Completed N: 48 Drop-outs: 35 Group 1 Randomised N: 44 Completed N: 25 Drop-outs: 19 Age, mean (s.d, range): 75.09 (15.37, 32 to 102 years) Males/females: 17/27 Mean weight: 130.35lbs. Karnofsky performance status (0% dead to 100% nor mal activity level): 36.25% (severely disabled and required special care and assistance). Most common diagnoses: dehydration (n=10), fever of unknown origin (n=10), pneumonia (n=7),	Group 1: Air suspension bed (Therapulse, Kinetic concepts) Group 2: Foam mattress overlay (Geomatt, SpanAmerica) Wound care standardised for 2 groups.	Outcome 1: Mean ulcer size divided into grade 2 and grade 3/4 ulcers.	Stage II Group 1: 7.3 (s.d 2.4) Group 2: 5.3 (2.1) Stage III and IV Group 1: 37.1 (8.1) Group 2: 12.4 (3.5) All pressure ulcers: Ancova: F [1,78] = 0.35, p>0.05	Funding: in part by Kinetic Concepts Inc. Limitations: unclear randomisation, allocation concealment and blinding, insufficient reporting of incomplete outcome data, not all of the pre-specified outcomes were analysed. Did not report initial ulcer sizes. Additional outcomes: N/A Notes: no p values given, but all analyses reported as not statistically significantly different. Comfort score results only completed by half the subjects (Group
			Outcome 2: Mean comfort scores	Group 1: 4.1 (sd 1.3) n=20 Group 2: 3.7 (s.d 1.3) n=19 T[37] 0.91, p>0.05	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
baseline comparability for initial ulcer size : no significant differences(low risk) Study power/sample size: power calculation given, underpowered. Setting: hospital Length of study: 7 day follow Assessment of PUs: not reported Classification of PUs: NPUAP grading system Multiple ulcers: 22 patients in the air-suspension group and 17 in the foam overlay group had multiple pressure ulcers, the most severe ulcer was selected for analysis	dementia (n=7), respiratory failure (n=7) Modified Norton Scale scores: 8.84 (s.d 2.84) (n=44) Group 2 Randomised N: 39 Completed N: 23 Drop-outs: 16 Age, mean (s.d, range): 77.13 (10.76, 54 to 93 years) Males/females: 18/21 Mean weight: 125.83lbs. Karnofsky performance status (0% dead to 100% normal activity level): 36.66% (severely disabled and required special care and assistance). Most common diagnoses: dehydration (n=10), fever of unknown origin (n=7), urinary tract infection (n=6), pneumonia (n=5) Modified Norton Scale Scores: 9.03 (s.d 3.19) (n=39) Inclusion criteria:				1, n=20; Group 2, n=21) Distribution of the ulcer size within each stage was highly skewed for both study groups so logarithmic transformation was applied to ulcer size in an attempt to meet the assumption of normality.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	hospitalised patients older than 18 years of age with a stage II, III or IV pressure ulcer(s); life expectancy of at least one week; activity limited to chair or bed during hospitalisation; informed consent signed by the patient, or patient's family or guardian; and permission of the attending physician Exclusion criteria: patient previously enrolled in the study; patient hospitalised for less than 7 days; patient having undergone skin grafting or flap within 7 days of enrolment in the study.				

Table 131: Devine 1995[69]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Devine 1995 **Title**: Alternating pressure air mattresses in the management of established pressure sores. **Journal:** Journal of Tissue Viability, 1995; 5; 94-8 Type of study: RCT Sequence generation: allocation to each group was achieved using a computer-generated list of random numbers kept separately from the trial co-ordinator (low risk) Allocation concealment: see above (low risk) Blinding: no blinding (high risk) Addressing incomplete outcome data: detailed (low risk) Statistical analysis: not reported Baseline differences: More people incontinent of urine in	Patient group: Elderly patients in hospital admitted with ulcers of grade 2 or above (grading system not reported) All patients Randomised N: 41 Completed N: 30 Drop-outs: withdrawal rates by group and reasons for withdrawal stated. 11 patients (24%) died (9) or moved to other hospitals (2). Age, mean (range): 82.5 years (69-98 years) Group 1 Randomised N: 22 Completed N: 16 Drop-outs: 5 (died) Group 2 Randomised N: 19 Completed N: 14 Drop-outs: 4 (died), 2 (moved to other hospital)	Group 1: Alternating-pressure mattress (Nimbus 1). Modular, with rows of figure-of-eight shaped cells. Two sets of cells are inflated and deflated over 10 min cycle. Group 2: Alternating-pressure mattress (Pegasus Airwave). Double layer mattress with a 3-cell alternating cycle lasting 7.5min. All patients were subject to the standard hospital protocol for wound dressings; details of this were not provided.	Outcome 1: Complete healing at 4 weeks	Group 1: 10/16 ACA Group 2: 5/14 ACA RR 0.57 (95% CI 0.26 to 1.27)	Funding: HNE Healthcare provided a grant for employment of a part time research nurse Limitations: no blinding; baseline differences and baseline ulcer size not reported. Additional outcomes: N/A
			Outcome 2: Decrease in pressure ulcer size	Group 1: 4/16 ACA Group 2: 6/14 ACA RR 0.58 (95% CI 0.21 to 1.65)	
			Outcome 3: Increase in pressure ulcer size	Group 1: 2/16 ACA Group 2: 3/14 ACA RR 0.88 (95% CI 0.21 to 3.66)	
			Outcome 2: Comfort	Group 1: median 8/10 Group 2: median 8/10 Should be interpreted with caution due to very small response rate.	
			Outcome 3: Median rate of reduction in area (cm/day)	Group 1: 0.089cm2/day Group 2: 0.107cm2/day Difference: 0.018 cm2 (95% CI 0.179 to 0.143, p=0.92) this difference was calculated using the median of all possible pairwise differences between the groups, not the difference in the 2 medians	
			Mortality	Group 1: 6/21 Group 2: 5/19 RR 1.43 (95% CI 0.38 to 2.86)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Nimbus group; more people catheterised in Airwave group. Baseline comparability for initial ulcer size not reported Study power/sample size: no power calculation, small sample size Setting: geriatric unit Length of study: 4-week follow-up Assessment of PUs: length and breadth to calculate surface area Classification of PUs: grading system not stated. Multiple ulcers: not reported	Inclusion criteria: ulcers of grade 2 or above; Exclusion criteria: not reported.				

Table 132: Evans 2000[72]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Evans 2000 **Title**: A clinical evaluation of the nimbus 3 alternating pressure mattress replacement system **Journal:** Journal of wound care, April 2000, 9 (4). **Type of study:** RCT Sequence generation: method of randomisation not stated (unclear risk) Allocation concealment: treatments were randomly allocated to sequentially-labelled sealed envelopes – no mention if opaque (unclear risk) Blinding: 2 research team members, blind to the surface used, carried out the WSA measurements (low risk) Addressing incomplete outcome data: no missing outcome data (low risk)	Patient group: hospital and nursing patients, over 65 years All patients Randomised N: 32 Completed N: unclear Drop-outs: Large proportion of patients did not complete follow-up (11/20 in nursing home group, 75% in hospital group) Group 1 Randomised N: 17 Completed N: 6 Drop-outs: 11 Group 2 Randomised N: 15 Completed N: 6 Drop-outs: 9 Inclusion criteria: over 65 years; either grade 2 or 3 ulcer or grade 2 and one or more of the following: difficult to reposition in	Group 1: Alternating-pressure mattress replacement system (APMRS) (Nimbus 3) Group 2: Alternating-pressure mattress replacement system (APMRS) for hospital patients (P.Biwave, P.Airwave, P.Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro) for nursing home patients.	Outcome 1: Absolute and relative reduction in wound surface area (calculated twice weekly by planimetry) in hospital patients	Median absolute reduction in wound surface area per day: Group 1: 0.12cm2 (range 0 to 0.21cm2) Group 2: 0.08cm2 (range 0.04 to 0.33cm2) P=0.570 (mann-whitney u-test) Median relative reduction in wounds surface area (and range): Group 1: 2.44% (range 0-7.14%) Group 2: 1.34% (range 1.11-2.88%) P=0.570 (mann-whitney u-test) There were insufficient data available in the study report to calculate the mean difference between the two interventions	Funding: not reported Limitations: method of randomisation not reported. Unclear allocation concealment. Large proportion of patients did not complete follow-up (11/20 in nursing home group and 75% of hospital group); very small sample size. Additional outcomes: N/A
			Outcome 2: Absolute and relative reduction in wound surface area (calculated twice weekly by planimetry) in nursing home patients	Median absolute reduction in wound surface area per day: Group 1: 0.11cm2 (range 0.04 to 0.41cm2) Group 2: 0.05cm2 (range 0 to 0-0.48cm2) P=0.570 (mann-whitney u-test) Median relative reduction in wounds surface area (and	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Mann-Whitney U-test. Normality tests on continuous data showed that some ordinal data sets did not come from normal distributions, so descriptive statistics used to summarise continuous data sets were medians and ranges. Baseline differences: baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: no sample size calculation, small sample. Setting: hospital and nursing home. Length of study: 2-week follow-up. Assessment of PUs: Planimetry. Classification of PUs: grading system not specified. Multiple ulcers: one ulcer per subject, if	bed, unable to tolerate 30 degree tilt, unable to move in bed, in bed for >20 hours/24 hours, >108kg and bed-bound, undergone spinal anaesthetic. Exclusion criteria: spinal metastases; exudating wounds that may lead to hygiene or infection control problems; weight >250kg (39 stone).			range): Group 1: 1.57% (range 0.45-5%) Group 2: 0.99% (range 0-2.54%) P=0.570 (mann-whitney u-test) There were insufficient data available in the study report to calculate the mean difference between the two interventions	
			Outcome 3: Comfort	Median comfort score hospital patients Group 1: 5 (very comfortable) Group 2: 4 (comfortable) P=0.006 Median comfort score nursing home patients: Group 1: 5 (very comfortable) Group 2: 4 (comfortable) P=0.002	
			Outcome 3: mortality	Hospital patients Group 1: 0/7 Group 2: 2/5 Nursing home patients Group 1: 7/10 Group 2: 1/10	
			Outcome 2:	Group 1: 14/18	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
more than one the largest with the highest grade used.			Comfort	Group 2: not reported	
			Outcome 3: Relief of redness	Group 1: 14/18 Group 2: 0/18 RR 29 (95% CI 1.86 to 425.00)	

Table 133: Ferrell 1993[74]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ferrell 1993 A randomised trial of low air loss beds for treatment of pressure ulcers. **Journal:** JAMA 1993; 269; 494-7 Type of study: RCT Sequence generation: method of unclear - randomisation in blocks of 10; 5 to each treatment (unclear risk) Allocation concealment: assignments were sealed in individual envelopes and opened sequentially on establishment of study criteria (low risk) Blinding: unclear (unclear risk)	Patient group: Elderly nursing home residents with multiple medical problems and with trunk or trochanter pressure ulcers (Shea grade 2 or greater) All patients Randomised N: 84 Completed N: 45 Drop-outs: 18 died, 8 transferred to another facility Group 1 Randomised N: 43 Completed N: 26 Drop-outs: 11 died, 4 transferred to another facility, 2 discontinued at subject's request	Group 1: LAL bed (KINAIR) Group 2: 10cm convoluted foam overlay on top of standard foam mattress. Both groups had similar co-interventions as per standard care i.e. mobilisation as much as possible; 2-hourly turning during walking hours; avoidance of head-of-bed elevation; avoidance of dragging patients on sheets; nutritional support; infection control.	Outcome 1: Rate of healing mm2/day - median (25th, 75th percentiles)	Group 1: 9.0 (4.0, 19.8) Group 2: 2.5 (0.5, 6.5) P=0.0002 P=0.004	Funding: supported in part by the Jewish Home for the Aging of Greater Los Angeles; the Sepulveda Veterans Affairs Geriatric Research Education and Clinical Center; the West Los Angeles Veterans Affairs Geriatric Research Education and Clinical Center and a gift by Kinetic Concepts International. Limitations: study terminated at interim analysis as
			Outcome 2: Ulcers completely healed (covered with epithelium)	Group 1: 26/43 (60%) Group 2: 19/41 (46%) RR 1.30 (95% CI 0.87 to 1.96) P=0.19	
			Outcome 3: mortality	Group 1: 11/43 (26%) Group 2: 7/41 (17%) P=0.34	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk). ITT analysis specified in study report (low risk) Statistical analysis: Student's tests for normally distributed continuous data and X2 or Wilcoxon rank-sum tests used to compare categorical variables or variables with non-normal distributions. Healing rates adjusted for follow-up using Kaplan-Meier and further covariate adjustment by Cox regression models. Baseline differences: groups appeared to be well matched at baseline, including ulcer area, except that patients in LAL bed group had significantly lower serum albumin. Study power/sample size: a priori sample size calculation;	Group 2 Randomised N: 41 Completed N: 19 Drop-outs: 7 died, 4 transferred to another facility, 2 discontinued at subject's request, 9 protocol deviators Inclusion criteria: Trunk or trochanter pressure ulcers (grade 2 or greater); Exclusion criteria: expected to survive < 1 month; had already participated in the study; surgery to the ulcer was planned.				difference much larger than expected. Method of sequence Unclear blinding; insufficient reporting of incomplete outcome data. Additional outcomes: superficial and deep ulcers given for rate of healing. Notes: study terminated early after finding a much larger difference between the two groups than initially anticipated.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: Nursing home. Length of study: median follow-up of 33 days (LAL group) and 40 days (foam mattress group) Assessment of PUs: Wound surface area was traced twice/week on plastic film, and area measured using planimetry. Classification of PUs: Shea grading system. Multiple ulcers: where patient had multiple ulcers, largest ulcer chosen as index ulcer.					

Table 134: Groen 1999[91]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Groen 1999 **Title**: Comparative study of a foam mattress and a water mattress. **Journal:** Journal of Wound Care 1999; 8(7): 333-5. Type of study: RCT Sequence generation: method of randomisation not stated (unclear risk) Allocation concealment: subjects were randomly divided into two groups of 60 by selection of sealed envelopes - no mention of envelopes being opaque (unclear risk) Blinding: no blinding (high risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Statistical analysis: categorical variables analysed using the chi-	Patient group: Nursing home patients >59 years old with pressure ulcer on trunk of grade 3 or 4 All patients Randomised N: 120 Completed N: 101 Drop-outs: withdrawals: 11 from Group 1, 8 from Group 2, but not stated at which time points withdrawals occurred. Reasons for withdrawals included severe illness and discharge. Group 1 Randomised N: 60 Completed N: 49 Drop-outs: 11 Average age: 81.9 years Pressure ulcer severity: 4.8 Group 2 Randomised N: 60 Completed N: 52 Drop-outs: 8	Group 1: Foam replacement mattress: 3 layers of polyurethane foam designated as comfort, load-distributing and support layers Group 2: Secutex water mattress: placed on top of standard hospital mattress, 3 PVC sections holding 26L water each, with heating element. Standard turning protocol (every 2-3 hours) for both groups.	Outcome 1: Proportion with healed ulcers at 4 weeks	Group 1: 27/60 (45%) Group 2: 29/60 (48%) RR 0.93 (0.63 to 1.37)	Funding: not reported Limitations: no details of randomisation method; unclear allocation concealment; no blinding; insufficient reporting of incomplete outcome data; no details of type of analysis; selective reporting. More patients reported slight pain (40%) than in group B (20%) at baseline. Additional outcomes: N/A
			Outcome 3: % with pain (final values)	Group 1: 4.1% Group 2: 3.8%	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
square test and Mann Whitney test was used for analysis of numerical values. Baseline differences: more patients in group reported slight pain than in group B. Baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: a priori sample size of 60 in each group Setting: 3 nursing homes Length of study: 4-week follow-up Assessment of PUs: ulcer severity assessed weekly using a validated quantitative scoring system, no details of how measured the wound. Classification of PUs: no grading system specified. Multiple ulcers: not reported	Average age: 83.5 years Pressure ulcer severity: 5.5 Inclusion criteria: 60 years or over, pressure ulcer on trunk of grade 3 (superficial cutaneous or subcutaneous necrotic) or grade 4 (deep subcutaneous necrotic). Exclusion criteria: severe or terminal illness.				

Table 135: Keogh 2001[113]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Keogh 2001 **Title**: Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. **Journal:** Journal of wound care 2001; 10(2):15-9. Type of study: RCT Sequence generation: the block design randomisation code was computer generated by an independent statistician using blocks of 8 (low risk) Allocation concealment: the allocation for each patient was placed in sealed, opaque envelopes that were numbered sequentially (low risk) Blinding: unstated (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions ; all	Patient group: surgical and medical ward patients, >18 years with tissue damage no greater than grade 1 (EPUAP) All patients Randomised N: 100 but only 14 had existing pressure ulcers at start of study Completed N: unclear Drop-outs: data incomplete 30 patients. The extent of follow-up was difficult to ascertain. Group 1 Randomised N: 50, but only 4 had pressure ulcers Completed N: unclear Drop-outs: unclear Group 2 Randomised N: 50, but only 10 had pressure ulcers Completed N: unclear Drop-outs: unclear	Group 1: Profiling bed with a pressure reducing foam mattress/cushion Group 2: Flat-based bed with a pressure relieving/redistributing mattress/cushion	Outcome 1: Proportion with healed grade 1 ulcers	Group 1: 4/4 Group 2: 2/10 RR 3.96 (95% CI 1.28 to 12.24)	Funding: Huntleigh Healthcare Ltd Limitations: unclear blinding; not all of the study's pre-specified outcomes were reported; not all patients had pressure ulcers (only 14 had existing pressure ulcers), so small sample size and uneven distribution, with only 4 in the experimental group). Grade 1 ulcers analysed only. Insufficient reporting of attrition/exclusions . High drop out from study and do not know how many of those who dropped-out had existing pressure ulcers at start of the trial.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
100 patients were included in an intent-to-treat analysis in respect of pressure ulcer incidence Statistical analysis: Fisher's exact test Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: a priori sample size calculation done; but only 14 patients had existing pressure ulcers and this was unevenly distributed. Setting: 2 surgical and 2 medical wards Length of study: 5-10 days' follow-up Assessment of PUs: not reported. Classification of PUs: EPUAP grading system Multiple ulcers: not reported	Inclusion criteria: > 18 years old; Waterlow score of 15-25; tissue damage no greater than grade 1 (EPUAP) Exclusion criteria: see above				Additional outcomes: * All 100 patients were included in an ITT analysis irrespective of pressure ulcer incidence. Except for secondary outcome n=70. Only 14 had existing grade 1 pressure ulcers, and had results.

Table 136: Mulder 1994[150]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Mulder 1994 **Title**: A study of pressure ulcer response to low air loss beds vs. conventional treatment. **Journal:** Journal of Geriatric Dermatology 1994;2(3): 87-91 Type of study: RCT Sequence generation: method of randomisation not stated. Authors state 'this was a single center study conducted as a randomised controlled trial' (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: unclear (unclear risk) Addressing incomplete outcome data: no details of which groups drop-outs came from (unclear risk); ITT analysis specified in study report (low risk) Statistical analysis: ANCOVA on log-	Patient group: Nursing home patients with grade 3-4 pressure ulcers All patients Randomised N: 49 Completed N: 39 Drop-outs: 10: 8 died, 1 lost to follow-up, 1 protocol violation. No information about groups from which withdrawals came. No explanation of why the stated 1:1 randomisation ratio resulted in such disproportionate groups Group 1 Randomised N: 31 Completed N: unclear Drop-outs: unclear Group 2 Randomised N: 18 Completed N: unclear Drop-outs: unclear Inclusion criteria: stage III or IV pressure ulcers	Group 1: Air suspension bed (Therapulse, Kinetic concepts): a pulsating air suspension therapy (cushions alternatively inflate and deflate but classed as LAL rather than AP) Group 2: Convoluted foam mattress overlay (Geomatt, SpanAmerica) Wound care and repositioning standardised for both groups.	Outcome 1: Wound closure.	Group 1: 5/31 Group 2: 3/18 RR 0.97 (95% CI 0.26 to 3.58)	Funding: grant from Kinetic Concepts Inc. Limitations: no details of randomisation method; unclear allocation concealment and blinding; no details of which groups drop-outs came from; not all of the pre-specified outcomes were reported; ulcer size not reported at baseline. Additional outcomes: N/A
			Outcome 2: Pressure ulcer improvement (pressure ulcer reduced by one grade or more, including healed completely)	Group 1: 10/31 Group 2: 5/18 RR 0.29 (95% CI 0.12 to 0.72)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
transformed decrease in ulcer area and volume. Baseline differences: baseline comparability for initial ulcer size not reported (unclear risk) Study power/sample size: no sample size calculation. Small sample Setting: nursing home Length of study: maximum 12 weeks follow-up, or until ulcers healed, whichever occurred first. Assessment of PUs: wound surface area assessed by photoplanimetry. Ulcer volume = ulcer length x width x depth (of deepest ulcer point). Classification of PUs: International Association of Enterostomal Therapists staging system). Multiple ulcers: not reported	within a range of 1.5cm x 1.5cm to 10.0 cm x 20.0 cm Exclusion criteria: carcinomatosis; osteomyelitis affecting the target ulcer; uncontrolled target ulcer infection; immune deficiency disorders; inadequate nutritional status.				

Table 137: Munro 1989[154]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Munro 1989 **Title**: Pressure ulcers: one bed or another? **Journal:** Geriatric Nursing 1989; 10:190-2. Type of study: RCT Sequence generation: method of randomisation not stated. Authors state 'eligible, consenting patients... were randomly assigned to the Clinitron bed (experimental group) or to a standard hospital bed (control group) Allocation concealment: unclear (unclear risk) Blinding: No blinding (high risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Statistical analysis: repeated-measures analysis of variance used to compare mean ulcer	Patient group: Male patients with grade 2 or 3 pressure ulcers. All patients Randomised N: 40 Completed N: unclear Drop-outs: unclear Group 1 Randomised N: 20 Completed N: unclear Drop-outs: unclear Group 2 Randomised N: 20 Completed N: unclear Drop-outs: unclear Inclusion criteria: patients with grade 2 or 3 pressure ulcers, expected to remain in hospital for at least 15 days. Exclusion criteria: patients with grade 4 ulcers; patients weighing >250lbs; patients at less than 70% of ideal body	Group 1: Air-fluidised bed (Clinitron) Group 2: Standard care The bed/mattress in the standard care group was not described. Sheepskins or gel pads were placed beneath ulcer areas. Standard care involved positioning and massage.	Outcome 1: Change in mean ulcer area (mm2) measured on day 15 but provided only mean values and no data regarding the spread of results. Final area presented as % of initial nursing time in minutes/8h shift.	Group 1: 1158mm2 Group 2: 2051mm2 Standard deviations not reported. P=0.05 There were insufficient variance data available from the study to calculate the mean difference between the two interventions.	Funding: grant from Support Systems International Limitations: Unclear allocation concealment; no information regarding sample size calculations, randomisation method, blinding, baseline characteristics or extent of follow-up. No raw data presented in the paper; insufficient reporting of incomplete outcome data. Additional outcomes: Change in mean ulcer area (mm2) measured on 1st, 3rd, 8th, 15th days; nursing time
			Outcome 2: Patients' perception of pain (11 point scale from no pain to worst pain imaginable on that day)	Group 1: not reported (n=13) Group 2: not reported (n=13) F=0.87, p=0.359	
			Outcome 3: Patient satisfaction (higher score more satisfaction)	Group 1: 57.5 (s.d 6.1)(n=8) Group 2: 48.6 (s.d 12.3)(n=10) T=1.99, p=0.067	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size; patient satisfaction on an 8-item scale. Pain measured by an adaptation of the Levitt and Derogatis scale. Baseline differences: groups described as comparable for age, diagnosis, size of ulcer, pain and Gosnell score at baseline, but data not presented by group. Baseline comparability for initial ulcer size not reported (unclear risk) Study power/sample size: no information regarding sample size calculations. Setting: hospital Length of study: 15-day follow-up Assessment of PUs: tracing perimeters on Saran-wrap sheet then digitizer tablet and Zeiss MOP videoplan used. Classification of PUs: Staging systems used to classify PUs not specified. Multiple ulcers: not	weight; patients with serum albumin <2.1g/100ml.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reported					

Table 138: Nixon 2006[162]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Nixon 2006 **Title**: Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. **Journal:** BMJ 2006; 332 (7555):1416 **Title** of 2nd publication: Pressure relieving support surfaces: a randomised evaluation Health Technology Assessment, 10, 22 Type of study: RCT Sequence generation: randomisation was	Patient group: patients in vascular, orthopaedic, medical or care of elderly wards with grade 2 pressure ulcers All patients Randomised N: 1971; only n=113 had pressure ulcers Completed N: unclear Drop-outs: unclear Group 1 Randomised N: 59 (with existing pressure ulcers of the 989 randomised to this group) Completed N: unclear Drop-outs: unclear Group 2 Randomised N: 54 (with	Group 1: Alternating-pressure overlay within 24 hours of admission Group 2: Alternating-pressure mattress within 24 hours of admission	Outcome 1: Healing of existing pressure ulcers	Group 1: 20/59 (34%) ITT Group 2: 19/54 (35%) ITT RR 0.96 (95% CI 0.58 to 1.60)	Funding: UK department of health through HTA programme. Limitations: no blinding. Additional outcomes: proportion of patients developing a new pressure ulcer of grade 2 or worse; time to development of new pressure ulcers; proportion of participants developing a new pressure ulcer within 30 days
			Outcome 2: time to healing (median time)	Group 1: 20 days Group 2: 20 days P=0.86, log rank test	
			Outcome 3: Patient acceptability (proportion of people requesting one or more changes for comfort and other device related reasons)	Group 1: 230/989 (23.3%) ITT Group 2: 186/982 (18.9%) ITT 4.4% (95% CI 0.7% to 7.9%), p=0.02, x2 test) This is all patients in the study, although only 113 patients had pressure ulcers.	
			Outcome 4: absolute change in surface area (cm2) – change values	Group 1: 1 (s.d 2.3) Group 2: 2 (s.d 6.1)	
			Outcome 5: % change in surface area (change values)	Group 1: -35 (s.d 605.5) Group 2: 34.4 (s.d 108.6)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
through an independent, secure, 24 hour randomisation automated telephone system (low risk) Allocation concealment: randomisation was through an independent, secure, 24 hour randomisation automated telephone system, ensuring allocation concealment (low risk) Blinding: no blinding (high risk) Addressing incomplete outcome data: no missing outcome data (low risk); ITT analysis specified in study report (low risk) Statistical analysis: X2 test for primary endpoint; logistic regression analysis to adjust for minimisation factors and pre-specified baseline covariates. As data on area of new ulceration were skewed they compared the	existing pressure ulcers of the 982 randomised to this group) Completed N: unclear Drop-outs: unclear Inclusion criteria: patients at least 55 years old; from vascular, orthopaedic, medical or care of the elderly wards; expected length of stay at least 7 days; Braden Score of 1 or 2; existing grade 2 pressure ulcer Exclusion criteria: pressure ulcer on admission of grade 3 or worse; had a planned admission to an intensive care unit after surgery; were admitted to hospital more than 4 days before surgery; slept at night in a chair; or weighted more than 140kg or less than 45k g (as per mattress specifications)		Outcome 6: negative comments for mattress motion	Group 1: 328/929 (35.3%) Group 2: 285/891 (32%)	Notes: study funded by HTA ITT analysis used in study. Although all withdrawal reasons given only 113 patients had pressure ulcers and do not know how many of these had missing data.
			Outcome 7: positive comments for mattress motion	Group 1: 272/929 (29.3%) Group 2: 263/891 (29.5%)	
			Outcome 8: patients commenting negatively on getting into/out of bed	Group 1: 124/929 (13.3%) Group 2: 127/891 (14.3%)	
			Outcome 9: commenting negatively on movement in bed	Group 1: 290/929 (31.2%) Group 2: 260/891 (29.2%)	
			Outcome 10: commenting positively on movement in bed:	Group 1: 25/929 (2.75) Group 2: 27/891 (3%)	
			Outcome 11: commenting on temperature as hot/warm	Group 1: 67/929 (7.2%) Group 2: 50/891 (5.6%)	
			Outcome 12: commenting on temperature as sweaty/sticky	Group 1: 32/929 (3.4%) Group 2: 23/891 (2.6%)	
			Outcome 13:	Group 1: 11/929 (1.2%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
maximum total area between the groups using a Mann-whitney U test. Using a X2 test to compare the proportions of participants between groups requesting a change owing to dissatisfaction with the trial surface. Log rank test used to compare time to complete healing of existing ulcers between groups. Cochran Armitage test used. Baseline differences: baseline comparability for initial area of ulcer also reported Study power/sample size: a priori sample size of 2000 for 80% power to detect a 50% reduction in the proportion of people developing a pressure ulcer of grade 2 or worse. 1972 were randomised. Setting: 11 hospitals in			commenting on cold/cool temperature	Group 2: 11/891 (1.2%)	
			Outcome 14: mattress not working properly	Group 1: 16/929 (1.7%) Group 2: 18/891 (2%)	
			Outcome 15: hard to tuck sheet/undersheets come off or gather/mattress cover slips	Group 1: 19/929 (2%) Group 2: 6/891 (0.7%)	
			Outcome 16: mattress/bed too high	Group 1: 72/929 (7.8%) Group 2: 48/891 (5.4%)	
			Outcome 17: mattress slippy	Group 1: 9/929 (1%) Group 2: 4/891 (0.4%)	
			Outcome 18: mattress too soft/edges soft or slope	Group 1:19/929 (2%) Group 2: 29/891 (3.3%)	
			Outcome 19: not able to use backrest	Group 1: 4/929 (0.4%) Group 2:2/891 (0.2%)	
			Outcome 20: Mattress-related fall	Group 1: 0/828 (0%) Group 2: 4/891 (0.4%)	
			Outcome 21: Mattress-related suspected contact dermatitis	Group 1: 0/929 (0%) Group 2: 1/891 (0.1%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
six NHS trusts Length of study: 30-day follow-up Assessment of PUs: skin assessment Classification of PUs: grading system not specified Multiple ulcers: not reported			Outcome 22: Mattress-related climbed over/fell through cot sides	Group 1:2/929 (0.2%) Group 2: 1/891 (0.1%)	
			Outcome 23: mattress deflation during transfer	Group 1:0/929 (0%) Group 2: 1/891 (0.1%)	
			Outcome 24: time in hospital (mean)	Group 1: 22.17 days Group 2: 20.05 days P=0.23	
			Outcome 4: mortality	Group 1: 20/59 (33.9%) Group 2: 12/54 (22.2%)	

Table 139: Osterbrink 2005[171]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Osterbrink 2005 **Title**: Clinical evaluation of the effectiveness of a multimodal static pressure relieving device. **Journal:** Journal of Wound Healing European Wound Conference 'From the Laboratory to the Patient: Future organisation and the	Patient group: Patients from aged care facility, acute care hospitals and home care settings with at least 1 grade 2 pressure ulcer at any bony prominence All patients Randomised N: 60 Completed N: 50 Drop-outs: 10	Group 1: Repose air-filled device Group 2: Small cell AP Group 3: Large cell AP Group 3: There was no standardisation of pressure ulcer care across the participating centres.	Outcome 1: Wound healing success (completely healed pressure ulcers)	Group 1: Air-filled device: 7/34 Group 2:(Small/large cell AP: 1/26 RR 5.35 (95% CI 0.70 to 40.84)	Funding: not reported but think it is Industry funded Limitations: unclear randomisation method, allocation concealment, blinding; insufficient reporting of incomplete outcome data;

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
care of problem wounds' September 15-17 2005. Type of study: RCT Sequence generation: unclear (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: unstated (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk); ITT analysis specified in study report (low risk) Statistical analysis: do not know as abstract only Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: very small Setting: recruited from aged care facility, acute care hospitals and home care setting. Length of study: for as long as clinical	Group 1 Randomised N: unclear Completed N: 28 Drop-outs: unclear Group 2 Randomised N: unclear Completed N: 12 Drop-outs: unclear Group 3: Randomised N: unclear Completed N: 10 Drop-outs: unclear Inclusion criteria: >18 years old; at least 1 grade 2 pressure ulcer at any bony prominence. If recruited from hospital, must have been nursed on care of the elderly, neurological or surgical units. Exclusion criteria: not reported				baseline ulcer size not reported. Very small study. Additional outcomes: Weekly changes in wounds (ulcer size, grade, wound bed, edge appearance and local wound treatment) Could not acquire full conference proceedings so used results from Cochrane Review on support surfaces for treatment alone.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
circumstances allowed (42 days maximum) Assessment of PUs: do not know as abstract only Classification of PUs: EPUAP classification system Multiple ulcers: not reported					

Table 140: Russell 2000[188]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Russell 2000 **Title**: Randomised controlled trial of two pressure-relieving systems. **Journal:** Journal of Wound Care 2000; 9(2):52-5. Type of study: RCT Sequence generation: "on admission to the study, subjects were randomly allocated to trial equipment".	Patient group: patients from elderly units with pressure ulcer of grade 2 or above All patients Randomised N: 141 Completed N: 112 Drop-outs: 29 Age: average 83.9 and 84.6 years Group 1 Randomised N: 70	2 types of alternating cell mattress systems with pressure-relieving cushions: Group 1: Huntleigh Numbus 3 with Aura cushion and 4-hourly turning Group 2: Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning.	Outcome 1: Ulcer healing: all types	Group 1: 65/71 ulcers Group 2: 65/70 ulcers RR 0.99 (95% CI 0.90 to 1.09)	Funding: not reported Limitations: no details of randomisation method; unclear allocation concealment. Additional outcomes: Ulcer healing: all types, and divided into heel and sacral
			Outcome 2: mortality	Group 1: 16/71 Group 2: 10/70	
			Outcome 3: average length of stay (for patients who completed the trial)	Group 1: 21.6 days Group 2: 21.7 days	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Method of randomisation not described (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: "images [of the pressure ulcers] were stored on compact discs, using codes that ensured image analysis could be carried out 'blind' to treatment group" Addressing incomplete outcome data: no missing outcome data Statistical analysis: Wilcoxon-Mann-Whitney rank sum test Baseline differences: baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: a priori sample size calculation of 80% power was 100 patients per group, the study was underpowered. Setting: care of elderly unit, hospital Length of study: Length	Completed N: 57 Drop-outs: 13 Age (mean): 83.9 years Group 2 Randomised N: 71 Completed N: 55 Drop-outs: 16 Age (mean): 84.6 years Inclusion criteria: patients from care of the elderly units; pressure ulcer of > grade 2; Exclusion criteria: patients excluded if randomised equipment unavailable (not stated how often this occurred)				ulcers at 12 and 18 months

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
of intervention period unclear. 18 month follow-up Assessment of PUs: insufficient information on outcome measurements. Ulcer healing was recorded by weekly camera and nurse gradings – called 'improvement factor'. Classification of PUs: Torrance classification system Multiple ulcers: if patient had two ulcers areas this counted as two separate ulcers.					

Table 141: Russell 2003[190]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Russell 2003 **Title**: Randomised comparison trial of the RIK and the Nimbus 3	Patient group: patients in hospital with grade 1 or 2 pressure ulcers All patients	Group 1: Alternating-pressure, multicell mattress with 10 minute cycle time (Nimbus 3) Group 2: Fluid overlay mattress	Outcome 1: improved ulcer response	Group 1: 60/83 Group 2: 56/75 RR 0.97 (95% CI 0.80 to 1.17)	Funding: from makers of Nimbus 3 mattress. Limitations: unclear

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
mattresses. **Journal:** British Journal of Nursing 2003; 12(4):254-9. Type of study: RCT Sequence generation: "allocations were made using a random number generator in Excel 97" (low risk) Allocation concealment: "allocation was by selection of a sealed envelope in which a trial number and bed allocation was enclosed" but opaque envelope not mentioned(unclear risk) Blinding: No blinding of treatment allocation to patients or clinicians described. Blinded photographic assessment of ulcer grading. (low risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Statistical analysis:	Randomised N: 199 were included but 41 were discharged before could be assessed more than one and were included from analysis Completed N: 158 Drop-outs: 41 Age (mean): 80 years Group 1 Randomised N: 100 Completed N: 83 Drop-outs: 17 Baseline Waterlow scores: 21.8 Baseline Burton scores: 14.6 Group 2 Randomised N: 99 Completed N: 75 Drop-outs: 24 Baseline Waterlow scores: 21.3 Baseline Burton scores: 14.2 Inclusion criteria: patients in hospital with grade 1 or	(RIK static) All patients had standard 4-hourly re-positioning, but could have additional turning at the patient's request – the effect of this co-intervention on treatment effect is unclear.			allocation concealment; no blinding of patients or caregivers; insufficient reporting of incomplete outcome data. Additional outcomes: N/A No information on reliability, specificity or sensitivity for identification and/or classification of ulcers.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Mann-Whitney test Baseline differences: patients well matched at baseline. Baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: power calculations stated. Setting: hospital Length of study: length of follow-up unclear, but presumably until discharge from enrolment hospital Assessment of PUs: all ulcers were photographed using a high-resolution digital camera at weekly intervals by a medical photographer. Classification of PUs: EPUAP classification system Multiple ulcers: either evaluated as the overall pressure ulcer burden as if aggregating all individual ulcers into one large ulcer, or by	2 pressure ulcers; Exclusion criteria: patients previously enrolled in the trial; obese patients (>25 stone); those with >grade 3 ulcers.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
examining the changes in the worst pressure ulcer present on admission to the trial.					

Table 142: Strauss 1991[213]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Strauss 1991 **Title**: The cost of home air-fluidized therapy for pressure sores. A randomised controlled trial. Type of study: RCT **Journal:** Journal of Family Practice 1991; 33(1):52-9. Sequence generation: randomisation took place "using forms created by a computerised random-number-generating system" (low risk) Allocation concealment: unclear (unclear risk) Blinding: "the study	Patient group: people with at least 1 grade 3 or 4 pressure ulcer All patients Randomised N: 112 Completed N: 97 Drop-outs: 15 Group 1 Randomised N: 58 Completed N: 29 (n=47 who did not completely drop-out) Drop-outs: 14 died during study; 4 partially dropped from study, 11 completely dropped from study. 7 patients had missing or uninterpretable pressure ulcer photographs/nurses	Group 1: Home air-fluidised therapy (CLINITRON) when grade 3 or 4 ulcers present, plus the consultative and technical services of a visiting nurse specialist Group 2: Conventional or standard therapy, patient specific and as prescribed, but included alternating –pressure pads, air-filled mattresses, water-filled mattresses, high density foam pads.	Outcome 1: Pressure ulcers classified by blinded observers as improved	Group 1: 19/2 Group 2: 9/13 RR 1.25 (95% CI 0.84 to 1.86)	Funding: Support Systems International Limitations: unclear allocation concealment; insufficient reporting of attrition/exclusions ; ulcer size at baseline not reported; high drop-out rate. Retrospective assessment. Additional outcomes: Pressure ulcer-related hospitalisations

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assessed clinical outcomes through reviews by two independent nurses who were experts in the care of pressure sores and who were blinded to treatment category" (low risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk); ITT analysis specified in study report (low risk) Statistical analysis: t tests or chi-square. Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: no a priori sample size calculation Setting: patient's homes Length of study: 36-week follow-up Assessment of PUs: measured and photographed. Classification of PUs:	notes and could not be reviewed for improvement by the blinded nurse assessors Group 2 Randomised N: 54 Completed N: 30 (but n=50 did not completely drop-out) Drop-outs: 19 died during study; 1 partially dropped from study; 4 completely dropped from study. 17 patients had missing or uninterpretable pressure ulcer photographs/nurses notes and could not be reviewed for improvement by the blinded nurse assessors Inclusion criteria: at least 1 grade 3 or 4 pressure ulcer; who would probably require future hospitalisation for the pressure ulcer; with severely limited mobility; for who home air-fluidised therapy was a practical option; likely to comply;				and costs/patients

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Shea classification Multiple ulcers: not reported	live at least 1 year; aged 16 years or over. Exclusion criteria: febrile or septic or otherwise required immediate hospitalisation; pressure sores on radiated skin.				

Table 143: Makhous 2009[135]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Makhsous 2009 **Title**: Promote pressure ulcer healing in individuals with spinal cord injury using an individualised cyclic pressure-relief protocol Type of study: RCT **Journal:** Advances in skin and wound care, 22 (11), 514-521 Sequence generation: no details Allocation concealment: no details Blinding: no blinding. Addressing incomplete outcome data: none Statistical analysis:	Patient group: inpatients or outpatients with spinal cord injury ulcers with stage II or stage III pressure All patients Randomised N: 44 Completed N: not reported Drop-outs: not reported Age: 18-79 years Group 1 Randomised N: 22 Completed N: not reported Drop-outs: not reported Age (year):42.4 (16.6)	Group 1: wheelchairs with an individually adjusted automated seat that gave cyclic pressure relief (manual and powered). The cyclic pressure-relief system consisted of a split seat and a backrest with an enhanced lumbar support. The wheelchairs were configured with the backrest reclined 5 degrees from perpendicular and a split seat cushion oriented parallel to the floor. The split seat cushion had a movable portion located at the posterior and tilted downward away from the individual, reducing the contact between the user's buttocks and the seat. The backrest had an inflatable air pouch as an	Outcome 1: median time to healing (days)	Group 1: 25.0 (2.9) Group 2: >30 P=0.007	Funding: supported in part by grant from National Institutes of Health Award. Limitations: no details of sequence generation, allocation concealment and blinding. Small sample size. Additional outcomes: Pressure ulcer-related hospitalisations and costs/patients
			Outcome 2: % reduction in wound area	Group 1: 45.0 (22.0) Group 2: 10.2 (34.9) P<0.001	
			Outcome 3: % improvement in PUSH score	Group 1: 21.9 (24.6) Group 2: 5.8 (9.2) P=0.003	
			Outcome 4: wound area closure (mm2)	Group 1: 785.0 (744.0) Group 2: 124.9 (520) P=<0.001	
			Outcome 5: wound area closure rate (mm2/day)	Group 1: 21.7 (14.6) Group 2: 2.3 (20.4) P=<0.001	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Kaplan Meier for median time and 30% reduction of the wound area; and log rank (Mantel-Cox) chi-square for group difference; % reduction in wound and % improvement in PUSH score t-test used. Baseline differences: no significant differences Study power/sample size: no power calculation and small sample size. Setting: Rehabilitation Institute of Chicago. Length of study: 30 days. Assessment of PUs: wound dimensions recorded with digital photographs twice a week. Classification of PUs: not reported. Multiple ulcers: not reported	BMI (kg/m2): 25.2 (6.7) Years on SCI: 6.1 (6.6) Sex (f/m): 1/21 Disability: paraplegia: 10; tetraplegia: 12 ASIA*: A: 11 B: 10 C: 1 Group 2 Randomised N: 22 Completed N: not reported Drop-outs: not reported Age (year): 44.5 (15.1) BMI (kg/m2): 25.2 (7.1) Years on SCI: 3.9 (2.9) Sex (f/m): 2/20 Disability: paraplegia: 9; tetraplegia: 13 ASIA*: A: 12 B: 10 C: 0 Inclusion criteria: stage II or III pressure ulcers in the sacral or ischial areas; able to independently use	adjustable lumbar support that inflated when the posterior portion of the split seat dropped. The participants were told of the pressure-relief of the chair and could either continue doing manual pressure relief or rely on the experimental seating device. Group 2: standard wheelchair (manual or powered ranging from 16- to 20- inch width and 16- to 20- inch depth fit according to the patient's body size). The participants were instructed to perform arm push-ups every 20 to 30 minutes for pressure relief. All patients had treatment by physician or a trained nurse and was patient-specific for each wound. A variety of wound care modalities were used, including topical wound dressings eg gel, hydrocolloid, alginate, foam and moisture barrier. More advanced modalities included silver antimicrobial dressing and NWPT.			
			Outcome 6: Wound PUSH score improvement	Group 1: 2.5 (2.3) Group 2: 0.7 (1.1) P=0.001	
			Outcome 7: proportion with 30% wound closure	Group 1: 16/22 Group 2: 8/22	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	either a manual or a power wheelchair; sitting tolerance for at least 4 hours per day. Exclusion criteria: patients with degenerative disorders of the spine and with histories of injury or surgery of the pelvis, hip joint, and the thigh, or with hip contractures; those with severe pain, spasm, and psychological concerns preventing proper cooperation.	Patients were required to sit for a minimum of 4 hours in the assigned wheelchairs daily.			

**ASIA: American Spinal Injury Association.*

Table 144: Cassino 2013[44]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cassino (2013) **Title**: A controlled, randomised study on the effectiveness of two overlays in the treatment of decubitus ulcers **Type of study:** multicentre RCT **Journal:** Minerva Chirurgia. Sequence generation: randomised 1:1 ratio Allocation concealment: inadequate, closed envelopes opened at moment of assignment Blinding: no, open trial Addressing incomplete outcome data: details given of what occurred to patients, only one who was not specified. ITT analysis used. Statistical analysis: two-tailed test or X^2 Baseline differences: no difference for age, weight, BMI, Norton and Braden scores. There	Patient group: long-term care patients All patients Randomised N: 72 Completed N: 28 Drop-outs: Age (year): 85.4 Sex (f/m): 55/17 Group 1 Randomised N: 35 Completed N: 17 Drop-outs: 18 Age (year): 84.9 Sex (f/m): not reported Grade of pressure ulcers: Grade 1: 11 (24%) Grade 2: 12 (27%) Grade 3: 12 (27%) Grade 4: 22% Group 2 Randomised N: 37 Completed N: 11 Drop-outs: 26 Age (year): 85.9 Sex (f/m): not reported Grade 1: 16 (36%)	Group 1: Three-dimensional overlay (AIARTEX), made of 3-D macro-porous material, 9mm thick, made completely of polyester and weighing 800grams, consisting of 2 parallel layers, one on top of the other, linked by transverse monofilaments. The function of the upper layer is to drain any exudates and convey them to the lower level by gravity and capillary action through the transverse monofilaments. Group 2: dry viscoelastic polyurethane polymer overlay (AKTON) 15.9mm thick, made of vulcanised rubber with a strong memory for shape, weighing 35kg	Outcome 1: completely healed	Group 1: 3/35 Group 2: 5/37	Funding: sponsored by Herniamesh Srl (Chivasso, Turin, Italy) Limitations: baseline differences for grade of pressure ulcers, but the higher grades were in the intervention group. Additional outcomes: ease of assistance and bed, making (nursing evaluation)
			Outcome 2: improved (including resolved)	Group 1: 16/35 Group 2: 9/37	
			Outcome 3: unchanged/worsened	Group 1: 16/35 Group 2: 22/37	
			Outcome 4: Suspension due to worsening	Group 1: 9/35 Group 2: 17/37	
			Outcome 5: Suspension due to intolerance	Group 1: 5/35 Group 2: 2/37	
			Outcome 6: mortality	Group 1: 3/35 Group 2: 7/37	
			Outcome 7: Comfort (poor)	Group 1: 4 (11.4%) Group 2: 26 (70.3%)	
			Outcome 7: Comfort (fair)	Group 1: 11 (31.4%) Group 2: 10 (27%)	
			Outcome 7: Comfort (good)	Group 1: 9 (25.7%) Group 2: 1 (2.7%)	
			Outcome 7: Comfort (excellent)	Group 1: 11 (31.4%) Group 2: 0 (0%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
were higher grades of pressure ulcers in the 3-D overlay group but statistical significance not given for this. Study power/sample size: no power calculation given, small study Setting: 8 long-term care Italian centres Length of study: 12 weeks Assessment of PUs: Norton and Braden scales Classification of PUs: EPUAP-NPUAP Multiple ulcers: does not mention how chose one ulcer from multiple ulcers	Grade 2: 16 (36%) Grade 3: 9 (20%) Grade 4: 3 (7%) Inclusion criteria: informed consent, aged >18 years, Braden score >6 and <14, Norton score of >5 and < 12; patients with EPUAP-NPUAP stages I to IV pressure ulcers; BMI >16 and <40; Exclusion criteria: patients without pressure ulcers; infection, terminal patients, immunosuppressive or antiblastic therapies; pregnant women; patients who need different aids; allergies to overlay materials; AIDS, HCV; patients enrolled in other studies in the 3 preceeding months.				

I.2.5 Adjunctive therapies

Table 145: Gentzkow 1991 [81]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gentzkow (1991) **Title:** Improved healing of pressure ulcers using Dermapulse, a new electrical stimulation device. Journal**:** Wounds: Compend Clin. Res. Pract.3, 5, 158-170 **Type of study:** RCT **Sequence generation:** not stated **Allocation concealment:** adequate **Blinding:** double-blind **Addressing incomplete outcome data:** gives details of what happened to drop outs and uses patients available. **Statistical analysis:** continuous variables two sample t-tests used. For categorical variables chi square test used. Yate's correction for continuity was used for	**Patient group:** patients with pressure ulcers that were open and grade 2, 3 or 4 (grade 2 – full thickness skin defect extending into subcutaneous tissue; grade 3, defect extending into muscle; grade 4, defect extending to bone or joint structure). 80% were inpatients, 50% were bedbound, 42% wheelchair bound or ambulatory (8%). **All patients** **Randomised N:** 49 ulcers **Completed N:** 40 ulcers (37 patients) **Drop-outs:** 6 (< 4 weeks treatment), 3 (protocol violation) **Group 1** **Randomised N:** 25 ulcers **Completed N:** 21 ulcers **Dropouts:** 2 (< 4 weeks	**Group 1:** Electrical stimulation: negative polarity unit, wound debrided and serosanguinous drainage appeared, then polarity alternated every 3 days; 128 pps, 35mA, 0.89 C per 30-minute treatment, twice daily for 4 weeks; when ulcer healed to grade 2, treatment at 64pps and polarity changed daily **Group 2:** Sham stimulation: identical procedures. Both groups: 100% received wound cleansing with normal saline and dressing; 10% received surgical or whirlpool debridement; 100% received turning to relieve pressure; 55% received bed rest and elevation of an extremity	**Outcome 1:** Mean+/-SD percentage of ulcers healed at 4 weeks	**Group 1:** 49.8+/-30.9% **Group 2:** 23.4+/-47.4% P=0.042	**Funding:** grant from Staodyn, Inc. **Limitations:** no details of randomisation method. Difference at baseline but likely to be in favour of sham group. Used length by width to estimate wound size. **Additional outcomes:** mean % wound healed as a possible function of various factors: metabolic condition, treatment group, tunnels, sex and grade. Patients who were crossed over from the sham to the unblended active
			Outcome 2: Rate of healing	**Group 1:** 12.5%/week **Group 2:** 5.8%/week	
			Outcome 3: Mean +/-SD healing at 1 week	**Group 1:** 18+/-19.6% **Group 2:** 3.7%+/-25.7% P=0.053	
			Outcome 4: Mean +/-SD healing at 2 weeks	**Group 1:** 33.2+/-29% **Group 2:** 10.2+/-38.1% P=0.037	
			Outcome 5: Mean +/-SD healing at 3 weeks	**Group 1:** 35.1+/-36.1% **Group 2:** 23.1+/-40.3% P=0.325	
			Outcome 6: withdrawal due to adverse event:	**Group 1:** 0/21 ulcers **Group 2:** 0/19 ulcers	
			Outcome 7: acceptability of treatment (uncomfortable sensations in the ulcer when current turned on)	**Group 1:** 13.6% of ulcers **Group 2:** 4.2% of ulcers	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
dichotomous variables. Stepwise multiple regression and three-way ANOVA for separate effects on % healed. **Baseline differences:** Ulcers in group 1 were larger, and therefore measures of percentage healing favours sham group. Ulcers were slightly deeper in the sham group. There were also a higher proportion of females in the sham group (favours sham according to multivariate analysis). **Study power/sample size:** A priori sample-size calculation required 23 patients to detect a 15% difference in healing at 4 weeks, error of 0.05 and 80% power an estimated variance of 18%. **Setting:** 9 site multi-centre trial in hospital and community, USA. **Length of study:** 4 weeks treatment period. Crossed over at 4 weeks and continued until	treatment), 2 (protocol violation) **Age mean +/- SD (range):** 63.3 +/-17.8 years (29-91 years) **Gender (m/f):** 61.9%/38.1% **Mean+/-SD ulcer depth at week 0:** 1.1+/-2.1cm **Mean+/-SD ulcer area at week 0:** 19.2+/-23.2cm^2 **Number of grade 2 ulcers:** 0 **Number of grade 3 ulcers:** 16 **Number of grade 4 ulcers:** 5 **Duration of ulcer </=12 months:** 85% **Duration of ulcer >12 months:** 15% **Group 2** **Randomised N:** 24 ulcers **Completed N:** 19 ulcers **Dropouts:** 4 (< 4 weeks treatment), 1 (protocol violation) **Age mean +/-SD (range):** 62.2+/-18.4 years (31-90 years)				therapy after the four week trial (n=15). They had healed an average of 13.4% in the sham group but after active stimulation had an average of 47.9% reduction in size for the 4 weeks of electrotherapy, (p=0.012) By last week of treatment had healed an average of 63.9%. 17 of the original electrotherapy group received additional treatment (average 10.7 weeks in total, range 5-2 weeks) had healed an average of 45% by end of therapy and by last week of therapy had healed an average of 74.6% .

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
average 9.8 weeks (range 5-10 weeks). **Assessment of PUs:** Ulcer length and width measured at 0,1,2,3 and 4 weeks. Size measured by longest diameter and widest width **Classification of PUs:** Classification system not reported but pressure ulcers described as: Grade 2 – full thickness skin defect extending into subcutaneous tissue; grade 3, defect extending into muscle; grade 4, defect extending to bone or joint structure **Multiple ulcers:** Patients could have more than one ulcer entered into the study (had to be opposite sides of the body) in which case each ulcer was randomised separately.	**Gender (m/f):** 47.4%/52.6% **Mean+/-SD ulcer depth at week 0:** 1.4+/-2.3cm **Mean+/-SD ulcer area at week 0:** 12.5+/-11.9cm^2 **Number of grade 2 ulcers:** 1 **Number of grade 3 ulcers:** 14 **Number of grade 4 ulcers:** 4 **Duration of ulcer </=12 months:** 66.7% **Duration of ulcer >12 months:** 33.3% **Inclusion criteria:** grade 2, 3 or 4 pressure ulcer **Exclusion criteria:** ulcer totally excluded by eschar, had bleeding or involved major blood vessels; located in pre-sternal, peri-orbital, laryngeal/pharyngeal regions; pregnant; cardiac pacemaker; osteomyelitis; peripheral vascular disease; malignancy; long-term steroids; chemotherapy; radio-				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	therapy; very obese.				

Table 146: Griffin91[88]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Griffin (1991) **Title:** Efficacy of high voltage pulsed current for healing of pressure ulcers in patients with spinal cord injury. Journal**:** Phys Ther, 71, 433-42 **Type of study:** RCT **Sequence generation:** no details on method of sequence generation, randomisation was stratified by grade of ulcer and smoking status **Allocation concealment:** no details **Blinding:** double blinded. No blinding of outcome assessors. **Addressing incomplete outcome data:** the authors stated why patients dropped out	**Patient group:** patients with spinal cord injury with pressure ulcers in the pelvic region. **All patients** **Randomised N:** 20 **Completed N:** 17 **Drop-outs:** 2 medical complications, 1 surgical repair of ulcer. **Group 1** **Randomised N:** 10 **Completed N:** 8 **Dropouts:** 2 **Median (range) age:** 32.5 years (17-54 years) **Median (range ulcer duration:** 4.5 weeks (2-116 weeks) **Mean (range) ulcer size at day 0:** 234.1mm^2 (126-	**Group 1:** Stimulation and routine dressings: frequency 100pps, 200V, negative polarity, 1 h/day for 20 consecutive days; pressure sore cleansed using Cara-Klenz, application of Carrington gel and a dry dressing; wound mechanically debrided as necessary. **Group 2:** Sham stimulation + routine dressing. All patients: 2 hourly turning; no change of mattress during the study. Patients received equivalent nursing care. Cleansing of ulcers twice a day, followed by gel and a dry dressing. Wounds were mechanically debrided, as necessary; enzymatic debridement was not used. All ulcers were cultured before	**Outcome 1:** median (range) change in wound surface area - day 5	**Group 1:** -32% (-12% to -100%) **Group 2:** -14% (+17% to -74%) P=0.03	**Funding:** funded in part by a grant from the foundation for Physical Therapy Inc. **Limitations:** Very small sample size. No details of sequence generation method or allocation concealment. No blinding of outcome assessors. The authors had designed the study with the assumption that ischial and sacral ulcers would occur equally in each group, but the placebo group had
			Outcome 2: median (range) change in wound surface area - day 10	**Group 1:** -47% (-23% to -100%) **Group 2:** -42% (+42% to -41%) P=0.14	
			Outcome 3: median (range) change in wound surface area - day 15	**Group 1:** -66% (-42% to -100%) **Group 2:** -44% (+22% to -100%) P=0.05	
			Outcome 4: median (range) change in wound surface area - day 20	**Group 1:** -80% (-52% to -100%) **Group 2:** -52% (-14% to -100%) P=0.05	
			Outcome 5: Number of grade 2 ulcers completely healed at 20 days	**Group 1:** 2/2 **Group 2:** 2/2	
			Outcome 5: Number of grade 3 ulcers completely healed at 20 days	**Group 1:** 1/5 **Group 2:** 0/6	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and they were similar reasons in the two groups. **Statistical analysis:** for the difference between groups for continuous variables the Mann-Whitney U test was used. For nominal data the Fisher's Exact Test was used. **Baseline differences:** significant difference between groups for duration of spinal cord injury, longer in the HVPC group. **Study power/sample size:** very small n=20, a sample size calculation was given of 10 in each group for 80% power to detect a 20% improvement between groups using a one-sided test; given a standard deviation of 15% **Setting:** inpatients, specialist spinal injuries unit, USA. **Length of study:** 20 days treatment. **Assessment of PUs:**	1027mm^2) **Ulcer grade 2:** 2 **Ulcer grade 3:** 5 **Ulcer grade 4:** 1 **Group 2** **Randomised N:** 10 **Completed N:** 9 **Dropouts:** 1 **Median (range) age:** 26 years (10-74 years) **Median (range ulcer duration:** 3.0 weeks (1-30 weeks) **Mean (range ulcer size at day 0):** 2771.8mm^2 (41-4067mm^2) **Ulcer grade 2:** 2 **Ulcer grade 3:** 6 **Ulcer grade 4:** 1 **Inclusion criteria:** male; spinal cord injury; pressure sore grade 2-4, Delisa system, on sacral/coccygeal or gluteal/ischial region **Exclusion criteria:** severe cardiac disease; cardiac arrhythmia; uncontrolled	treatment began. All possible efforts were made to keep pressure off the ulcer. A routine 2-hour turning schedule was followed when patients were in bed.	**Outcome 5:** Number of grade 4 ulcers completely healed at 20 days	**Group 1:** 0/1 **Group 2:** 0/1	a higher amount than the treatment group. The authors also state that both patient who were older than 70 years were in the placebo group, although they had appropriate healing or similar to another patient aged 26 years. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
measured at 0,5,10,15 and 20 days by computerised planimetry from projected transparencies. **Classification of PUs:** DeLisa classification system **Multiple ulcers:** if multiple ulcers, the largest in wound surface area was used.	autonomic dyreflexia; cardiac pacemaker				

Table 147: Wood 1993[245]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Wood (1993) **Title:** A multicentre study on the use of pulsed low-intensity direct current for healing chronic stage II and stage III decubitus ulcers. Journal**:** Arch Dermatol, 129, 999-1009. **Type of study:** multicentre RCT	**Patient group:** patients with grade 2 and 3 chronic pressure ulcers. **All patients** **Randomised N:** 71 patients, 74 ulcers **Completed N:** 63 patients **Drop-outs:** 6 died, 2 lost to follow-up.	**Group 1:** pulsed low-intensity direct current + standard treatment. 600UA, pulse frequency 0.8Hz, three applications around each ulcer, alternate days, three times weekly; for larger ulcers, on e or more additional electrode placements. **Group 2:** Sham pulsed low-intensity direct current + standard treatment.	**Outcome 1:** Number of ulcers completely healed at 8 weeks	**Group 1:** 25/43 (58%) **Group 2:** 1/31 (3%)	**Funding:** support from Veterans Administration Hospitals, the universities of Minnesota and Hambur, and by Harbor Medical Inc. **Limitations:** No details of sequence generation; unclear
			Outcome 2: Decrease in ulcer area>80% at 8 weeks	**Group 1:** 31/43 (72.9%) **Group 2:** 4/31 (12.9%) P<0.0001 (Fisher t-test)	
			Outcome 3: Mean +/-SD ulcer area at 8 weeks (number of ulcers)	**Group 1:** 0.41+/-0.99cm^2 (41) **Group 2:** 1.66+/-2.14cm^2 (25)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: method of randomisation not stated. **Allocation concealment:** instruments were labelled either A or B by an independent investigator before study began. Multicentre study. **Blinding:** double-blinded. **Addressing incomplete outcome data:** details of drop-outs and how many followed-up. **Statistical analysis:** Fisher Exact Test (two tailed) **Baseline differences:** no significant differences **Study power/sample size:** small n=41 **Setting:** 4 centres, USA **Length of study:** 8 weeks treatment. **Assessment of PUs:** diameter, perimeter and photograph of ulcer taken weekly over weeks 0-8.	**Group 1** **Randomised N:** 41 patients, 43 ulcers **Completed N:** 39 patients **Dropouts:** 2 died, 0 lost to follow-up Mean age: 75.6 years Gender (m/f): 26/15 Mean duration of ulcer: 5.5 months Mean ulcer area: 2.61 cm^2 Mean ulcer depth: 2.81cm **Group 2** **Randomised N:** 30 patients, 31 ulcers **Completed N:** 24 **Dropouts:** 4 died, 2 lost to follow-up Mean age: 74.9 years Gender (m/f): 15/15 Mean duration of ulcer: 4.9 months Mean ulcer area: 1.91 cm^2, $p<0.05$ (between groups) Mean ulcer depth: 2.84cm **Inclusion criteria:** grade 2 or 3 chronic pressure sores showing no improvement with	Standard treatment: wound cleansing, simple moist dressing whirlpool baths; no hydrocolloids, films or foam dressings were used.	**Outcome 4:** Mean+/-SD ulcer depth at 8 weeks	**Group 1:** 1.0+/-1.1cm **Group 2:** 2.6+/-1.0cm	allocation concealment. Difference in number of participants in group 1 and group 2. High drop-out in control group. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: classification system not reported **Multiple ulcers:** data presented by ulcers rather than by patients	standard nursing care over preceding 5 weeks **Exclusion criteria:** patients receiving steroids or other drugs that influence wound healing				

Table 148: Adunsky 2005[2]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Adunsky (2005) **Title:** Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomised double-blinded placebo controlled study. Journal**:** Archives of Gerontology and Geriatrics 41, 261-269. **Type of study:** multicentre, double-blind randomised placebo-controlled trial **Sequence generation:** randomisation in each	**Patient group:** post-acute care in-patients from geriatric and rehabilitation medicine departments with grade 3 degree non-diabetic pressure ulcers lasting >/= 30 days (defined by NPUAP scoring system). **All patients** **Randomised N:** 63 (54 elderly patients and 9 spinal cord injured patients). **Completed N:** 38 **Drop-outs:** 25 (ten elderly patients due to a variety of	**Group 1:** decubitus direct current treatment (DDCT) – the DDCT is a mains-powered stand-alone device, connected to a computer with a software to file such information as patient database and photographs of the ulcer at different points of time. During the trial the device provided wound size measurement and recorded the electrical activity around the wound before and after each treatment. During DDCT treatment, electrical currents are transferred to the healthy skin surrounding the necrotic wound area, through the use of soft external	**Outcome 1:** Closure (complete healing) of ulcers at end of follow-up (147 days)	**Group 1:** 9/35 (25.7%) ITT **Group 2:** 10/28 (35.7%) ITT P=0.28	**Funding:** supported by the Lifewave Medical Devices Company. **Limitations: no details of allocation concealment. High drop-out, per protocol was used but control arm denominator was unclear.** **Additional outcomes:**
			Outcome 2: Closure by end of treatment (57 days)	**Group 1:** 5/35 **Group 2:** 3/28 P=0.39 **Per protocol** **Group 1:** 5/25 (20%) **Group 2**: 1/?	
			Outcome 3: Speed of wound closure (mean time to complete closure)	**Group 1:** 63.4 (15.1) days **Group 2:** 89.7 (9.2) days P=0.16 Model of logistic regression applied for calculating odds	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
department using a block design of size 4, to assure a ratio of 50:50 in the two groups **Allocation concealment:** no details **Blinding:** double-blinded and placebo used. **Addressing incomplete outcome data:** ITT and per protocol - although 38 completed trial (54% of treatment group and 64% of placebo group = 37). Details drop-outs from which arms but unclear. Primary objective ITT analysis used. **Statistical analysis:** two-sample t-test and non-parametric tests for testing differences between groups for quantitative parameters. Chi-square and Fisher's exact tests for testing difference between groups for the categorical parameters. A multiple linear regression was applied to compare the effect of	reasons. Other 15 patients (but none of the paraplegic patients) were withdrawn during this study owing to adverse events such as a need for limb amputation (n=3), deterioration of ulcer status (n=1), acute clinical deterioration (n=8: massive pneumonia, urosepsis, ischemic colitis, installation of a cardiac pacemaker), patient's consent withdrawal (n=2), technical difficulty (n=1). **Mean age (years):** 71.1 (18.8) **Males/females:** 13/22 **Ulcer area (cm^2):** 7.4 (1.8) **Ulcer depth (cm^2):** 1.5 (1.4) **Ulcer width (cm^2):** 3.2 (1.3) **Ulcer length (cm^2):** 4.4 (1.6) **Ulcer duration (days):** 3.8 (1.5) 63 patients with 63 Pus with 25 located over the sacrum, 13 on the	electrodes placed on the healthy skin surrounding the wound. The treatment consisted initially of three such 20-min sessions daily, reduced to two daily sessions after 14 days. **Group 2:** placebo (sham). Both groups received conservative treatment of wounds (eg surgical debridement, if deemed necessary, followed by the application of hydrocolloid or collagen dressings) and placebo- DDCT		ratio between groups OR 1.6 (95% CI 0.4-4.73)	
			Outcome 4: absolute ulcer area reduction at day 147	**Group 1: 13.56** **Group 2: 14.54** **MD -0.98**	
			Outcome 5: speed of healing: (standardised estimate for trend of healing speed): (rate of wound area reduction reflected by change from baseline of ulcer area, percentage). Using model of linear regression (standardised estimate of healing speed)	**Group 1: -0.44** **Group 2: -0.14** **Group 1:** -0.24 **Group 2:** -0.25 P=0.78	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
change in the wound area along the weeks. **Baseline differences:** no **Study power/sample size:** 31 patients were required in each group. **Setting:** 11 departments of geriatric and rehabilitation medicine. **Length of study:** 8 weeks treatment; followed up for 12 weeks (90 days) from DDCT treatment termination. **Assessment of PUs:** measurements of the surface area using a specific software program to assure accuracy of method of measuring the wounds size. **Classification of PUs:** classification system not reported. **Multiple ulcers:** no	trochanters, 13 on the calves and ankles, 6 on the heels, 4 on the buttocks and 2 on the ischium. The distribution of these was similar in both groups. **Group 1** **Randomised N:** 35 **Completed N:** 19 **Dropouts:** 16 (5 elderly due to a variety of medical reasons) **Mean age (years): 71.4 (18.9)** **Males/females: 26/37** **Ulcer area (cm^2): 7.5 (2.1)** **Ulcer depth (cm^2): 1.5 (1.3)** **Ulcer width (cm^2): 3.2 (1.4)** **Ulcer length (cm^2): 4.4 (1.8)** **Ulcer duration (days): 4.2 (1.0)** **Group 2** **Randomised N:** 28 **Completed N:** 18 **Dropouts:** 10 (5 elderly due to a variety of medical				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	reasons) **Mean age (years): 71.8 (19.5)** **Males/females: 13/15** **Ulcer area (cm^2): 7.6 (1.1)** **Ulcer depth (cm^2): 1.5 (1.3)** **Ulcer width (cm^2): 3.3 (1.5)** **Ulcer length (cm^2): 4.4 (2.0)** **Ulcer duration (days): 5.0 (1.2)** **Inclusion criteria:** age >18 years, informed consent, ulcer duration less than 24 months, ulcer size greater than 1cm^2 but smaller than 50cm^2, no recent history (minimum of 30 days) of growth factors or vacuum-assisted treatment. **Exclusion criteria:** grades other than 3 degree, liver function enzymes higher than twice the upper limit of normal values, renal failure with creatinine >2mg%, anaemia (haemoglobin <10g%),				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	albumin <2.6g%, and patients having a pacemaker. Also those with significant medical disorder that might interfere with treatment results, patients with recent (2 months) use of steroids, chemotherapy or other immuno-compromising drugs. Withdrawal criteria were applied to remove patients from the study whenever considered necessary for their well-being.				

Table 149: Houghton 2010[101]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Houghton (2010) **Title:** Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury	**Patient group:** people in the community with spinal cord injuries with pressure ulcers (grade 2 to 4) **All patients** **Randomised N:** 34 **Completed N:** 34 **Drop-outs:** 0 at 3 months	**Group 1:** Electric stimulation therapy (EST) (self-guided) as part of a community-based interdisciplinary wound care program in addition to a standard wound care program. Patients, family, and/or community nurses were trained	**Outcome 1 (study's primary outcome):** % decrease in wound surface area at the end of 3 months - mean (sd)	**Group 1:** 70% (25%) **Group 2:** 36% (61%) P=0.048	**Funding:** Ontario Neurotrauma foundation grant. **Limitations:** small sample size. No blinding of caregiver and participant but the
			Outcome 2: proportion of wounds that improved (by at	**Group 1:** 12/15 (80%) **Group 2:** 5/14 (36%) OR: 7.2 (95% CI 1.4-38.3),	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Journal**:** Arch Phys Med Rehabil, 91, 669-678. **Type of study:** single-blind, parallel-group RCT **Sequence generation:** stratified into 4 groups according to ulcer duration and severity before randomisation. Randomised using a concealed random process by an independent person with random number generation. **Allocation concealment:** used an opaque envelope prepared by an independent person **Blinding:** single-blinded. Outcome assessor was blinded. **Addressing incomplete outcome data:** Clear flow diagram of patients completing treatment. The EST treatment and regular wound dressing changes continued during the 3 month intervention or until the ulcer healed. Once	Mean age (SD): 51 (14) **Group 1** **Randomised N:** 16 **Completed N:** 16 (at 3 months, n=14 at 6 months) **Dropouts:** treatment discontinued n=1, those who used EST <100 hrs n=3. Age: 50.3 (SD 17, range 23-74) Males/females: 8/8 Quadriplegia: 7 Paraplegia; 6 Spina bifida: 3 Wound location (no of subjects): Buttock region -ischial tuberosity:8 - sacrum, coccyx, hip:4 Leg: foot, ankle, knee: 4 Wound duration (years): 1.2 (SD 1.0, range 0.3-4.1) No of subjects with duration of ulcer > 2 years: 3 Wound severity (no of subjects) NPUAP grades:	to apply daily treatments of EST – included a 1 hour general inservice followed by 2 to 3 half-hour sessions in which specific instructions were provided by experienced study personnel to 2 to 3 caregivers at the bedside. Wounds were loosely packed with silver nylon dressing premoistened in sterile water or coated in hydrogel (in order to conduct electric current throughout the wound bed and to the base of deep wounds). Additional inactive packing materials (silver, zinc, hypertonic saline) or petrolatum-based products were added in order to manage the wound moisture properly for each subject. In most cases (11/16 subjects) a single electrode (4.8x10.2cm) was placed directly over the wound and a larger (12.7x20.3cm) dispersive electrode was placed on intact skin at least 20cm from the wound. A small portable, programmable device (micro Z) was used to deliver a twin –peaked monophasic pulsed current (high-voltage pulsed current) with 50us pulse	least 50% reduction) at end of 3 months	p=0.02	authors say it is not possible for EST. **Additional outcomes:** Notes: for ethical reasons, those who did not have EST were offered after the 3 month intervention period. And those with reduction on EST were offered to continue after the 3-month intervention period. Wound surface area (cm2) was determined at initial assessment before treatment and was measured at monthly intervals for 3 months.
			Outcome 3: changes in wound appearance at end of 3 months - mean PWAT scores (sd):	**Group 1:** 9 (5.1) - previously 13.38 (3.0), p=0.031 **Group 2:** not reported.	
			Outcome 4: Proportion with improved PWAT scores:	**Group 1:** 12/16 (75%) **Group 2:** 8/18 (44%) P=0.070	
			Outcome 5: Proportion with wounds that increased (worsened):	**Group 1:** 0/16 (0%) **Group 2:** 4/18 (22%) P=0.01	
			Outcome 6: Proportion with improved PSST scores:	**Group 1: 8/16 (50%)** **Group 2: 9/18 (50%)** **P=0.560**	
			Outcome 7: Proportion of grade II ulcers healed	**Group 1:** 1/1 (100%) **Group 2:** 4/4 (100%) P=0.620	
			Outcome 8: Proportion of grade III, IV, X ulcers healed:	**Group 1:** 5/15 (33.3%) **Group 2:** 1/14 (7.1%) 0.550	
			Outcome 9: Proportion of grade	**Group 1:** 12/15 (8**0%)** **Group 2:** 5/14 (36%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
healed the subject was discharged from wound care services, however monthly evaluations continued for at least 6 months when possible. **Statistical analysis:** student tests for continuous variables and chi-square analysis for categorical data. **Baseline differences:** no statistically significant differences found. **Study power/sample size:** small **Setting:** Community-based home care setting, Ontario, Canada. **Length of study:** evaluated on a monthly basis for at least 3 months and thereafter followed up for an average of 4 months **Assessment of PUs:** Wound surface area (cm2) was determined at initial assessment before treatment and was measured at monthly intervals for 3 months.	Grade II: 1 Grade III: 6 Grade IV: 7 Grade X=2 Initial wound surface area (cm2): 3.38 (sd 3.44, range 1.2 s.d 12.0) No. of subjects with multiple wounds: 8 No of subjects with previous or recurrent problems with pressure ulcers: 10 **Group 2** **Randomised N:** 18 **Completed N:** 18 **Dropouts:** 0 at 3 months, 1 at 6 months. Age: 50.3 (SD 17, range 23-74) Males/females: 8/8 Quadriplegia: 8 Paraplegia; 8 Spina bifida: 2 Wound location (no of subjects): Buttock region -ischial tuberosity: 11 - sacrum, coccyx, hip: 4	duration, intensity of the machine 50 -150v at a level that was below the level of muscle contraction and based on sensory level on intact skin. Provided 20 minutes at a pulse frequency of 100Hz followed by 20 minutes at 10Hz and then 20 minutes off cycle each hour for 8 hours each day for a period of at least 3 months. The polarity of the active electrode used in monopolar set-up was initially negative (cathode) and alternated each week.. EST protocol was incorporated into regular wound dressing changes scheduled every 1 to 3 days. **Group 2:** Standard wound care program. Both groups received standard wound care. Standard wound care program: evaluated in their homes and in clinic setting by nurses, occupational therapists, physical therapist or dieticians	III, IV, X ulcers at least 50% smaller:	P=0.020	
			Outcome 10: EST compliance - mean (s.d) and proportion using the recommended time:	**Group 1:** 3.0 (1.5)h/d (recommended treatment time 8h/d) 4/16 Those who healed used the EST longest (539 total hours; 3.54h/d); those who did not heal (331 total hours; 2.24h/d).Average for those who healed: 136.4 days (4.5 months)	
			Outcome 11: Adverse reactions:	**Group 1:** Red area or burn under the active electrode after EST treatment, area resolved within 48 hours and remedied by turning down the intensity of subsequent EST treatments. One patient complained of dizziness and delusions while receiving EST but was evaluated as withdrawal from narcotics after lapse in prescription.	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of Outcomes: wound surface area determined using Visitrak system – previously validated, which involves tracing the wound perimeter onto acetate film and digitising using a calibrated tablet. Change in wound appearance evaluated using the PWAT and PSST. EST compliance - a meter tracked the total no. of hours the machine was used to determine amount of time EST applied for each subject. **Classification of PUs: stratified into 4 groups using NPUAP definitions for grades:** grade 2 or 3 ulcers present for more than 2 years, grade 2 or 3 pressure ulcers present for less than 2 years, grade 6 or ungradeable (grade X) ulcers present for more than 2 years, and grade 6 or X pressure ulcers present for less than 2 years.	Leg: foot, ankle, knee: 3 Wound duration (years): 3.0 (s.d 5.6, range 0.3-15.20) No. of subjects with duration of ulcer > 2 years: 4 Wound severity (no of subjects) NPUAP grades: Grade II: 4 Grade III: 4 Grade IV: 10 Grade X: 0 Initial wound surface area (cm2): 2.73 (s.d 2.89, range 1.1 -10.9) No. of subjects with multiple wounds: 5 No of subjects with previous or recurrent problems with pressure ulcers: 11 **Inclusion criteria:** people with paraplegia or quadriplegia caused by congenital, medical or traumatic SCI, over the age of 18 years, living in the community, had a grade II to IV pressure	with experience of treating SCI and/or pressure ulcers. Medical and wound histories collected. Patient activity schedule completed to identify all surfaces encountered and the type of transfers performed daily. If wheelchair seating a concern an assessment conducted. A review of nutritional issues conducted. Blood analysis performed. A wound assessment was performed to assess wound dressing required. Tailored program of needs of each subject for nutritional intervention, optimisation of wound dressing protocol and continence management. Subjects did not receive the same wound dressing protocol and had a customised program. A comprehensive pressure management program was also included. The program was described to patients prior to randomisation so they could decide if they wished to participate in the study.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: no	ulcer between 1 and 20cm^2 present for at least 3 months in standard wound care program that included appropriate pressure redistribution **Exclusion criteria:** Serious or multiple medical conditions that would limit healing; any condition that was contraindicated for EST (cardiac pacemaker, osteomyelitis, pregnancy, cancer).				

Table 150: Franek 2011[79]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Franek 2011 **Title:** Effect of high voltage monophasic stimulation on pressure ulcer healing: results from a randomised controlled trial Journal**:** Wounds 2011, 23(1), 15-23 **Type of study:** RCT **Sequence generation:** computer-generated	**Patient group: patients with stage I, II and III pressure ulcers** **All patients** **Randomised N:** 58 **Completed N:** 58 **Drop-outs:** 0 **Group 1** **Randomised N:** 29 **Completed N:** 29	**Group 1:** high voltage monophasic stimulation (double-peaked monophasic impulses of 100us and frequency 100Hz were applied at 100v. Treatment performed with a current amplitude, which produced sub-motor stimulation that caused a mild tingling sensation. Electrodes were made of silver or conductive carbon rubber. The active electrode size was matched to the wound size and	**Outcome 1:** Proportion of patients with ulcers healed	**Group 1:** 8/29 (27.6%) **Group 2:** 4/29 (13.8%)	**Funding:** no details **Limitations:** small study, no blinding (although authors say not possible for EST but no mention of outcome assessors **Additional outcomes:**
			Outcome 2: relative change of total surface area	**Group 1:** 85.38% **Group 2:** 40.08%	
			Outcome 3: relative change in length	**Group 1:** 71.22% **Group 2:** 30.38%	
			Outcome 4: relative change in width	**Group 1:** 76.09% **Group 2:** 32.48%	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
randomised numbers **Allocation concealment:** the generated random numbers were sealed in sequentially numbered envelopes and group allocation was independent of place and person delivering the treatment. **Blinding:** no blinding. **Addressing incomplete outcome data:** no mention of drop-outs. **Statistical analysis:** chi-square independence test used for analysis of the indicators. Mean values of the Gilman Index, total area, length, width and volume of the ulcers before and after therapy were compared in both groups by Wilcoxon matched-pairs signed-rank test and the Mann-whitney U-test was used to evaluate differences in relative changes between the groups. To define relationships between the change of wound are	**Dropouts:** 0 **Females/males:** 10/19 **Age (years):** 59.90 (s.d 8.8, range 19-87) 3 patients had ulcers from poorly fitting footwear, 3 from poorly fitted artificial limbs (prosthesis), 6 from plaster cast usage after a bone fracture, and 2 due to complication of unhealed post-operative wounds, 3 from internal pressure from surgical metal plates and screws following orthopaedic operation, 4 from prolonged immobilisation, other patient's ulcers were from mechanical soft tissue injuries (abrasion, scratch etc) **Ulcer grade (no. of patients):** **Grade 1:** 7 **Grade 2:** 13 **Grade 3:** 9 **Ulcer location:** Lower leg: 16 Foot: 8 Gluteal/ischial: 2	placed on saline soaked gauze directly into the wound. The return electrode was positioned on intact periwound skin. Each procedure lasted 50 minutes. Stimulation was repeated once daily for 5 days a week. Treatment always began with cathode stimulation to clean the wounds of nonviable tissue. Cathode stimulation time lasted for 2 weeks. This was followed by anode stimulation, performed for 4 weeks. **Group 2:** pharmacologic agents, administered identically as in group 1. Both groups: pharmacological agents, including wound cleansing with potassium permanganate. The ulcer base was covered with compresses of fibrolan, colistin, and iruxol and wet dressings of 10% sodium chloride. Dressings were changed daily (in experimental group local bath, compresses, and wet dressings were provided after HVMS procedures).	**Outcome 5:** relative change in volume	**Group 1:** 20.69% **Group 2:** 9.39%	
			Outcome 6: relative change in Gilman Index	**Group 1:** 0.64cm **Group 2:** 0.28cm P</=0.001 in favour of group A	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and volume with changes of linear dimensions the Spearman correlation index was used. **Baseline differences:** no statistically significant differences. **Study power/sample size:** small, no power calculation **Setting:** the Traumatic Surgery Hospital, Piekary Skaskie, Poland. **Length of study:** 6 weeks treatment. **Assessment of PUs:** measured by planimetry of congruent projections of the wounds onto transparency paper then using a digitzing pallet. The depth was measured at various point by precision micrometry. Measurements of area (total and isolated areas covered with pus or granulation) and volume were performed in each person before therapy and every week during treatment. Length and	Ankle: 2 Hand: 1 **Duration of disorder (months):** mean 3.17 (s.d 2.33, range 1-6) **Initial wound area (cm2):** mean 4.45 (s.d 3.39, range 1.11-15.81) **Initial wound volume (cm2):** mean 0.04 (s.d 0.12, range 0.01-1.24) **Group 2** **Randomised N:** 29 **Completed N:** 29 **Dropouts:** 0 **Age (years):** 60 (s.d 9.97, range 14-88) Females/males: 18/11 1 patient had pressure ulcers from poorly fitting footwear, 3 from a poorly fitted artificial limb (prosthesis), 2 from plaster cast usage after a bone fracture and three as a result of complications of unhealed postoperative wounds, 3 had ulcers related to internal pressure from surgical metal plates and screws after an orthopaedic				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
perpendicular width dimension measurements were also recorded. Observation of healing process supported by precisely calculated parameters such as the Gilman index and relative changes. **Classification of PUs:** classification system not reported. **Multiple ulcers:** no.	operation, 7 had ulcers from prolonged immobilisation, the rest had ulcers from mechanical soft tissue injuries. p>0.05 **Ulcer grade (no. of patients):** **Grade 1:** 8 **Grade 2:** 13 **Grade 3:** 8 p>0.05 **Ulcer location:** Lower leg: 13 Foot: 6 Gluteal/ischial: 4 Ankle: 2 Hand: 4 **Duration of disorder (months):** mean 2.80 (s.d 2.32, range 1-6) **Initial wound area (cm2):** 4.93 (s.d 4.95, range 1.14-15.09) **Initial wound volume (cm2):** 0.04 (s.d 0.11, range 0.01-1.29) **Inclusion criteria:** Grade I (erythema of intact skin - darker skin, discoloration				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	of the skin, warmth, edema, hardness); Grade II (partial-thickness, skin loss, involving the epidermis, dermis or both; the injury is superficial and clinically presents as an abrasion, blister or shallow crater); or Grade III (total-thickness skin loss, involving damage to or necrosis of subcutaneous tissue that may extend down to fascia or muscle; pressure ulcer appears clinically as a deep crater). **Exclusion criteria:** spinal cord injuries or other loss of sensitivity (paresis or paralysis), chronic venous insufficiency, arteriosclerosis (ABPI <0.9), diabetes, ventricular arrhythmia, cardiac pacemakers, metal implants, pregnancy, and post-steroid therapy.				

Table 151: Kloth 1988[118]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kloth 1988 **Title:** Acceleration of wound healing with high voltage, monophasic, pulsed current Journal**:** Physical therapy, 68 (4), 503-508 **Type of study:** RCT **Sequence generation:** coin tossed by person not involved in the study **Allocation concealment:** no details **Blinding:** sham placebo used. **Addressing incomplete outcome data:** no missing data. **Statistical analysis:** none **Baseline differences:** no details **Study power/sample size:** very small study/no sample calculation given **Setting:** no details , assume hospital **Length of study:** 16 weeks treatment. **Assessment of PUs:** the	**Patient group:** patients with grade 4 pressure ulcers **All patients** **Randomised N:** 16 **Completed N:** 16 **Drop-outs:** 0 Age range: 20-89 years of age **Group 1** **Randomised N:** 9 **Completed N:** 9 **Dropouts:** 0 Age (mean): 71 (s.d 21) years **Group 2** **Randomised N:** 7 **Completed N:** 7 **Dropouts:** 0 3 patients whose ulcers did not heal were re-assigned arbitrarily to the treatment group to assess whether their ulcers would respond to the HVS treatment.	**Group 1:** high voltage, monophasic, pulsed current (daily electrical stimulation from a commercial high voltage generator - Dyna Wave model 12 high voltage, monphasic twin-pulsed generator) The frequency was 105Hz, an intraphase interval of 50usec, and a voltage just below that capable of producing a visible muscle contraction (100-175 V). At 100 V with an intraphase interval f 100usec, the single-phase charge was calculated at about 1.6uC with a total-pulse charge accumulation of 342uC/sec. Patients received 45 minutes of ESTR once a day, five days a week. **Group 2:** had the electrodes applied daily but received no stimulation. Sham treatments were given for periods of 4,5 and 16 weeks to three patients in the control group - the wound dimensions either increased or did not change in size and they were then reassigned to the treatment group.	**Outcome 1:** proportion with ulcers healed completely healed (total ulcer surface area change (%))	**Group 1:** 9/9 (100%) over mean period 7.3 weeks **Group 2:** 0/7 (0%) (increased by 28.93% s.d 89.8%) over mean period of 7.4 weeks	**Funding:** no details **Limitations:** very small sample size**.** No allocation concealment. No mention of outcome assessor blinding. **Additional outcomes:** three patients who were crossed over from control to treatment group had a healing rate of 38.1%per week after being reassigned and had 100% healing over 8.3 weeks.
			Outcome 2: healing rate (%/week) Wound surface area reduction per week	**Group 1:** 44.80% (s.d 22.6) **Group 2:** -11.59% (s.d 18.6)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
same physical therapist recorded surface area wound dimensions before and after treatment at weekly treatment intervals. Plastic wrap was placed over the wound and traced (three times) round the wound's perimeter with a fine-tipped transparency marker. Metric graph paper used to determine the wound area to nearest hundredth of a square centimetre. Analysed wound area weekly from % change in wound dimensions. Additionally 35mm macro slides at weekly intervals to further document wound dimensions. **Classification of PUs:** classification system not reported. **Multiple ulcers:** no	Age (mean): 66 (s.d 21) years **Inclusion criteria: (not strictly listed as inclusion criteria but common to all participants:** intact peripheral nervous systems; grade IV ulcers that had eroded into or through a muscle; ulcers had been unresponsive to previous treatments administered by other health care personnel. **Exclusion criteria:** no details	Both groups: all patients who had ulcers caused by pressure against the skin used a pressure-relieving device that reduced exogenous cutaneous pressure. All patients took a high-protein dietary supplement to help offset nitrogen loss from wound protein breakdown. Wounds were debrided manually and with enzymes. Thick eschar and the outermost necrotic tissue were debrided manually. A proteolytic enzyme ointment Elase was applied twice daily for the first 3 days of treatment to selectively digest the necrotic protein. Any remaining necrotic collagen was debrided on the 4th treatment day with a collagenase enzyme ointment, Biozyme-C. The wound was packed with saline-moistened gauze during enzymatic debridement to absorb slough and was covered with plastic wrap to retain moisture until the healing was complete. Enzyme residues were flushed from the wound with a saline solution before electrode			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
		placement and the wound was packed loosely and covered with sterile, saline-saturated gauze sponges to enhance electrical conductivity. The positive electrode was placed over the wound and the edge-to-edge distance between the anode and the cathode was maintained at 15cm with the anode cephalad to the cathode and close to the nueraxis, this was maintained unless the patient reached a plateau in wound healing. 4 patients in the treatment group reached an initial healing plateau, then the cathode was moved over the wound, and the anode repositioned 15cm cephalad. When the same patients reached a second healing plateau, electrode polarity on the wound was alternated daily.			

Table 152: Ahmad 2008 [5]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ahmad 2008 **Title:** High-voltage pulsed galvanic	**Patient group:** patients with an indolent pressure ulcer of grade 2 (Yarkony-Kirk classification) chronic	**Group 1:** high-voltage pulsed galvanic current (HVPC) for 45 minutes seven days a week **Group 2:** HVPC for 60 minutes	**Outcome 1:** reduction in wound surface area (cm2)	**Group 1 (45 min):** MD 2.02 **Group 2 (60 min):** MD 6.52 **Group 3 (120 min):** MD 6.3 **Group 4 (control):** MD 1.82	**Funding:** No details **Limitations:** no details of sequence

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
stimulation: effect of treatment on healing of chronic pressure ulcers Journal**:** Journal of Burns and Fire Disasters, vol XXI, 3, 124-128 **Type of study:** multicentre RCT **Sequence generation:** no details **Allocation concealment:** no details **Blinding:** control group was sham treatment but other groups differed on duration of HVPC so not blinded between these groups. **Addressing incomplete outcome data:** no details of withdrawals. **Statistical analysis:** paired t-test to compare wound areas at baseline and after 3 and 5 weeks. An unpaired t-test was used to compare the three treatment groups with the control group. **Baseline differences:** no **Study power/sample size:** no sample size	pressure ulcers **All patients** **Randomised N:** 60 (60 wounds) **Completed N:** unclear **Drop-outs:** unclear Number of wounds: 60 Age: 30 to 50 years. **Group 1** **Randomised N:** 15 **Completed N:** unclear **Dropouts:** unclear Male/female: 6/9 Mean age (sd): 38.40 (6.82) Mean wound duration months (sd): 4.41 (0.9) **Group 2** **Randomised N:** 15 **Completed N:** unclear **Dropouts:** unclear Male/female: 7/8 Mean age (sd): 38.47 (1.68) Mean wound duration months (sd): 4.40 (0.9)	seven days a week **Group 3:** HVPC for 120 minutes seven days a week **Group 4:** control group - sham HVPC for 45 minutes seven days per week in addition to conventional wound therapy wet dressing and whirlpool therapy four or five times per week) All wounds were debrided before admission to the study Equipment: small, portable high-voltage monophase twin-pulsed generator. Frequency of 120Hz, an interphase interval of 50usec, and a voltage just below that capable of producing a visible muscle contraction (100-175 V). Patients in the treatment groups received 45, 60 and 120 minutes of HVPC applied to the ulcer site once daily seven days per week. A piece of heavy-duty aluminium foil, slightly wet and larger than the perimeter of the ulcer, was attached with an alligator clip to the negative			generation, allocation concealment. No blinding between treatments as duration. No details of withdrawals. Small sample size in each group and no sample size calculation. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
calculation. Small sample in each group. **Setting:** 4 sites. **Length of study:** 5 weeks treatment. **Assessment of PUs:** wound surface area was measured by tracing the wound perimeter (Kloth and Feedar). A sterilised transparency film was placed over ulcer and the perimeter was traced by using the film-tipped transparency marker (three time). This was then traced onto metric graph paper and the number of square millimetres counted. **Classification of PUs:** Yarkony-Kirk classification system. **Multiple ulcers:** no.	**Group 3** **Randomised N:** 15 **Completed N:** unclear **Dropouts:** unclear Male/female: 8/7 Mean age (sd): 39.40 (1.74) Mean wound duration months (sd): 4.41 (0.9) **Group 4** **Randomised N:** 15 **Completed N:** unclear **Dropouts:** unclear Male/female: 9/6 Mean age (sd): 39.40 (1.69) Mean wound duration months (sd): 4.48 (0.9) **Inclusion criteria:** pressure ulcer of grade 2 (Yarkony-Kirk classification) **Exclusion criteria:** cardiac pacemaker, peripheral vascular diseases disposing them to thrombosis, or active ostemyelitis and if they were pregnant or receiving long-term	lead of the HVPC unit. The foil electrode was placed over the ulcer on top of saline-soaked gauze. A sandbag or elastic wrap was used if needed to hold the wound electrode in place. The dispersive electrode was strapped over the patient's medial thigh with wet gauze placed between the electrode and the patient's skin. The active electrode was of negative polarity for the first three days of HVPC application, while the dispersive electrode was positive. After this 3-day period, positive polarity was in the active electrode and negative polarity was in the dispersive electrode. Positive polarity was maintained in the active electrode until the wound healed or a healing plateau was noted. If such a plateau was reached, the protocol of negative polarity in the wound site for a 3-day period was restarted. Patients in the control group had electrodes applied in the same manner as patients in the treatment groups, except that voltage was maintained at zero.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	radiation therapy, steroid therapy, or chemotherapy.				

Table 153: Adegoke 2001[1]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Adegoke 2001 **Title:** Acceleration of pressure ulcer healing in spinal cord injured patients using interrupted direct current Journal**:** African Journal of Medicine and Medical Sciences, 30, 195-197. **Type of study:** RCT **Sequence generation:** no details about how sequence was generated. **Allocation concealment:** randomly assigned by an individual with no knowledge of the treatment modality. **Blinding:** placebo but no details of blinding of outcome assessors. **Addressing incomplete**	**Patient group:** spinal cord injured patients with grade 4 pressure ulcers located in the pelvic region **All patients** **Randomised N:** 7 **Completed N:** 6 **Drop-outs:** 1 Age: 21-60 years (mean 43.8, s.d 13.9) **Group 1** **Randomised N:** 3 (there was one other patient but they were discharged from the hospital before the end of the study but does not say which arm this patient was in). **Completed N:** 3 **Dropouts:** 0/1 Age: median 54.0 years	**Group 1:** routine nursing care plus interrupted direct current **Group 2:** routine nursing care plus placebo interrupted direct current. Both groups: After cleaning, treatment group were covered with sterilised gauze soaked in 0.9% saline. Two pieces of aluminium plate electrodes cut to sizes slightly larger that the ulcers' perimeters were then attached to the leads of the IDC machine. The electrodes were wrapped in 6 layers of lint soaked in 0.9% saline; the active electrode was placed directly over the ulcer and the inactive electrode on any suitable part of the body. The IDC unit was then turned on and the intensity gradually increased until a 'minimal	**Outcome 1: %** reduction in surface area	**Group 1:** 22.2% (week 0 - mean 15.8, sd 14.3, end of week 2 - mean 13.3, sd 14.1 (15% change), end of week 4 - mean 12.3, s.d 14.1 (7.5% change) **Group 2:** 2.6% (week 0 - mean 15.4, sd 3.6, end of week 2 - mean 15.1, sd 3.6 (1.9% change), end of week 4 - mean 15.0, s.d 0.7 (2.6% change)	**Funding:** no details **Limitations:** very small sample size. No details of sequence generation. Unclear allocation concealment. No details of blinding of outcome assessors. 1 drop-out but no details of which arm. Difference at baseline. **Additional outcomes:** *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: 1 drop out but unsure which arm and discounted as they requested to be discharged from the hospital before the end of the study **Statistical analysis:** no statistical tests used. **Baseline differences:** difference in age, although the authors say there was no statistically significant differences for age or other physical characteristics. **Study power/sample size:** very small, no sample size calculation given. **Setting:** neurology wards of the University College Hospital, Ibadan, Nigeria. **Length of study:** 4 weeks treatment. **Assessment of PUs:** measured for surface area on day 0, 2 weeks and 4 weeks. The surface of a double sheet of tracing paper that was in contact with the ulcer was first	(mean 52.7, sd 8.1) Ulcer duration (weeks): 12.0 , s.d 2.0. Ulcer surface area 15.8 (s.d 14.3) Ulcer location at baseline: Greater throcanter: 2 Sacrum: 1 Diagnosis: Quadriplegia: 3 Paraplegia: 0 **Group 2** **Randomised N:** 3 **Completed N:** 3 **Dropouts:** 0/1 Age: median 36.9 years (mean 35.0, s.d 13.5) Ulcer duration (weeks): 8.0 (s.d 2.0) t value 1.94 Ulcer surface area 15.4 (s.d 3.2, t value 0.05). Ulcer location at baseline: Greater throcanter: 1 Sacrum: 2 Diagnosis: Quadriplegia: 2 Paraplegia: 1 **Inclusion criteria:** not	perceptible contraction' was produced. The intensity was then turned down to a level just below that capable of producing muscle contractions. The rest to surge ratio was 2:1 at a frequency of 30Hz and the wave form was rectangular. Each treatment session lasted 45 minutes.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
cleaned with methylated spirit. The ulcer's perimeter was then traced with a fine-tipped marker, the surface of the tracing paper in contact with ulcer cut off and the ulcer's impression transferred onto a metric graph paper from where the surface area of the ulcer was measured. The number of square millimetres on the metric graph paper which fell within the ulcer tracing were counted to determine the ulcer area to the nearest tenth of a square centimetre. **Classification of PUs:** no classification system reported. **Multiple ulcers:** no.	stated **Exclusion criteria:** not stated				

Table 154: Baker 1996[18]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Baker 1996 **Title:** Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury Journal**:** wound repair and regeneration **Type of study:** RCT **Sequence generation:** no details **Allocation concealment:** no details **Blinding:** blinded outcome assessor. **Addressing incomplete outcome data:** unclear **Statistical analysis:** comparison of mean healing rates was done with a one-way analysis of variance. An ANOVA with repeated measures design and covariate was used when comparing ulcers which were treated with both control and stimulation protocols. Multiple and stepwise regression	**Patient group:** spinal cord injury patients with one or more pressure ulcers **All patients** **Randomised N:** 80 (Ulcers N: 192) **Completed N:** unclear **Drop-outs:** unclear Number of pressure ulcers: 192 (all of which received one of four treatment protocols) **Group 1** **Randomised N:** 20 (Ulcers N: 67) **Completed N:** unclear **Dropouts:** unclear Males/females: 17/3 Age (mean, sd, range): 34 (sd, 19-64) No. of wounds: 67 Duration of ulcer (range, days): 183 (42), 2-454 Ulcer location: Foot:9 Thigh: 10 Ischial: 20	**Group 1:** asymmetric biphasic electrostimulation Amplitude: below contraction Phase duration (usec): 100 Frequency (pulses/sec): 50 On/off time (sec) 7:7 **Group 2:** symmetric biphasic electrostimulation Amplitude: below contraction Phase duration (usec): 300 Frequency (pulses/sec): 50 On/off time (sec) 7:7 Group 3: microcurrent (was to be control group but preliminary data showed some therapeutic effect) Amplitude: 4mA Phase duration (usec): 10 Frequency (pulses/sec): 1 On/off time (sec) 7:7 Group 4: control group - received same stimulation procedures as the microcurrent treatment groups but special leads interrupted the passage of current so the patient	**Outcome 1:** Healing rates - mean % reduction per week (sd)	**Group 1:** 36.4 (6.2) **Group 2:** 29.7 (5.1) **Group 3:** 23.3 (4.8) **Group 4:** 32.7 (7.0)	**Funding:** grant from the National Institute on Disability Research and Rehabilitation, department of Education. **Limitations:** no details of sequence generation or allocation concealment **Additional outcomes:** stratified mean healing rates according to good response and poor response.
			Outcome 2: Healing rates - mean cm2 (taken from initial area to final area)	**Group 1:** 2.2 cm2 **Group 2:** 1.3 cm2 **Group 3:** 5.1 cm2 **Group 4:** 3.1 cm2	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
analyses were also used. **Baseline differences:** no significant differences. **Study power/sample size:** n=80 patients, 192 ulcers **Setting:** hospital **Length of study:** 4 weeks treatment. Crossed over if required. **Assessment of PUs:** tracing of the wound edge onto a clear acetate sheet. Measured every week for inpatients and every 2 to 4 weeks for outpatients. In addition a calibrated photograph was used to assist in the later interpretation of the tracing. The surface area of the wound was digitized from the tracing by a technician who was not knowledgeable about the treatment received by the patient. When there was a significant depth to an ulcer several techniques were used. The volume of sterile	Sacral: 24 Other: 3 Ulcer source: Surgery: 31 Pressure: 36 Infected (yes/no): 47/19 Duration of stimulation therapy (days): 34 (5) Stimulation time (hr/day): 1.4 (0.1) **Group 2** **Randomised N:** 21 Ulcers N: 58 **Completed N:** unclear **Dropouts:** unclear Males/females: 16/5 Age (mean, sd, range): 40 (sd 2, 21-64) No. of wounds: 58 Duration of ulcer (range, days): 231 (38), 2-1095 Ulcer location: Foot: 5 Thigh: 13 Ischial: 18 Sacral: 19 Other: 3 Ulcer source:	received no electrical stimulation. All inpatients were seen 5 days a week by a physical therapist working on the research project. Three treatment sessions of 30 minutes duration were provided with a short break between sessions. After each break the stimulator was programmed to automatically restart the treatment session. The patient was instructed to remove the stimulator after three sessions. Compliant stimulation time was considered to be 1.5 hours per day, with half that amount (45 minutes) defined as semicompliant stimulation. If patients chose to remain on stimulation for longer periods of time this was monitored by the therapist each day through the compliance feature of the stimulation unit. Subjects treated as outpatients were monitored regularly through clinic appointments, home visits and frequent phone calls. Compliance to the			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
saline solution which filled the wound but was not possible for patients due to not being able to position the ulcer perpendicular to gravity. **Classification system:** classification system not reported. **Multiple ulcers:** patients could be used with more than one ulcer. Reported data by ulcer.	Surgery: 41 Pressure: 17 Infected (yes/no): 24/34 Duration of stimulation therapy (days): 42 (5) Stimulation time (hr/day): 1.6 (0.1) **Group 3** **Randomised N:** 20 Ulcers N: 42 **Completed N:** unclear **Dropouts:** unclear Males/females: 17/3 Age (mean, sd, range): 36 (sd 2, 17-64) No. of wounds: 42 Duration of ulcer (range, days): 154 (39), 5-961 Ulcer location: Foot: 3 Thigh: 11 Ischial: 12 Sacral: 10 Other: 6 Ulcer source: Surgery: 17 Pressure: 25 Infected (yes/no): 21/21	stimulation treatment was monitored through the compliance meter on the stimulator whenever the patient was seen by the research therapist. Follow-up was done every 2 to 4 weeks. Electrical stimulation was given through surface electrodes mad of carbon-rubber. The sizes of the electrodes varied, depending on the size and location of the ulcer, but ranged from 2.5 x 2.5 to 5x10cm. Electrodes were placed proximal and distal to the treated ulcers, but medical and lateral placements were used in some regions (coxygeal ulcers). The electrodes of patients in group 1 had the negative electrode during the leading phase of the waveform proximal to the wound, with the more positive electrode placed distally. Stimulation amplitude was set for each subject and each wound by increasing the intensity until a minimal muscle contraction was observed. The intensity was then decreased until the			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Duration of stimulation therapy (days): 38 (5) Stimulation time (hr/day): 1.9 (0.2) **Group 4** **Randomised N:** 19 Ulcers N: 25 **Completed N:** unclear **Dropouts:** unclear Males/females: 16/3 Age (mean, sd, range): 33 (sd 4, 19-76) No. of wounds: 25 Duration of ulcer (range, days): 86 (24), 5-415 Ulcer location: Foot: 2 Thigh: 4 Ischial: 10 Sacral: 9 Other: 0 Ulcer source: Surgery: 16 Pressure: 9 Infected (yes/no): 12/13 Duration of stimulation therapy (days): 20 2) Stimulation time (hr/day): 0.2)	contraction was no longer present. This procedure was followed for patients treated in group 1 and 2 only. Stimulation amplitude was fixed at 4mA for the microcurrent and control groups, the minimal intensity necessary to allow the stimulator's compliance monitor to function.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Inclusion criteria: patients with spinal cord injuries **Exclusion criteria:** no details				

Table 155: Asbjornsen 1990[14]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Asbjornsen 1990 **Title:** the effect of transcutaneous electrical nerve stimulation on pressure sores in geriatric patients Journal**:** Journal of clinical and experimental gerontology, 12 (4), 209-214 **Type of study:** RCT **Sequence generation:** no details **Allocation concealment:** no details **Blinding:** placebo used. blinded outcome assessor **Addressing incomplete outcome data:** 4 did not participate for a	**Patient group:** geriatric patients with pressure sores on the heels or the sacral region **All patients** **Randomised N:** 20 **Completed N:** 16 **Drop-outs:** 4 did not participate for minimum of 4 weeks, in the treatment group one had early discharge, one had leg amputation and one got tired of treatment. One patient in the control group's disease progressed and he died. **Group 1** **Randomised N:** 10	**Group 1:** low frequency transcutaneous electrical nerve stimulation (TENS) 30 minutes twice daily for 4-6 weeks (5 days per week). The stimulator delivered pulses at rate of 3Hz, stimulus had duration of 85 ms and consisted of a train of square wave pulses with an internal frequency of 100Hz. The electrodes were placed one between the first and second metacarpal bones and one at the ulcer edge of the same hand. The intensity was increased until contractions of adjacent muscles occurred without producing pain (usually 20-30mA) **Group 2:** placebo TENS (similar manner) - same procedure as treatment group except no electrical output to the	**Outcome 1:** Proportion of ulcers completely healed **Outcome 2:** proportion of ulcers reduced **Outcome 3:** proportion of ulcers increased	**Group 1:** 0/7 **Group 2:** 2/9 **Group 1:** 4/7 **Group 2:** 9/9 **Group 1:** 3/7 **Group 2:** 0/9	**Funding:** no details **Limitations:** very small sample. No details of sequence generation or allocation concealment or baseline differences. Higher drop-out in the treatment group. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
minimum of 4 weeks. Used numbers available at 4 weeks. **Statistical analysis:** no statistical tests **Baseline differences:** only baseline values mentioned are similar age and distribution of ulcer size. No statistical significance given. **Study power/sample size:** very small. **Setting:** assume a hospital. **Length of study:** 6 weeks treatment. **Assessment of PUs:** one of the researchers who did not know the patients allocation to treatment or control group measured the ulcers. Measurement of perpendicular diameters. **Classification of PUs:** classification system not reported. **Multiple ulcers:** no	**Completed N:** 7 **Dropouts:** 3 (one had an early discharge, one had a leg amputation and one got tired of the treatment). **Age (mean, range):** 83 years(73-94) Ulcer region: Sacral: 3 Heel: 4 **Group 2** **Randomised N:** 10 **Completed N:** 9 **Dropouts:** 1 (one patient's disease progressed and he died). Age (mean, range): 83 years (73-91) Ulcer region: Sacral: 2 Heel: 7 **Inclusion criteria:** pressure ulcers of the heels or sacral region. **Exclusion criteria:** no details	electrodes. Both groups: conventional pressure sore treatment including measures to improve their general condition, adequate local care and avoidance of pressure by staff members not involved in the study.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments

Table 156: Jercinovic 1994 [107]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Jercinovic 1994 **Title:** Low frequency pulsed current and pressure ulcer healing Journal**:** ICEEE transactions on rehabilitation engineering, 2 (4), 225-233 **Type of study:** RCT **Sequence generation:** no details **Allocation concealment:** no details **Blinding:** The authors state that because of visible muscle contractions, it was not possible to conduct a double-blind clinical trial. **Addressing incomplete outcome data:** unclear number randomised and	**Patient group:** spinal cord injured patients with 109 pressure ulcers **All patients** **Randomised N:** 73 **Completed N:** unclear **Drop-outs:** unclear Age: 18 to 68 years (mean 36 years, s.d 15 years) Patients had been disabled from one month to several years (mean 32 s.d 60 months). **Group 1** **Randomised N:** unclear **Completed N:** unclear **Dropouts:** unclear Number of ulcers: 61 Mean initial area (s.d) cm2: 10.6 (13.3) Mean initial depth (s.d) mm: 3.0 (8.5)	**Group 1:** electrical stimulation with low frequency pulsed current and standard wound care. The patients received two hours of electro stimulation daily, five times per week. The electrostimulation was delivered by two flexible self-adhering electrodes measuring 75 or 50mm in diameter, which were placed on healthy skin approximately 3cm from the edge of the ulcer. Biphasic, asymmetric, charge-balanced pulses having a repetition frequency of 40pps and a pulse duration of 205us were used. Pulses were delivered repeatedly in trains lasting 4s, followed by a 4-s pause. The amplitude was adjusted (up to 35mA) for each patient individually to achieve minimal muscle contraction, when feasible.	**Outcome 1:** mean healing rate (s.d)	**Group 1:** 2.2% (2.1) per day (linear fitting method) 5.7% (7.1) per day (exponential fitting method) **Group 2:** 1.5% (1.7) per day (linear) 2.7% (3.6) per day (exponential)	**Funding:** supported by the Ministry of Science and Technology of the Republic of Slovenia and the National Institute for Disability and Rehabilitation Research Department of Education, Washington, USA. **Limitations:** no details of sequence generation or allocation concealment. No blinding. Unclear number randomised and missing outcome data.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
completing. **Statistical analysis:** wound area values evaluated using exponential and linear fitting. For parallel groups two sample t-tests were used; for crossover group paired t-test was used. **Baseline differences:** ulcers in the control group were more complex regarding their initial size, and ulcers in the electrostimulation group were more complex regarding their tissue characteristics (appearance of granulation or necrotic tissue). **Study power/sample size:** n=73 **Setting:** no details **Length of study:** four weeks treatment then crossed over if required. **Assessment of PUs:** weekly measurements of wound area and changes in wound depth, appearance of	Number of ulcers with initial depth <5mm: 51 (83%) Number of ulcers with granulation: 27 (44%) Mean ulcer duration (s.d) days: 158 (284) n=60 Number of ulcers on - sacral: 14 - trochanter: 16 - legs: 18 - gluteal: 5 - other: 8 **Group 2** **Randomised N:** unclear **Completed N:** unclear **Dropouts:** unclear Number of ulcers: 48 Mean initial area (s.d) cm2: 17.2 (20) Mean initial depth (s.d) mm: 4.0 (8.2) Number of ulcers with initial depth <5mm: 36 (75%) Number of ulcers with granulation: 25 (52%) Mean ulcer duration (s.d) days: 125 (129) n=41	**Group 2:** standard wound care The standard treatment included initial selective debridement, the application of a new standard dressing to the ulcer two or more times per day, as needed, and a broad spectrum antibiotic in cases of infection, which were rare. The patients were lying on dry-floatation mattresses and were turned to a new position every four hours during the night. They were included in the standard rehabilitation program one to two hours per day, depending on their conditions. **Crossover group -** patients were offered to crossover to electrostimulation after the four week trial period.			**Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
granulation were recorded. **Classification of PUs:** classification system not reported. **Multiple ulcers:** patients with 109 pressure ulcers were included and reported by ulcers.	Number of ulcers on - sacral: 20 - trochanter: 11 - legs: 10 - gluteal: 4 - other: 3 **Inclusion criteria:** not explicitly states as inclusion criteria but all participants had pressure ulcers that had developed in decentralised skin below the spinal cord lesion level and before the study they were only treated with standard wound care. Twenty-four patients had more than one pressure ulcer at a time. The duration of pressure ulcers prior to study varied from one month to several years. Total 109 ulcers: - sacral area: 34 - critical areas of the legs (heel, foot, knee) - trochanter area: 27 - gluteal area: 9 - other locations: 11				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Exclusion criteria: no details				

Table 27: Franek 2012[78]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Franek 2012 **Title:** using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: results of a randomised, controlled clinical study Journal**:** Ostomy wound management (2012), 58 (3), 30-44. **Type of study: RCT** **Sequence generation:** randomly allocated but no details of sequence generation method **Allocation concealment:** Adequate. The physician allocating patients to groups had 60 envelopes, each containing a piece of	**Patient group:** grade 2 and 3 lower extremity pressure ulcers (legs, feed, lateral and medial ankles, and greater femoral trochanter. Had pressure ulcers for 1 to 6 months before the study. **All patients** **Randomised N: 50** **Completed N: 45** **Drop-outs: 5 (author says 5 dropped out but no details of other 2 randomised).** **Group 1** **Randomised N: 26** **Completed N:** **Dropouts:** 3 (2 complications unrelated to treatment and directed to other hospital, 1 withdrew	**Group 1:** Standard care plus HVES procedures (Ionoson device). Voltage exceeded 100V, twin monophasic pulses lasting 100us in total and frequency of 100HZ applied. Five 50-minute procedures per week (one procedure per day). Treated until healed or for maximum of 6 weeks. The first 1 to 2 weeks cathodic stimulation was used to facilitate granulation tissue formation, followed by anode stimulation for the rest of the treatment period. **Group 2:** standard care (see below) Both groups: measures to prevent the development of additional pressure ulcers were implemented for all patients. Pressure-redistribution surfaces	**Outcome 1: Change in surface area (%)(s.d)**	**Group 1: 88.90 (14.00)** **Group 2: 44.40 (63.10** **P=0.00003**	**Funding:** no details **Limitations: the study length (4 years) could have introduced some variability in methods and procedures. No blinding and no placebo in the control group.** **Additional outcomes:** no adverse events observed. The amperage evoked a tingling sensation in the patients, but no motor effects were
			Outcome 2: Change in the longest length (%)(s.d)	**Group 1: 74.00 (29.60)** **Group 2: 36.10 (33.90)** **P=0.0003**	
			Outcome 3: change in the longest width (%) (s.d)	**Group 1: 79.00 (25.10)** **Group 2: 36.30 (41.90)** **P=0.00008**	
			Outcome 4: Change in cavity volume (%) (s.d)	**Group 1: 100 (0)** **Group 2: 54.0 (39.40)** **P=0.008**	
			Outcome 5: change in granulation tissue area (%) (s.d)	**Group 1: 37.66 (76.17)** **Group 2: 10.36 (43.46)** **P=0.18**	
			Outcome 6: Gilmann parameter (s.d)	**Group 1: 0.66 (0.24)** **Group 2: 0.26 (0.30)** **P=0.000003**	
			Outcome 7:	**Group 1:** **Group 2:**	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
paper marked with either A or B. The physician would draw and open an envelope in the presence of a physiotherapist to see the symbol and direct the patient to one of the groups. **Blinding:** no blinding **Addressing incomplete outcome data:** unclear. **Statistical analysis:** Wilcoxon matched pairs test used to compare average wound areas, volumes, lengths and widths as well as average relative granulation tissue areas before and after treatment within each group. The Mann-Whitney U test compared average percentage change in relative granulation tissue areas. ANOVA and Tukey's post-hoc test for unequal sample sizes to compare average wound areas and average relative granulation	for personal reasons) **Age mean (range): 59 (19 to 87 years** **Gender (f/m): 8/18** **Body mass mean (range): 75.4kg (55 to 112 kg).** **BMI > 30: 7** **Grade II ulcers: 17 (5 were IIA)** **Group 2** **Randomised N:** 24 **Completed N:** **Dropouts:** 2 (1 complications unrelated to treatment and directed to other hospital, 1 died) Age mean (range): 56.2 (14 to 88) years Gender (f/m): 14/10 Body mass mean (range): 69.4kg (45 to 96kg) **Inclusion criteria: lower extremity pressure ulcers** **Exclusion criteria: ankle-brachial pressure index (ABPI <0.9, diabetes mellitus, systemic sclerosis, a cancer diagnosis, pareses, and**	and devices and pillows were used as needed. Patients were also instructed to change their positions frequently and to relieve pressure on the ulcer area as much as possible. Patients who were unable to move were repositioned by the physical therapist at least every 2 hours. All wounds received standard topical care, including cleansing with potassium permanganate followed by covering the ulcer base with dressing. Dressings were tailored to meets the patient's needs and to promote moist interactive healing. Wound dressings included nonadherent gauze pads, dressings moistened with 0.9% sodium chloride, hydrogel, propolis extractum and solcoseryl. If wound infection was suspected, desoxyribonucleasum plus fibrinolysinum, ethacridine lactate and colistinum were additionally applied. Dressings suspected of adversely interacting with electrical stimulation, such as topical agents with metal ions and	**Outcome 8:**	**Group 1:** **Group 2:**	induced.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
tissue areas. Correlations from the Spearman test. **Baseline differences:** distribution of men and women only significant difference (p=0.03). **Study power/sample size:** no sample size calculation. Small study. **Setting:** Janusz Daab Surgery Hospital, Poland **Length of study:** treated until healed, until maximum of 6 weeks. **Assessment of PUs:** change in wound area, volume, longest length and width and granulation tissue calculated. Gilman method estimates wounds size based on surface area and length of perimeter used. **Classification of PUs:** classification system not reported. **Multiple ulcers:** no	**paralysis caused by injuries to the central or peripheral nervous system; patients whose pressure ulcers required surgical intervention.**	petrolatum-based products, were not prescribed in electrical stimulation group. Sharp debridement was performed in a relatively small number of subjects (four in HVES group and six in control group). Before electrical stimulation was applied, pressure ulcers were thoroughly cleansed with 0.9% sodium chloride solution. As soon as procedure complete, dressings were applied. All immobilised patients received low-molecular-weight heparin (enoxaparin) as a standard therapy. Patients with elevated leukocyte levels were administered antibiotics based on culture and sensitivity testing of microbiological swabs taken from pressure ulcers.			

Table 28: Karba 1995[110]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Karba (1995) **Title:** Combination of occlusive dressings and electrical stimulation in pressure ulcer treatment **Journal:** Med. Sci Res (1995), 23, 671-673. **Type of study: RCT** **Sequence generation:** 'randomly assigned' but no further details **Allocation concealment:** no details **Blinding:** sham treatment as placebo **Addressing incomplete outcome data:** describes patients in control group who had to be stopped but unclear which reason for which patient. **Statistical analysis:** student's t-test used to test the hypothesis regarding the equality of mean relative healing rate. **Baseline differences:** no details **Study power/sample**	**Patient group: male patients with spinal cord injuries who had developed pressure ulcers** **All patients** **Randomised N: 12** **Completed N: 6** **Drop-outs:** 6 from control group switched to electrical stimulation **Age (range): 29-42 years** **Group 1** **Randomised N: 6** **Completed N: 6** **Dropouts:** 0 **Group 2** **Randomised N:** 6 **Completed N: 0** **Dropouts:** 6 (switched to electrical stimulation) **Inclusion criteria: no details** **Exclusion criteria: no details**	**Group 1: electrical stimulation (ES) group. 4 second trains of biphasic, charge-balanced asymmetrical current stimuli, which alternated with pauses of the same duration (4 seconds). The stimulation intensity was set in the active stimulators so that a slight, scarcely visible contraction of the muscles in the wound area was achieved.** **Group 2: sham treatment control group (CO)** **All patients: self-adhesive stimulation electrodes placed on healthy skin at the dressing edge for two hours daily and connected to the stimulators. Half of the devices actually delivered electrical stimulation (ES group), while other half were inactive (CO group).** Cleaning given with a physiological solution and covering with semiocclusive foam gel dressings. The dressings were changed as	**Outcome 1: proportion of ulcers completely healed (from graphs)** **Outcome 2: relative healing rate (mean)**	**Group 1: 6/6** **Group 2: 0/6 – see comments, this group were stopped, when crossed over 2 were completely healed in this group.** **Group 1: 7.13 (s.d 1.46)% per day** **Group 2: -0.66 (s.d 1.16)% per day**	**Funding:** supported by the Ministry of Science and Technology of the Republic of Slovenia. **Limitations:** no details of sequence generation or allocation concealment or whether outcome assessors were blinded. Very small sample size. No details of baseline differences or inclusion /exclusion criteria. **Additional outcomes:** **Notes:** Treatment had to be stopped in the control group after an unpleasant odour, unhealthy exudate, non-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: no sample size calculation but very small sample size **Setting:** hospitalised at the Rehabilitation Institute, Slovenia **Length of study:** 98 days. Not stated but graph showed some patients at 98 days. **Assessment of PUs:** measured at dressing changes and photographs taken. **Classification of PUs:** classification system not reported **Multiple ulcers:** no		necessary or at the latest after one week.			healing and in some cases also pain observed. These patients were crossed over to a combination of conventional treatment with standard gauze dressing and electrical stimulation and all six cases improved and healed with an average relative healing rate of 2.93 (s.d 1.01)% per day.

Table 157: Ashby 2012[15]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author: Ashby 2012 **Title**: A pilot randomised controlled trial of negative pressure wound therapy to treat grade III/IV pressure ulcers **Journal:** Trials, 2012, 13; 119 **Study type**: pilot randomised controlled trial Study quality: Sequence generation: pre-generated randomisation programme with permuted blocks (of four and six) Allocation concealment: nurses telephoned a secure and remote randomisation service Blinding: blinded outcome assessor Addressing incomplete outcome data: ITT analysis Statistical analysis: descriptive Baseline differences: not	Patient group: All patients Randomised N= 12 Completed N= 12 Drop-outs: 0 Age: median 25th to 75th centiles: 67.5 (54.5 to 82 years) M/F: 5/7 Patients: acute n=3; general ward n=3; patient's home n=8; nursing home n=1 Grades: III n=7; IV n=5. Location: heel n=1; trochanter n=1; sacrum n=5; buttocks/gluteal n=3; Ischial n=2. Group 1 Randomised N: 6 Completed N: 6 Dropouts: 0 M/F; not reported by group Age (mean): not reported by group Wound size (mean, SD, range): not reported by	Group 1: NPWT (vacuum-assisted wound closure) VAC therapy Units and Systems range (Kinetic Concepts Inc). Duration determined by nurse. VAC WhiteFoam or GranuFoam dressings; other dressings or treatments/procedures applied/performed as necessary. Group 2: Standard care chosen by nurse – a spun hydrocolloid (fibrous hydrocolloid) dressing, oa foam dressing or an alginate dressing (all non-silver) Frequency of dressing changes determined by the nurse (standard practice). Non-trial treatment – participants who could no longer receive the trial treatments received a non-trial treatment and remained in the trial. This was applied at the discretion of the treating clinician.	Outcome 1: Proportion completely healed	Group 1: 1/6 Group 2: 0/6	Funding: Medical Research Council grant. Limitations: Pilot study not designed to detect a treatment effect. All 6 patients withdrew from NPWT (recurrence of black slough when VAC applied; reference ulcer too small to continue VAC treatments – no further improvements noted from VAC treatment; white foam embedded in granulation tissue, deterioration of pressure ulcer, possible wound infection; patient refused to have VAC dressing; difficult to maintain seal on VAC dressing, patient
			Outcome 2: Time to healing (days):	Group 1: 79 Group 2: N/A	
			Outcome 3: Mortality	Group 1: 1/6 Group 2: 0/6	
			Outcome 4: Pain	Group 1: 2/6 Group 2: 0/6	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
detailed by group but did say that a greater number of comorbidities were recorded in the NPWT group. Study power/sample size: underpowered, very small sample size (pilot study) Setting: NHS Leeds Primary Care Trust area Length of study: 2-6 months follow-up Assessment of PUs: photographs were reviewed by outcome assessor. Width, length and depth recorded. Classification of PUs: EPUAP classification system Multiple ulcers: the deepest ulcer was defined as the reference ulcer.	group Group 2 Randomised N: 6 Completed N: 6 Dropouts: 0 M/F: not reported by group Age (mean): not reported by group Wound size (mean, SD, range): not reported by group Inclusion criteria: must have a pressure ulcer grade III or IV (EPUAP); must receive primary care via Leeds primary care trust (PCT); pressure ulcer should contain at least 80% viable tissue or have a very thin layer of slough (nonviable tissue) requiring no further debridement prior to use of Negative Pressure Wound Therapy Exclusion criteria: presence of unclear undermining in the				not compliant with VAC treatment and 1 withdrew from the standard care, they were still followed up. Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	pressure ulcer cavity, precluding the sue of NPWT (i.e. the deepest point of ulcer cannot be measured); pressure ulcer has necrotic tissue, eschar or necrotic bone present; patient has a limited life expectancy e.g undergoing end-stage palliative care; pressure ulcer located where, in the opinion of the treating clinician, a vacuum seal cannot be obtained, e.g. the anus; pressure ulcer too close to exposed blood vessels and/or organs, anastomotic sites and/or nerves; patient is unable to give valid informed consent because of incapacity; patient is unable to consent as trial materials are not available in a suitable language; patient does not wish to consent to participation within the trial; a clinical judgement has been made that the patient is not receiving adequate nutrition to allow treatment with NPWT;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	other reasons, in the clinical judgement of the treating clinician or nurse, which exclude the patient from the trial.				

Table 158: Wanner 2003[241]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author: Wanner (2003). **Title:** Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study Journal**:** Scand J Plast Reconstr Surg Hand Surg, 37, 28-33 **Type of study:** randomised controlled trial **Study quality:** **Sequence generation:** no details **Allocation concealment:** no details	**Patient group:** spinal injury patients - paraplegic or tetraplegic patients with higher than grade 2 ulcers in the pelvic region **All patients** **Randomised** N=24 Study numbers show that it was n=24 patients and 2 dropped out after randomisation (1 due to lack of data and 1 from severe diahorrea) but authors specify n=22 randomised. **Completed N=**22 **Drop-outs:** 2	**Group 1:** vacuum-assisted wound closure **Group 2:** wet-to-dry/wet-to-wet technique with gauze soaked in Ringer's solution three times per day	**Outcome 1:** time to reach 50% of the initial volume (at that point all ulcers were then closed with a flap) mean (SD)	**Group 1:** 27 (10) days **Group 2:** 28 (7) days **WMD:** -1.00 day; 95% CI -8.21 to 6.21 P=0.79	**Funding:** no financial support received. **Limitations:** very small sample size, no details of sequence generation, allocation concealment or blinding. The mean wound size was larger in the vacuum-assisted than the wet-to-dry/wet-to-wet group.
			Outcome 2: actual reduction in mean wound volume at 42 days(read from graph)	**Group 1:** 26.5ml **Group 2:** 27.3ml **MD:** 0.8ml [there is a p-value of 0.2 but unsure if this is correct for this value]	
			Outcome 3: % reduction in mean wound volume at 42 days(read from graph)	**Group 1: 53%** **Group 2: 65%** **MD:** 12% larger	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: No blinding of health care providers or patients. Outcome assessors were not blinded. **Addressing incomplete outcome data:** withdrawals are described. No ITT analysis. **Statistical analysis:** Wilcoxon rank-sum test used. Equivalence test set at 20% of the mean for adjusted and non-adjusted values. **Baseline differences:** The mean wound size was larger in the vacuum-assisted than the wet-to-dry/wet-to-wet group. **Study power/sample size:** small (n=22), no sample size calculation. **Setting:** hospital in Switzerland. **Length of study:** endpoint defined as when wound volume decreased by 50% because all ulcers were	**Group 1** **Randomised N: 12** **Completed N:11** **Dropouts: 1** **Age (mean): 49 (25-73 years)** **Wound size (mean, SD, range): 50 (33), 3-132** **Group 2** **Randomised N: 12** **Completed N:11** **Dropouts:1** **Age (mean): 53 (34-77) years** **Wound size (mean, SD, range): 42 (16), 5-68.** **Inclusion criteria:** pressure sore in the pelvic region, deeper than grade 2 (described by Daniel et al, which means at least a penetration in the subcutaneous fat). **Exclusion criteria:** not stated explicitly but excluded 7 patients because pressure sore not				**Additional outcomes**: there was no significant difference between the two groups (T50 variable, Wilcoxon rank-sum test, p=0.9) or when the mean values of the two groups were adjusted with the absolute initial volume (p=0.2).

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
then closed by a flap, 42 days follow-up **Assessment of PUs:** Measurement of wound healing: reduction in wound volume calculated by wound impressions **Classification of PUs:** Daniel et al (1979) **Multiple ulcers:** not reported	in the pelvic region, three because depth of pressure sore less than grade 3; one patient could not be analysed because of lack of data and one excluded because he developed severe diarrhoea which made it impossible to fix the vacuum dressing properly.				

Table 159: Ford 2002[77]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author: Ford (2002)[77] **Title:** Interim analysis of a prospective, randomised trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers Journal**:** Ann Plast. Surg, 49, 55-61. **Type of study:** randomised controlled trial **Study quality:**	**Patient group:** patients with one to three full-thickness decubitus ulcers which were present for a minimum of 4 weeks **All patients** **Randomised N=28 patients with 41 pressure ulcers** **Completed N= 22 (with 35 pressure ulcers)** **Drop-outs: 6** in total: 3 patients lost to follow-up, 1 patient noncompliant with	Group 1: ulcer debridement followed by 6 weeks treatment with Vacuum-Assisted Closure device (VAC) Group 2: ulcer debridement followed by 6 weeks treatment with Healthpoint system (HP) – three FDA –approved gel products – accuzzyme, iodosorb, and panafil. Patients randomised to HP and whose wounds showed substantial exudate received	**Outcome 1: proportion of ulcers healed**	**Group 1:**2/20 (10%) NR **Group 2:** 2/15 (13%) NR **Relative risk:** 0.75 **95% CI:** 0.12, 4.73	**Funding:** Alpha Omega Alpha Student Research fellowship, plastic surgery education foundation scientific essay award winner, grants from the plastic surgery education foundation and Kinetic Concepts. **Limitations:**
			Outcome 2: mean % reduction in wound volume over 6 weeks	**Group 1:** 51.8% **Group 2:** 42.1% **MD:** 9.7% P=0.46	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: randomisation by table of random letters, V or H, generated before trial began. **Allocation concealment:** no details **Blinding:** blinded clinic staff (nurses, medical students and interns) measured wounds and took plaster impressions. Plaster impressions, soft-tissue biopsies and bone biopsies were coded. Volume displacements of plaster impressions were determined by a medical student. No patient blinding. **Addressing incomplete outcome data:** not ITT. 3 patients lost to follow-up reasons given but don't know from which group. **Statistical analysis:** patient demographics compared by Fisher's exact test. Student's t-test used to compare mean changes in dimension, volume, and histopathological data.	treatment and removed, 1 patient died of coronary artery disease and 1 patient died of respiratory arrest secondary to Guillain-Barre syndrome **Age:** 18-80 years **Group 1** **Randomised** N: 20 **Completed N:** not sure which group drop-outs were from **Dropouts:** not sure which group drop-outs were from **Age (mean): 41.7 years** **Group 2** **Randomised N:** 15 **Completed N:** not sure which group drop-outs were from **Dropouts:** not sure which group drop-outs were from **Age (mean):** 54.4 years **Inclusion criteria:** presence of stage III or IV ulcer for 4 or more weeks;	Iodosrot or Iodoflex; those whose ulcers were clean and granulating received Panafil. Because all wounds were debrided surgically as appropriate, Accuzyme was not used. VAC dressings were changed Mondays, Wednesdays and Fridays. HP dressings were changed once or twice daily, depending on the degree of wound drainage.			difference in age at baseline, no details of allocation concealment. No patient blinding. Inclusion criteria specified patients aged 21-80 but enrolled patients aged 18 -80 years. 3 patients lost to follow-up. **Additional outcomes:** One lateral malleolar ulcer in a patient with diabetes, hypertension and vascular insufficiency was treated with VAC and complicated by sepsis, requiring amputation. There were no other treatment complications. Six wounds in the VAC group (30%) and 6 wounds in the HP group (40%)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: yes, difference in average age. **Study power/sample size:** small, no sample size calculation. **Setting:** plastic surgery clinic and inpatient physician referral at Boston Medical Centre, USA. **Length of study:** treatment period 6 weeks, 3 -10 months follow-up **Assessment of PUs:** 3-week evaluation included photograph of wound site, a plaster wound impression and measurement of wound dimensions. The 6-week evaluation included a series of post-treatment tests, consisting of a photograph of the wound site, a soft-tissue biopsy, a plaster wound impression and measurement of wound dimensions. If a bone biopsy and MRI were performed as part of	albumin >//=2.0; aged 21-80 years; ulcer volume after debridement = 10-150ml. **Exclusion criteria:** fistulas to organs or body cavities; malignancy in the wound; pregnant or lactating female; hashimoto thyroiditis; graves disease; iodine allergy; systemic sepsis; electrical burn; radiation exposure; chemical exposure; cancer; connective tissue disease; chronic renal or pulmonary disease; uncontrolled diabetes; corticosteroids or immunosuppressive agents; cardiac pacemaker; ferromagnetic clamps; recent placement of orthopaedic hardware.				underwent flap surgery. Three patients with 3 wounds completed 6 weeks of treatment followed by a second 6 weeks with the other treatment. The mean reduction in ulcer volume was 57% with VAC and 25% with HP The mean reductions in length, width and depth were 36.9cm, 40cm and 33.6cm in the VAC group compared with 18.7cm, 19cm and 31cm in the HP group, p=0.10, p=0.11 and p=0.90). 3/15 (20%) wounds treated with HP showed improved osteomyelitis (2 by bone biopsy and

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
pre-treatment testing, then these tests were repeated at 6 weeks. **Classification of PUs:** does not state which classification system used but includes full-thickness ulcers (stage 3 and 4). **Multiple ulcers:** all ulcers included					one by MRI) there was no improvement in osteomyelitis for VAC group (by bone biopsy or MRI).

I.2.6 Debridement

Table 160: Alvarez 2000[9]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Alvarez, 2000 **Title**: Chemical debridement of pressure ulcers: a prospective, randomized, comparative trial of collagenase and papain/urea formulations **Journal:** Wounds; 12 (2): 15-25. Type of study: A prospective, three-center, parallel-group, comparative trial Sequence generation: patients who qualified to participate in the study were assigned to either the collagenase debriding ointment or the papain/urea debriding ointment groups according to computer-generated randomization	Patient group: Patients with pressure ulcers requiring debridement, who were stable or improving after a two-week screening period All patients Randomised N:22 Completed N:21 Drop-outs:one patients who was randomized died prior to treatment Group 1 Randomised N:10 Completed N:10 Dropouts: ? Age:80 (77-86) Gender (m/f): (5/5) Other relevant patient characteristics:ulcer area = 878.1 (175-3150); partial thickness II = 1; full thickness III-IV = 9; yellow slough = 4; hard / soft black eschar = 6; necrotic tissue size = 806.0 (175-	Group 1:The collagenase product (collagenase santyl ointment, Knoll Pharmaceutical Company, Mount Olive, NJ) is an ointment containing 250 bacterial collagenase units per gram of white petrolatum USP. The collagenase is isolated from Clostridium histolyticum in a partially purified form. The collagenase debriding ointment is stable at room temperature and is supplied sterile in 15g and 30g tubes. The collagenase ointment was purchased from Medical Services Group Inc. (MSG) Wayne, PA. Group 2:The papain / urea product (Accuzyme, Papain/urea debriding ointment, Healthpoint, Fort Worth, TX) is a hydrophillic ointment containing papain (1.1 *	Outcome 1: Percent reduction of ulcer size from baseline Outcome 2: Side effect (skin rash)	Outcome 1: Group 1: Week 1: 5.8 +- 17.4 Week 2: 19.9 +- 29.2 Week 3: 27.3+-28.5 Week 4: 33.9 +- 26.17 Group 2: Week 1: 1.9+-7.6 Week 2: 23.7+-25.8 Week 3: 34.8+-25.2 Week 4: 55.4+-33.5 No significant healing rates between the two groups. Outcome 2: Group 1: 0/21 Group 2: 0/10 Relative risk: 3.27 95% CI:0.17-72.23 P value: A skin rash was observed in one patient who was being treated with collagenase but was not related to the study agent.	Funding: The papain / urea debriding ointment was provided by Healthpoint (Dallas, Texas), as sponsor of the study. Limitations: Setting is unclear Concealment method is unclear Papain / urea debriding ointment was provided by a sponsor of the study Additional outcomes:Treatment with both debriding ointments was easy and convenient. The application of either ointment was associated with any pain or discomfort. Treatment with the combination of papain/urea proved more effective than collagenase alone for the debridement of pressure ulcers by both clinical evaluation and

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
schedules. Allocation: Not reported Blinding: Not reported Addressing incomplete outcome data: Not reported Statistical analysis: Summarized numerical parameters were evaluated using Student's t-test after testing for normality. Values representing percent reduction in necrotic tissue and percent reduction in wound size were also compared using Student's t-test for testing the difference between the means of two independent samples. Significant differences were evaluated using an alpha level of 0.05. The power of the test was also computed for each contrast. Incidence data were evaluated using the	3150) Group 2 Randomised N:11 Completed N:11 Dropouts:? Age:84 (53-90) Gender (m/f): (4/7) Other relevant patient characteristics:ulcer area = 1062.5 (125-3025); partial thickness II = 2; full thickness III-IV = 9; yellow slough = 6; hard / soft black eschar = 5; necrotic tissue size = 758.9 (125-1825) Inclusion criteria:To enroll the patient the pressure ulcer must in the opinion of the investigator require debridement. A pressure ulcer requiring debridement must have nonviable tissue attached to the base of the wound. Exclusion criteria: Clinical signs of infection Cellulitis	106 units of activity per gram) and urea (100 mg per gram). It is indicated for debridement of necrotic tissue and liquefaction of slough in acute and chronic wounds. The papain / urea debriding ointment is stable at room temperature and is supplied sterile in 30g tubes. The papain / urea debriding ointment was provided by Healthpoint (Dallas, Texas), a sponsor of the study. Both groups: Upon identifying the target ulcer, the wound and devitalized tissue were assessed and measured. The wound was cleansed with normal saline and in order to avoid mechanical debridement the wound was dressed with a non-adherent primary dressing and moist to moist saline gauze. Dressing changes were performed one			planimetry (measurement of nonviable tissue). When compared with the collagenase debriding ointment, at each of the weekly evaluations, the papain/ urea debriding ointment was an average of 2.6 times more effective in dissolving nonviable tissue. The percent reduction in the area of necrotic tissue covering the ulcers over time was significantly greater for the papain/urea group at week 3 ($p<0.05$) and week 4 ($p<0.01$) than the collagenase group. Pressure ulcers treated with papain/urea had a greater degree of granulation than those treated with collagenase at every clinical evaluation point. Mean time to 50 percent granulation (time in days for 50 percent of the wounds to be covered with granulation tissue) was 6.8 days for the papain/urea group and greater than 28 days for the collagenase group (no

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Mann-Whitney Rank Sum Test. The gross cumulative life table method was used to calculate debridement and healing rates. The Z-test was used to make statistical comparisons between the rates of debridement discontinuation between the collagenase and papain/urea treatment groups. P values of less than 0.05 (double sided) were considered as statistically significant. Baseline differences: There were no significant differences between the collagenase debriding ointment and the papain/urea debriding ointment groups in patient demographics, baseline ulcer size, type/amount of necrotic tissue. Study power/sample size: No a priori sample size calculation Setting:	Osteomyelitis Inadequate nutrition Uncontrolled diabetes Other clinically medical conditions that would impair wound healing inclusive of renal, hepatic, hematologic, neurologic or immunological disease Patients receiving corticosteroids, immunosuppressive agents, radiation, chemotherapy within one month prior to entry into the study If the pressure ulcer was located on the feet, appropriate vascular studies (ankle to branchial index of >0.75 or a normal pulse volume recording) were recorded in order to exclude arterial disease.	daily or according to needs. No other topical agents or dressing were used throughout the screening period. At the end of two weeks if the target pressure ulcer and area of necrosis were stable (<20% change in size) or improving (decrease in size), the patient was advanced into the randomization phase of the trial. Wound cleansing with sterile normal saline without preservative was performed before the application of the test agent. There was no forceful irrigation technique and no other cleansing agents utilized. The same dressing technique was used throughout the study. It consisted of moist saline gauze, which was lightly fluffed and covered with sufficient dry gauze to create a moist environment. If the wound was covered with			mean value was possible for the collagenase patients) Papain / urea was more effective than collagenase in dissolving either type of substrate (slough and eschar). Both chemical debridement agents were slightly more effective in dissolving soft or hard black eschar than slough. There were no statistically differences (p<0.05) in the quantity of resident bacteria (bacterial burden) as a result of the treatment regimen. For example, the mean baseline bacterial count was log 5.6 CFU/mL for the papain/urea group and log 5.4 CFU/mL for the collagenase group. At the final (week 4) evaluation, the mean count was log 4.6 CFU/mL for the papain/urea group and log 5.0 CFU/mL for the collagenase group. The overall wound response to treatment is the clinical assessment of

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Not reported Length of study: Two weeks screening and 4 weeks follow-up Assessment of PUs: Patients were evaluated prior to starting the screening phase and once weekly during screening for a minimum of two weeks. At the end of two weeks, if the target pressure ulcer and area of necrosis were stable (< 20% change in size) or improving (decrease in size), the patient was advanced into the randomization phase of the trail. Then evaluations were performed once daily for the first two weeks and twice weekly for the second two weeks. One investigator or clinical study coordinator at each site performed all evaluations after practicing the evaluation procedures (tracing and clinical wound assessments) in the		a thick, hard eschar the surface was crosshatched with a #10 scalpel blade to allow more surface contact and assist in penetration. If the wound was infected, the infection had to be resolved prior to enrollment. Wound infection was determined by clinical assessment. Manufacturer suggestions concerning dosage and administration were followed in accordance with the package insert whenever possible. Treatment with the study medication was performed once daily. Using a tongue depressor enough study medication (approximately 2mm) was applied over the entire surface of the nonviable tissue. If the dressing came off or became soiled only one additional application of			wound improvement taking into consideration the relative resolution of necrotic tissue and wound appearance (granulation, edema, erythema, induration, undermining, odor, exudate type, and epithelialization). Pressure ulcers treated with papain/urea received a significantly (p<0.01) higher score than ulcers treated with collagenase. Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
same five patients prior to starting the trial). The nonviable tissue type was described as: adherent yellow/ grey/ white slough, adherent soft black eschar or firmly adherent hard black eschar. The line of demarcation between nonviable and viable tissue was measured and the percentage of the wound covered with nonviable tissue was estimated. Wound evaluation included overall wound condition, wound edges (undermining), wound odor, wound pain, wound exudate, peripheral tissue induration, edema, erythema, amount of granulation and amount of re-epithelialization. Nonviable tissue amounts and wound granulation were determined by clinical estimation (percentage of wound base covered), photographs and		the test agent was allowed. If necessary, additional dressing changes were permitted but no more than two applications per day of the test agents could be performed. Appropriate support surfaces such as dynamic air mattresses replacement systems, low air loss beds, air-fluidized beds, alternating pressure mattress overlays, and wheel chair cushions were provided to all study patients. Support surface selection was performed by the investigational team and was dependent on the location of the wound and needs of the individual patient according to the AHCPR Clinical Practice Guidelines for the Treatment of Pressure Ulcer Patients. Patients confined to bed were repositioned from			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
tracings. Ulcer healing was evaluated and recorded by photographs and wound tracings. The size of the necrotic tissue attached to the wound base and the size of the wound were determined by computerized planimetry of surface tracings made with an acetate transparent film. Length, width and depth of the wound were also recorded at each evaluation. The wound's bacterial burden (quantitative microbiology of the wound) was also determined prior to treatment, at one week, at four weeks and when the wound was free of devitalized tissue. Classification of Pus: AHCPR classification Multiple ulcers: Not reported		supine onto right and left 30° oblique positions every two hours using pillows and foam wedges whenever possible. Written turning schedules and diaries were kept for all the study patients.			

Table 161: Burgos 2000[40]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Burgos, 2000 (a) **Title**: Cost, Efficacy, Efficiency and Tolerability of Collagenase Ointment versus Hydrocolloid Occlusive Dressing in the Treatment of Pressure Ulcers **Journal:** Clin Drug Invest, 2000; 19 (5): 357-365 Type of study: Muliticentre randomized non-blinded parallel group study Sequence generation: Computer generated randomization list into blocks of 4 patients Allocation concealment: no details Blinding: Total surface area of the ulcers was calculated using planimetry by an observer blind to therapeutic assignment	Patient group: Patients > 55 years presenting with grade III pressure ulcers (skin disruption, tissue damage and exudate, and subcutaneous tissue involvement) All patients Randomised N: 37 Completed N: 23 Drop-outs: 14 Reasons in group 1: Unrelated death (N=3) Discharge from hospital (N=3) Transfer to other centre (N=3) Reasons in group 2: Unrelated death (N=1) Deterioration of general condition (N=1) Discharge from hospital (N=1) Protocol violation (N=2) Lack of efficacy (N=1)	Group 1: Collagenase ointment (Iruxol® Mono, Laboratorios Knoll, SA) applied once daily in a 1 to 2 mm thick layer to the ulcer bed Group 2: Application of a hydrocolloid dressing (Varihesive®, Convatec, SA) that was changed every 3 days. If hydrocolloid dressings showed leakage due to excessive exudate, dressings were changed more frequently. Varihesive® paste was applied to deep ulcers or ulcers with a large amount of exudate according to the investigator's judgment. Both groups: /	Outcome 1: Proportion of PU with reduction in pressure ulcer area after 12 weeks of treatment Outcome 2: Proportion of PU with complete healing of pressure ulcer after 12 weeks of treatment Outcome 3: Mean reduction in ulcer area after 12 weeks of treatment (cm2) Outcome 4: Pain intensity decrease	Outcome 1: Group 1: 15/18 (83.3%) Group 2: 14/19 (73.7%) Relative risk: 1.13 95% CI:0.81-1.59 P value:0.754 Outcome 2: Group 1: 3/18 (16.6%) Group 2: 3/19 (15.8%) Relative risk: 1.06 95% CI:0.24-4.57 P value:0.451 Outcome 3: Group 1: 9.1 + 12.7 Group 2: 6.2 + 9.8 Relative risk: 95% CI: P value:0.369 Outcome 4: Group 1: Group 2: Relative risk:	Funding: this study was supported by Labotorios Knoll, SA, Madrid Limitations: Underpowered Unclear allocation concealment Not all outcome assessors were blinded Relatively high drop-out No baseline differences reported. Additional outcomes: No significant differences were observed in cost and efficiency between collagenase ointment and hydrocolloid dressing in the treatment of pressure ulcers. Granulation tissue formulation increased (p>0.0005) and exudate production decreased (p>0.0005) in both treatment groups. Odour was not modified throughout the study

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: For those patients who did not complete the study, final ulcer area was that recorded at the last measurement, for those who presented complete healing, the final ulcer area was zero. To ascertain the potential effect of study discontinuation, mean ulcer area and mean reduction of ulcer area in patients who discontinued the study and those who completed the study were compared. Intra- and intergroup comparisons were performed. Normal distribution of data was assessed with the Kolmogorov-Smirnov test, and Student's t – test or the Mann-Whitney U test were used for intergroup comparisons Statistical analysis:	Group 1 Randomised N: 18 Completed N: 9 Dropouts:9 Age: 81.9 + 12.7 Gender (m/f): 8/10 Other relevant patient characteristics: Amell scale score (range): 17.7 + 3.4 Ulcer age : 3.2 + 2.0 months Previously treated ulcers (No. (%)): 15 (83.33) Localisation (no. (%)): Sacrum: 8 (44.44) Trochanter: 4 (22.22) Heel: 3 (16.66) Other: 3 (16.66) Group 2 Randomised N: 19 Completed N: 13 Dropouts: 6 Age: 78.6 + 10.4 Gender (m/f): 9/10 Amell scale score (range): 20.2 +5.9 Ulcer age (range): 2.6 +		Outcome 5: Patients with adverse reactions	95% CI: P value: 0.001 Outcome 5: Group 1: 1/18 Group 2: 2/19 Relative risk: 0.53 95% CI: 0.05-5.33 P value:	period.* *no concrete data provided Notes: any notes the reviewer thinks may be important

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Efficacy analysis by intention-to –treat was carried out using Student's t-test and the Mann-Whitney U test. Efficacy analysis per protocol was carried out using factorial analysis of variance 2X9 with repeated measurements of the last factor. Primary outcome measure, ulcer area decrease in absolute terms expressed in cm2, was obtained by subtracting ulcer area at the end of the study treatment from baseline ulcer area. Cost analyses by intention-to –treat and per protocol were carried out using Student's t-test. The mean cost per patient and 95% confidence intervals were calculated. Overall cost efficacy and sub-analysis of the study products costs on outcome was analyzed. To assess reliability of ulcer measurements	1.9 months Previously treated ulcers (No. (%)): 17 (89.47) Localisation (no. (%)): Sacrum: 7 (36.84) Trochanter: 4 (21.05) Heel: 6 (31.57) Other: 2 (10.53) Inclusion criteria: 55 y grade III ulcer for < 1 year Exclusion criteria: End-stage organ disease Localized or systemic signs or symptoms of infection Hypersensitivity to collagenase				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
absolute differences in mean ulcer area between transparent acetate film and slide measurements at baseline and at the end of the study were calculated. Similarly, differences in percentages of mean ulcer areas in both treatment groups were calculated according to the formula (σt-σs/σt) x 100, where σt is the mean value obtained from transparent acetate films and σs is the mean value obtained from the slides. The statistics used were the t-test for mean equality. Analysis of ulcer characteristics was carried out using the Friedman test for longitudinal analysis and the Mann-Whitney U test for cross-sectional analysis. The number and percentage of patients presenting ulcer bacterial colonization and the location of colonized					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ulcers were analyzed by chi-square test and Fisher's exact test. Analysis of tolerability was carried out by calculating the relative risk of adverse reaction occurrence. Statistical significance was set at p<0.05. Baseline differences: Not reported Study power/sample size: No a priori sample size calculation Setting: 7 hospitals in Spain Length of study: 12 weeks of treatment or until healing of the ulcer, whichever occurred first Assessment of PUs: Indirect procedure: After placing an adhesive identification label at one of its margins, the ulcers were photographed according to a standardized method at 50 cm from the focus. The slide of each ulcer					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
was projected and focused in such a way that the size of the attached label matched the actual label size (2.5 cmx 5 cm), and then the contour of each ulcer was transferred to a transparent acetate film. Direct procedure: Were performed by tracing the outline of each ulcer perimeter onto on adequately labeled transparent acetate film. Total surface area of the ulcers was calculated usingplanimetry (HAFF-Planimeter no. 315, GebrüderHaff, Germany, calibrated for measurements in cm2). Examinations were made at 1-week intervals. Ulcer characteristics were measured on a 5-point scale and included: Pain (no pain, minimal, bearable, intense, unbearable)					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
% granulation tissue (< 10%, 11 to 30%, 31 to 60%, 61 to 90%, > 90%) Exudate (none, minimal, moderate, intense, excessive) Odour (none, minimal, tolerable, intense, repulsive) Classification of PUs: not reported, grade III pressure ulcers (skin disruption, tissue damage and exudate, and subcutaneous tissue involvement) Multiple ulcers: No details Unit of analysis = patient. However no patient had more than 1 PU.					

Table 162: Lee 1975 [130]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Lee, 1975 **Title**: Collagenase therapy for	Patient group: 11 patients with chronic diseases in poor physical condition. Four had	Group 1: Collagenase (Santyl) was given as 250 units per gram of white	Outcome 1: Proportion of PU that reduced in volume of PU assessed with the aid of a	Outcome1: Group 1: 8/17 Group 2: 0/11 Relative risk: 11.33	Funding: none mentioned Limitations:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
decubitus ulcers. **Journal:** Geriatrics, 1975; 30 (5): 91-8 Type of study: Double-blinded randomized clinical trial Sequence generation: no details Allocation concealment: No details Blinding: No details Addressing incomplete outcome data: No details Statistical analysis: Only descriptive statistics Baseline differences: No details Study power/sample size: No a priori sample size calculation Setting: US, no further details Length of study: 4 weeks of treatment and follow-up unless complications developed	neoplastic disease; 4 atherosclerotic heart diseases or cerebrovascular accident or both; 2 had Parkinson's disease and 1 had a femoral neck fracture. All patients Randomised N: 11 patients with a total of 28 advanced PU Completed N: 28 PU in 11 patients Drop-outs: 0 Age: 67. 6 (47-90) Gender (m/f): 3/8 Other relevant patient characteristics: / Group 1 Randomised N: 17 PU Completed N: 17 PU Dropouts: 0 Age: / Gender (m/f): / Other relevant patient characteristics: /	petrolatum. Group 2: The placebo was a heat-inactivated preparation of the ointment used in the experimental group. Both groups: The ointment was applied once daily to each ulcer except when the ulcer required more frequent cleaning because of occasional contamination from incontinence of urine or faeces, or both. In the latter instance, the ointment was applied twice daily. Before the ointment was applied, the area was washed with liberal amounts of sterile buffered saline (pH=7.5) in a attempt to remove films of necrotic tissue. The ointment was applied directly to the decubitus ulcer and covered with a sterile gauze pad. Wound pH was determined regularly.	volume mold Outcome 2: Proportion of PU that increased in volume of PU assessed with the aid of a volume mold Outcome 3: Proportion of PU with odor at the end of treatment Outcome 4: side effects	95% CI:0.72-178.54 P value: Outcome 2: Group 1: 4/17 Group 2: 6/11 Relative risk: 0.43 95% CI:0.16-1.19 P value: Outcome3: Group 1: 7/17 Group 2: 5/11 Relative risk: 0.91 95% CI:0.38-2.14 P value: Outcome 4: Group 1: 1/17 (mild bleeding and a burning sensation) Group 2: 0/11 Relative risk: 2 95% CI:0.09-45.12	Underpowered Unclear randomization process Unclear allocation concealment Not clear whether outcome assessors were blinded Additional outcomes: A corollary immune diffusion study was carried out in 10 patients who had been treated with collagenase. After 6 to 30 days of treatment, no circulating collagenase or anticollagenase precipitin-type antibodies could be demontsrated by the Ouchterlony plate method. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
or patient died Assessment of PUs: Two diameters of the PU were measured and a color photograph of the lesion was made. A volume mold was made with Jeltrate®. Five scoopfuls of Jeltrate were mixed with 7 oz of water and vigorously stirred to eliminate air bubbles. The mixture was then poured into the PU with the aid of a spatula, was allowed to set for 3 minutes and then was removed. The volume of the mold was measured by volume displacement in a graduated cylinder. These measurements were repeated weekly and at the end of the study when possible. Classification of PUs: Not reported Multiple ulcers: Ulcers were the unit of analysis	Group 2 Randomised N: 11 PU Completed N: 11PU Dropouts: 0 Age: / Gender (m/f): / Other relevant patient characteristics: / Inclusion criteria: no details Exclusion criteria: no details.	Antiseptics containing heavy metal ions and hexachlorophene were not used. If bacteriologic studies showed contamination, polimyxin B-bacitracin-neomycin powder was applied locally.		P value:	

Table 163: Milne2012 and Milne 2010[145]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Milne (2012) and Milne (2010) **Title**: A comparison of collagenase to hydrogel dressings in maintenance debridement and wound closure and a comparison of collagenase to hydrogel dressings in wound debridement. **Journal:** Wounds 2012, 24 (11), 317-322 and Wounds 2010, 22 (11); 270-274. Type of study: randomized controlled trial (rollover evaluation) Sequence generation: no details Allocation concealment:no details Blinding: investigators were blinded Addressing incomplete outcome data: ITT Statistical analysis: descriptive statistics Baseline differences: yes wound size was statistically different –	Patient group: inpatients of a long-term care facility All patients Randomised N: 27 Completed N: 13 Drop-outs: 14 Group 1 Randomised N: 13 Completed N: 10 Dropouts: Phase 2: 3: 1 did not complete phase 1 successfully; 1 eliminated within first week of phase 2; 1 lost to follow-up when transferred to an acute care facility for treatment of pneumonia Age: 80.23 (range 44-94) Gender (m/f): 18.5%/29.6% Other relevant patient characteristics: Mean wound size (cm2):12.29 Mean initial PUSH tool	Group 1: Collagenase (Santyl ointment) Group 2: Hydrogel (SoloSite Gel) Both groups: dressing change consisted of normal saline irrigation with a device providing 4-15 psi followed by application of the assigned therapeutic agent, 'nickel thick' to the entire wound bed. After application of the assigned agent the wound was then filled to the depth equal to that of the surrounding wound tissue with gauze dampened with normal saline, so there was no excess moisture noted when pressure from the clinician's hand was applied. The wound was then covered with a semi-occlusive dressing (CoverSite). Dressing changes were performed daily and as needed by nurses	Outcome 1: proportion of patients with complete wound closure by 84 days (Milne 2012) Outcome 2: reduction in PUSH tool score (Milne 2010) calculated from initial and final scores Outcome 3: mortality (all-cause)	Outcome 1: Group 1: 9/13 (69%) ITT but ACA for phase 2: 9/10 (90%) Group 2: 3/14 (21%) ITT but ACA for phase 2: 3/3 (100%) because a lot more of the patients did not debride successfully in phase 1. Relative risk: 95% CI: P value: Outcome 2: Group 1: 5.03 Group 2: 3.99 Relative risk: 95% CI: P value: Group 1: 9/13 (69.2%) Group 2: 3/14 (21.4%) Relative risk: 95% CI: P value:	Funding: Authors have received unrestricted grants from Healthpoint. Limitations: Only those who had successfully completed phase 1 (debridement was successful at day 42 – patients who did not achieve complete debridement were removed from the study to receive other methods of debridement) were included in phase 2. Therefore we have only reported data from phase 1. No details of sequence generation or allocation concealment. Basline differences in wound size. Small sample size. Additional outcomes: no. of days to achieve epithelialization; Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
overall the collagenase group presented with larger wounds (p<0.004) when entering phase 1 Study power/sample size: no power calculation; small sample size Setting: long-term care facility Length of study: 84 days Assessment of PUs: subject and wound assessment weekly as well as wound photographs. Wound photos were evaluated using calibrated digital wound measurement software. Photos were assigned a wound bed score (WBS) or a pressure ulcer scale for healing tool score (PUSH). Classification of PUs: not reported Multiple ulcers: not reported	score: 11.1 (range 8-15) Group 2 Randomised N: 14 Completed N: 3 Dropouts: Phase 2: 11: 9 did not complete phase 1 successfully; 1 eliminated within first week of phase 2; 1 discontinued after developing cellulitis at the wound site. Age: 78.79 (range 54-94) Gender (m/f): 25.9%/25.9% Mean wound size (cm2): 7.90 Mean initial PUSH tool score: 11.7 (range 9-16) Inclusion criteria: aged > 18 years; presence of at least 85% necrotic nonviable tissue on a pressure ulcer between 1cm2 and 64cm2; hydrogel or collagenase dressing naïve onnn study pressure ulcer; no current use of parenteral or oral antibiotics except				55% of pressure ulcers were related to devices such as splints, braces, ill-fitting wheelchair arm rests, or prostheses.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	for urinary tract suppressive therapy; hemoglobin A1C (HbA1c) <7.9%; Currently receiving adequate pressure redistribution to the affected area via devices such as a group 2 or group 3 specialty bed, and a static air wheelchair cushion if our of bed, and/or an offloading device if the pressure ulcer was located on the lower extremity; compliance with nutritional interventions per registered dietician; no allergies to collagenase or hydrogel; no allergies to semiocclusive secondary dressing; written informed consent Exclusion criteria: steroid use >5mg daily; inability to cooperate with offloading recommendations; ankle-brachial index < 0.85 if the pressure ulcer was				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	located on the lower extremity; presence of callus requiring sharp or surgical debridement within 3 days prior to enrollment; medical instability as deemed by the investigator; pregnancy; participation in another clinical trial or wound dressing evaluation in the 30 days prior to enrollment				

Table 164: Muller 2001[152]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Müller (2001) **Title**: Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. **Journal:** PharmacoEconomics, 19 (12); 1209-1216.	Patient group: Hospitalized female patients with grade IV heel PUs. All patients Randomised N: 24 patients and 26 ulcers Completed N: 23 patients and 26 ulcers Drop-outs: 1 (failed treatment)	Group 1: Collagenase dressing (Novuxol®). Ulcers were cleansed with saline 0.9%. Ulcers were treated with collagenase-containing ointment, paraffin gauze (Jelonet®) and an absorbent bandage. Ulcers were treated once a day. Group 2: Hydrocolloid dressing (DuoDerm®). Ulcers were cleansed with saline 0.9% and covered with the dressing.	Outcome 1: Proportion of patients completely healed Outcome 2: Time to achieve complete healing (mean weeks; range)	Group 1: 11/12 Group 2: 7/11 P value: <0.005 Group 1: 10; 6-12 Group 2: 14; 11-16 P value: <0.005	Funding: Unrestricted grant from Knoll AG, Ludwigshafen, Germany. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding;

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: drop-out excluded. Statistical analysis: Log-rank for efficiency in terms of the rate of complete healing and the Wilcoxon test for time to achieve complete healing were calculated. Tests were two-sided with p <0.05 Baseline differences: Difference not statistically measured. Study power/sample size: The sample size (n=12) was calculated for the parameter 'time to achieve compete healing' for a power of 80%. Setting: Naaldhorst	Group 1 Randomised N: 12 patients and 13 ulcers Completed N: 12 patients and 13 ulcers Dropouts: 0 Age (mean years; range): 74.6; 68-79 Gender (m/f): 0/12 Group 2 Randomised N: 12 patients and 13 ulcers Completed N: 11 patients and 12 ulcers Dropouts: 1 (failed treatment) Age (mean years; range): 72.4; 65-78 Gender (m/f): 0/12 Inclusion criteria: Grade IV PU Exclusion criteria: life expectancy of less than 6 months	Ulcers were treated twice a week. Both groups: Before randomization autolysis and surgical debridement was performed. Occasionally remaining necrosis was treated with collagenase.			no ITT analysis; sample size calculation unclear; very small sample size; no measurement of statistical difference between groups; no information on PU classification; little information on PU assessment; no information on preventive measures Additional outcomes: Cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
hospital, Naaldwijk in the Netherlands Length of study: not reported. Complete healing was achieved at maximum 16 weeks. Assessment of PUs: Ulcer size and depth was assessed weekly by a physician. Photographs were taken. Classification of PUs: not reported Multiple ulcers: two patients had two ulcers					

Table 165: Parish 1979[174]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Parish, 1979 **Title**: Decubitus ulcers: a comparative study **Journal:** Cutis; 23 (1): 106-110 Type of study: Double-blinded study Sequence generation:	Patient group: Patients with pressure ulcers in a long-term care institution for the chronically ill and physically disabled. All patients Randomised N:Not reported Completed N:17	Group 1: Dextranomer powder is employed in the treatment of secreting skin lesions. Dextranomer (Debrisan, Pharmacia Laboratories) consists of beads of cross-linked dextran molecules 0.1 to 0.3 mm in diameter in a three-	Outcome 1: Proportion of PU improved for patients treated with dextranomer versus patients treated with collagenase (%) Outcome 2:	Outcome 1: Group 1:12/14 (85.7%) Group 2:5/11 (45.5%) Relative risk: 1.89 95% CI: 0.95-3.73 P value:<0.02 Outcome 2: Group 1:12/14 (85.7%)	Funding:not reported Limitations: No inclusion or exclusion criteria reported. Small sample size Blinding failed Randomization method not reported Six patients changed

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Patients were assigned at random, but no randomization method was reported. Allocation: No details Blinding: Neither the principal investigator, nor the patients knew who was assigned to which treatment regimen. The authors state however that while the attempted to keep the study double-blinded, it became obvious which regimens were being used. Addressing incomplete outcome data: Not reported Statistical analysis: A fisher exact test was used to evaluate the data. Average ulcer dimension= square root of surface area. Baseline differences: Not reported. Study power/sample	Drop-outs:Not reported Group 1 Randomised N:Not reported Completed N:7 Dropouts:Not reported Age:29-57 Gender (m/f): Not reported Other relevant patient characteristics: Number of ulcers (n=14) Average ulcer dimension in cm = 4.5 Group 2 Randomised N:not reported Completed N:5 Dropouts:1 (patient not responding to the collagenase treatment was switched to the dextranomer group). Age:28-59 Gender (m/f): Not reported Other relevant patient	dimensional porous network. The beads are hydrophilic and each gm of dry beads has the capacity to absorb 4 ml of fluid. Experimental studies show dextranomer capable of transporting bacteria, inflammatory mediators and debris away from the wound surface and into the bead layers. Patients paced on the dextranomer program were given saline soaks. Dextranomer was poured into the ulcer in a layer of at least 3mm deep and the sores were then covered with dry dressings. The dextranomer dressings were changed one to three times daily depending on the amount of wound exudate. The removal of the dextranomer beads was accomplished by saline irrigation. Group 2:Patients	Proportion of PU improved for patients treated with dextranomer versus patients treated with sugar and egg white Outcome 3: Proportion of PU improved for patients treated with collagenase versus patients treated with sugar and egg white Outcome 4: Proportion of patients with ulcer closure for patients treated with dextranomer versus patients treated with collagenase Outcome 5: Proportion of patients with ulcer closure for patients treated with dextranomer versus patients treated with	Group 3: 0/9 (0%) Relative risk: 16.67 95% CI: 1.11-250.76 P value:<0.0001 Outcome 3: Group 2:5/11 (45.5%) Group 3: 0/9 (0%) Relative risk: 9.17 95% CI: 0.57-146.40 P value: not significant Outcome 4: Group 1:4/7 (57%) Group 2: 1/5 (20%) Relative risk: 2.86 95% CI:0.44-18.48 P value: not significant Outcome 5: Group 1: 4/7 (57%) Group 3: 0/5 (0%) Relative risk: 6.75 95% CI:0.44-102.80 P value: <0.08 Outcome 6:	treatment during the study. No information was given if there was a washing-out period Additional outcomes:All seven patients treated with dextranomer improved during the course of the study. In the collagenase group, two of five patients improved. None of the patients treated with sugar and egg white showed improvement. In four patients treated with dextranomer, improvement was observed within one week of the start of treatment and in two other patients improvement was seen within one month. In the collagenase group, none of the five patients improved within one week of treatment and two patients improved within one month of treatment. All five patients who failed to respond to the sugar and egg white treatment were changed to either

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: Not reported Setting: The Inglis House is a long-term care institution for the chronically ill and physically disabled. Patients in this institution have such incapacitating disorders as paraplegia, quadriplegia, Parkinson's disease, rheumatoid arthritis, cerebral palsy, and multiple sclerosis. Of approximately three hundred residents, about 10 percent have decubitus ulcers at any one time. Length of study: The initial study was to have lasted four weeks, but many subjects were treated and observed for up to four months or longer. Assessment of PUs: Pressure ulcers were assessed as dry or moist.	characteristics: Number of ulcers (n=11) Average ulcer dimension in cm = 3.2 Group 3 Randomised N:not reported Completed N:5 Dropouts:5 (patients not responding to the sugar and egg white treatment were switched to the dextranomer (n=4) or collagenase group (n=1)). Age:32-70 Gender (m/f): Not reported Other relevant patient characteristics: Number of ulcers (n=9) Average ulcer dimension in cm = 2.4 Inclusion criteria:not reported Exclusion criteria:not reported	receiving collagenase (Collagenase, Santyl, Knoll Pharmaceutical Co) were given a saline wash. Collagenase was then applied daily with a wooden applicator, and the ointment was covered with a dry dressing, as recommended by the package insert. Group 3: Patients receiving sugar and egg white were also given a saline wash. The mixture was applied liberally to the area four times daily and allowed to dry. All groups: if a patient did not respond satisfactorily to any treatment at the end of four weeks, the regimen was changed to one of the two other treatments.	sugar and egg white Outcome 6: Proportion of patients with ulcers closure for patients treated with collagenase versus patients treated with sugar and egg white Outcome 7: Proportion of ulcer closed for patients treated with dextranomer versus patients treated with collagenase Outcome 8: Proportion of ulcer closed for patients treated with dextranomer versus patients treated with sugar and egg white Outcome 9: Proportion of ulcer	Group 2: 1/5 (20%) Group 3: 0/5 (0%) Relative risk: 3 95% CI:0.15-59.89 P value: not significant Outcome 7: Group 1: 6/14 (43%) Group 2: 1/11 (9%) Relative risk: 4.71 95% CI:0.66-33.61 P value: not significant Outcome 8: Group 1: 6/14 (43%) Group 3: 0/9 (0%) Relative risk: 8.67 95% CI:0.55-137.33 P value: <0.05 Outcome 9: Group 2: 1/11 (9%) Group 3: 0/9 (0%) Relative risk: 2.50 95% CI:0.11-54.87 P value:not significant	dextranomer or collagenase treatment. The four patients switched to dextranomer all improved, with three patients attaining complete closure of their ulcers (four ulcers). One patient with four decubitus ulcers was switched to the group receiving collagenase. This patient improved, with one of four ulcers closing. One patient for whom collagenase treatment failed to produce an adequate response and who was crossed over into the dextranomer group also improved with one of two ulcers closing. The authors did not see any change in the progress of healing whether the patient was turned every two hours, as they had been initially or whether they were allowed to remain in the same position for many hours. Similarly, cleaning the patients and changing their linens frequently led to none but aesthetic improvements.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: The authors believe that there is no purpose in further categorizing the ulcers than dry and moist. Multiple ulcers: All pressure ulcers of the included patients were treated and assessed.			closed for patients treated with collagenase versus patients treated with sugar and egg white Outcome 10: Proportion of patients improved treated with dextranomer versus patients treated with collagenase Outcome 11: Proportion of PU closed treated with dextranomer versus collagenase after 1 week Outcome 12: Proportion of PU closed treated with dextranomer versus collagenase after 1 month	Outcome 10: Group 1:7/7 Group 2:2/5 Relative risk: 2.25 95% CI:0.86-5.9 P value: Outcome 11: Group 1:6/14 Group 2:0/11 Relative risk: 10.40 95% CI:0.65-166.71 P value: Outcome 12: Group 1:8/14 Group 2:3/11 Relative risk: 2.10 95% CI:0.72-6.09 P value: Outcome 13: Group 1:8/14 Group 2:5/11 Relative risk: 1.89	All patients received the same diet as the other residents of the Inglis House. Sepsis did not develop during the course of the study. Bacteriologic cultures, both aerobic and anerobic were done before, during and after treatment, but no significant trends were noted. Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
				95% CI:0.95-3.73 P value:	
			Outcome 13: Proportion of PU closed treated with dextranomer versus collagenase after 2 months	Outcome 14: Group 1:12/14 Group 2:5/11 Relative risk: 1.89 95% CI:0.95-3.73 P value:	
			Outcome 14: Proportion of PU closed treated with dextranomer versus collagenase after more than 2 months	Outcome 15: Group 1:4/7 Group 3:0/5 Relative risk: 11.25 95% CI:0.79-160.81 P value:	
			Outcome 15: Proportion patients improved treated with dextranomer versus patients treated with sugar and egg white	Outcome 16: Group 1:6/14 Group 3:0/9 Relative risk: 8.67 95% CI:0.55-137.33 P value:	
			Outcome 16: Proportion of PU closed treated with	Outcome 17:	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
			dextranomer versus sugar and egg white after 1 week Outcome 17: Proportion of PU closed treated with dextranomer versus sugar and egg white after 1 month Outcome 18: Proportion of PU closed treated with dextranomer versus sugar and egg white after 2 months Outcome 19: Proportion of PU closed treated with dextranomer versus sugar and egg white after more than 2 months	Group 1:8/14 Group 3:0/9 Relative risk: 11.33 95% CI:0.73-175.10 P value: Outcome 18: Group 1:8/14 Group 3:0/9 Relative risk: 11.33 95% CI:0.73-175.10 P value: Outcome 19: Group 1:12/14 Group 3:0/9 Relative risk: 16.67 95% CI:1.11-250.76 P value: Outcome 20: Group 2:2/5 Group 3:0/5 Relative risk: 5 95% CI:0.30-83.69 P value:	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
			Outcome 20: Proportion of patients improved treated with collagenase versus patients treated with sugar and egg white Outcome 21: Proportion of PU closed treated with collagenase versus sugar and egg white after 1 week Outcome 22: Proportion of PU closed treated with collagenase versus sugar and egg white after 1 month Outcome 23: Proportion of PU closed treated with collagenase versus sugar and egg white after 2 months	Outcome 21: Group 2:0/11 Group 3:0/9 Relative risk: 95% CI: P value: Outcome 22: Group 2:3/11 Group 3:0/9 Relative risk: 5.83 95% CI:0.34-100.03 P value: Outcome 23: Group 2:5/11 Group 3:0/9 Relative risk: 9.17 95% CI:0.57-146.40 P value: Outcome 24: Group 2:5/11 Group 3:0/9 Relative risk: 9.17 95% CI:0.57-146.40	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
			Outcome 24: Proportion of PU closed treated with collagenase versus sugar and egg white after more than 2 months Outcome 25: Side effects	P value: Outcome 25: Group 1: 0/7 Group 2:0/5 Group 3:0/5 Relative risk: 95% CI: P value:	

Table 166: Pullen 2002[179]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Püllen, 2002 **Title**: Prospective randomized double-blind study of the wound-debriding effects of collagenase and fibrinolysin/deoxyribonuclease in pressure ulcers **Journal:** Age and Ageing, 2002;	Patient group: Patients with pressure ulcers, Seiler grade 2,3 or 4, in the pelvic region with fibrinous and/or necrotic slough from 17 hospitals All patients Randomised N: 135 Completed N: 78	Group 1: Twice-daily treatment with collagenase (1.2 U/g) (Novuxal). Group 2: Twice-daily treatment fibrinolysin/DNAse (1 U Loomis and 666 Christensen/g) (Fibrolan) Both groups: The ointments were applied by nurses in a 2 mm layer	Outcome 1: proportion of persons reporting adverse events Outcome 2: Proportion of serious adverse events reported	Outcome 1: Group 1: 45/66 (68.2%) Group 2: 34/69 (49.3%) Relative risk: 1.38 95% CI:1.03-1.85 P value: Outcome 2: Group 1: 54/118 Group 2: 24/103	Funding: none mentioned Limitations: Underpowered Unclear randomization process Unclear allocation concealment Additional outcomes: No

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
31: 126-30 Type of study: Prospective double-blind randomised controlled trial Sequence generation: No details Allocation concealment: No details Blinding: Outcome assessors were blinded for therapeutic assessment Addressing incomplete outcome data: No details Statistical analysis: Wilcoxon's test Intention to treat analysis including all patients who received study medication. This population was evaluated by end-point analysis. Per-protocol analysis including only patients who met all criteria for inclusion and none for exclusion and who	Drop-outs: 57 For 14 patients pictures of the wounds were not assessable. These were excluded from the intention to treat analysis. 16 patients from group 1 and 27 from group 2 were excluded from the per-protocol analysis because of protocol violations Group 1 Randomised N: 66 Completed N: 44 Dropouts: 22 Age: 78.4 + 8.9 Gender (m/f): Other relevant patient characteristics: Mean duration: 1.3 + 0.6 Seiler decubitus grade (No. (%)): 2: 18 (27.3) 3: 44 (66.7) 4: 4 (6.1) Support: Normal mattress: 18 (27.3)	to the ulcer and covered with gauze. They were not irrigated between treatments. The physician determined the type of mattress and frequency of repositioning		Relative risk: 1.96 95% CI: 1.31-2.93 P value:	statistically significant difference between 2 groups with respect to change in necrotic wound area, wound environment*, wound margins*, wound depth*, pocketing*, area and slough*, and wound healing*. *no concrete data provided

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
completed the study without major protocol violations. Patients who discontinued the trial prematurely and whose withdrawal was related to the therapy were included in the analysis. SAS software was used. Baseline differences: None Study power/sample size: Planning of the study was based on an estimated probability of 0.69 that collagenase reduces the necrotic wound surface to a greater extent than fibrinolysin/DNAse. A sample size of 50 patients per treatment arm was calculated in order to identify the supposed difference between the products with a 90% probability at a specified error probability of 5% using Wilcoxon's test. Taking an assumed drop-out rate of about 30% into account, the required	Extremely soft mattress: 12 (18.2) Other: 36 (54.5) Mean modified Norton scale: 18.6 + 4.5 Group 2 Randomised N: 69 Completed N: 34 Dropouts: 35 Age: 79.7 + 8.1 Gender (m/f): Mean duration: 1.4 + 1.0 Seiler decubitus grade (No. (%)): 2: 20 (29.0) 3: 43 (62.3) 4: 6 (8.7) Support: Normal mattress: 23 (33.3) Extremely soft mattress: 16 (23.2) Other: 30 (43.4) Mean modified Norton scale: 19.1 + 4.7 Inclusion criteria: Seiler grade 2, 3 or 3				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
sample size was set at 130 patients. Setting: 17 hospitals in Germany providing acute care and rehabilitation services for elderly patients Length of study: 4 weeks of treatment or until complete wound debridement whichever occurred first. Assessment of PUs: The treating physician took at least 12 photographs of the reference pressure ulcer under standard conditions at the beginning of the study and about every 4 days thereafter. The last photograph of the ulcer was taken within 2 days of the last application of study medication. A specific camera was used (Canon Eos 100 QD, Compact-Macro EF 50 mm lens, f/2.5) with a special flash (Canon Ringblitz Macro Ring Lit	Fibrinous or necrotic slough Ulcers between 2 to 14.5 cm in diameter Exclusion criteria: Alcohol or drug dependency End stage malignant disease Hypersensitivity to collagenase or fibrinolysin/DNAse Planned co-medication with local antiseptics, antibiotics, occlusive wound dressings, hydrogels or hydrocolloids Ulcers with black eshar only Ulcers that did not permit parallel positioning of the reference scale				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ML 3). Each physician was trained in the use of the camera. A scale displaying a range of colours was placed adjacent to the pressure ulcer to facilitate standardized evaluation of the lesions. An automatic distance meter ensured that photographs were always taken from the same distance. The change of necrotic wound area was clinically assessed by 2 independent dermatologists (blinded to therapeutic assignment) by means of 13x18 cm photographs of the wound and classified into 5 categories: Marked increase by at least 100% Appreciable increase by at least 30% No appreciable increase Appreciable reduction by at least 25% Marked reduction by at					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
least 50% Additional efficacy criteria assessed were environment of the wound, wound margins, wound depth, pocketing area and wound healing. Classification of PUs: Seiler classification. Multiple ulcers: If several pressure ulcers were present, the worst ulcer was chosen as the reference ulcer.					

Table 167: Agren 1985[3]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Agren (1985) **Title**: Topical Treatment of Pressure Ulcers **Journal:** Scand J Plast Reconstr Surg, 19: 97-100 Type of study: randomized controlled	Patient group: Geriatric patients with necrotic PUs. All patients Randomised N: 28 Completed N: 28 Drop-outs: 0 Group 1 Randomised N: 14	Group 1: Zinc oxide (400µg ZnO/cm²). Dry, sterile gauze compresses were premedicated with zinc oxide. Zinc dressings were changed once a day according to manufacturer's recommendations. Group 2: Streptokinase-streptodornase (Varidase®) Streptokinase works indirectly by	Outcome 1: Median percentage reduction in ulcer area Outcome 2: Proportion of patient with infection Outcome 3: Proportion of	Group 1: 2.4 Group 2: -18.7 Group 1: 0/14 Group 2: 1/14	Funding: / Limitations: sequence generation by matched pairs; no report on allocation concealment; no blinding of patients and nurses; small sample size; no

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
trial Sequence generation: Patients were consecutively matched in pairs. Each member of the pair was randomly allocated. Allocation concealment: not reported Blinding: an independent surgeon from another hospital assessed the result of therapy from photographs of the ulcers. Addressing incomplete outcome data: Not drop-outs Statistical analysis: The statistical test was performed at 5% level. The authors tested whether the probability of the patient being assessed as successful was the same for zinc and the Varidase group. For the statistical test the result was measured as successful or unsuccessful. A	Completed N: 14 Dropouts: 0 Age (mean years; range): 81 (46-92) Gender (m/f): (5/9) Diabetes: 5 PU location: Trochanter major: 1 Ichial tuberosity: 1 Knee: 1 Lower leg: 1 Malleolus: 2 Heel: 7 Base of big toe: 1 Initial ulcer area (median cm²; range): 5.8; 1.2-26.0 Group 2 Randomised N: 14 Completed N:14 Dropouts: 0 Age (mean years): 86 Gender (m/f): (3/11) Diabetes: 4 PU location: Trochanter major: 1 Ischial tuberosity: 1 Lower leg: 2 Malleolus: 1	transforming plasminogen into the active proteolytic enzyme plasmin via streptokinase-proactivator complex. Streptodornase dissolves deoxyribonucleoproteins commonly presented in pus (Hellgren). Varidase is believed to be beneficial in the treatment of necrotic and infected wounds. The varidase solution (100 000 IU streptokinase and 25 000 IU streptodornase dissolved in 20 ml sterile isotonic saline solution; Lederle Laboratories) was applied on a sterile gauze compress. Varidase was changed twice daily according to manufacturer's recommendations. Both groups: Dressings were secured with porous acrylic-based tapes. Before the study began, loosely attached necrotic material was removed, but ulcers were not surgically debrided subsequently. No patients were given antibiotics. Nursing care followed the standard routine of the department.	patient with skin reaction	Group 1: 0/14 Group 2: 1/14	information on PU classification or stages Additional outcomes: Disappearance of necrotic tissue occurred in 7 (50%) patient (4 women) treated with zinc and in 6 (43%) patients (5 women) treated with Varidase; The sequential analysis revealed a non-significant difference between the two treatments. The initial ulcer area was larger in the zinc group than in the Varidase group. The ulcers which were cleansed were on average half the size of the non-cleansed ulcers for both treatments. The median time to

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
sequential test procedure was used to minimize expected sample size. Baseline differences: The two groups were comparable with respect to age, sex, having diabetes mellitus, site of ulcer and initial ulcer area (cm²). Study power/sample size: The statistical test was designed to have the power of 0.95 to detect a 75% success rate in one group and a 25% success rate in the other. If a statistical non-significant difference was found it is reasonable to conclude that there is no large difference between the treatments. The number of patients needed with a conventional test (McNemar's Test) to achieve this power was too great to be practicable. A sequential	Heel: 7 Lateral edge foot: 1 Sole: 1 Initial ulcer area (median cm²; range): 4.2; 1.2-18.2 Inclusion criteria: Geriatric patients with one or more necrotic PUs Exclusion criteria: /				desloughing was 23 days (rage 7-56 days) for the zinc and 21 (range 7-42) days for the Varidase treated ulcers. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
test procedure was used to minimize expected sample size. Setting: Hospitalized and outpatients Length of study: 8 weeks of treatment Assessment of PUs: The ulcers were photographed and the area was determined with a planimeter from in situ tracings made by one of the authors at weekly intervals. An independent surgeon from another hospital assessed the result of therapy from photographs of the ulcers. It was judged successful if the ulcer was free of necrotic tissue within 8 weeks – otherwise it was classified as unsuccessful. Classification of PUs: not reported. Multiple ulcers: In case of multiple					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
necrotic ulcers, these were treated uniformly, but only the largest was monitored.					

I.2.7 Topical antimicrobials and antibiotics

Table 168: Moore 2011[148]

Reference	Method	Patient characteristics	Intervention	Results	Critical appraisal of review quality
Author and year: Moore (2011) **Title**: Wound cleansing for pressure ulcers (Review). **Journal:** Cochrane Database of Systematic Reviews, 2.	Design: systematic review Source of funding: / Search date: 1966-2010 Searched databases: Ovid Medline; Ovid Embase; EBSCO CINAHL; CENTRAL; Cochrane wounds group specialist register; contact: drug companies as identified in the British National Formulary (2003), experts wound care, members EPUAP, NPUAP European Wound Management Association, and World Union of Wound Healing Societies Included study designs: randomized controlled trials Inclusion criteria: cleansing as intervention, cleansing was defined as the application of fluid to the pressure ulcer to aid removal of exudate, debris and contaminants, but not the use of	Eligibility criteria: patients of any age, in any health care setting, with existing PUs Patient characteristics Elderly patients with a Grade II to IV PU (according to the NPUAP classification)	Interventions (group 1): Saline spray with aloe vera, silver chloride and decyl glucoside (Vulnopur). Comparator (group 2): Isotonic saline Both groups: Patient were treated for 14 days. The PSST was used to measure the outcome	Outcome 1: Percentage reduction in PSST from baseline Group 1: 27.8 (SD 31.3; min. 69.8, max. -123.5) Group 1: 20.5 (SD 24.1; min. 65.8, max. -22.7)	The validity of each study was initially appraised critically to check methodological rigour, using the quality assessment criteria suggested by Verhagen (1998) and Khan (2001). Bellingeri 2004: No adequate sequence generation, allocation concealment, and blinding. Incomplete data was addressed. The study was free of selective reporting and free of other bias. No ITT analysis. Small sample size. Note: The Bellingeri (2004)[27] study was published in Italian. Excluded studies: Burke (1998)[41] and Griffiths (2001)[89]

Reference	Method	Patient characteristics	Intervention	Results	Critical appraisal of review quality
	dressings or mechanical debridement; comparators were no cleansing, another cleansing solution, another technique; primary outcomes were pressure ulcer healing, such as time to complete healing; absolute or percentage change in pressure ulcer area or volume over time; proportion of pressure ulcers healed at the completion of the trial period; or healing rate; secondary outcomes were procedural pain and ease of use of the method of cleansing. Number of included studies: three studies were included in the Cochrane review. However, only one study met the inclusion criteria of our review.				

Table 169: Agren 1985[3]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Agren (1985) **Title**: Topical Treatment of Pressure Ulcers **Journal:** Scand J Plast Reconstr Surg, 19: 97-100 Type of study: randomized controlled trial Sequence generation: Patients were consecutively matched in pairs. Each member of the pair was randomly allocated. Allocation concealment: not reported Blinding: an independent surgeon from another hospital assessed the result of therapy from photographs of the ulcers. Addressing incomplete outcome data: No drop-outs	Patient group: Geriatric patients with necrotic PUs. All patients Randomised N: 28 Completed N: 28 Drop-outs: 0 Group 1 Randomised N: 14 Completed N: 14 Dropouts: 0 Age (mean years; range): 81 (46-92) Gender (m/f): (5/9) Diabetes: 5 PU location: Trochanter major: 1 Ichial tuberosity: 1 Knee: 1 Lower leg: 1 Malleolus: 2 Heel: 7 Base of big toe: 1 Initial ulcer area (median cm²; range): 5.8; 1.2-26.0	Group 1: Zinc oxide (400µg ZnO/cm²). Dry, sterile gauze compresses were premedicated with zinc oxide. Zinc dressings were changed once a day according to manufacturer's recommendations. Group 2: Streptokinase-streptodornase (Varidase®) Streptokinase works indirectly by transforming plasminogen into the active proteolytic enzyme plasmin via streptokinase-proactivator complex. Streptodornase dissolves deoxyribonucleoproteins commonly presented in pus (Hellgren). Varidase is believed to be beneficial in the treatment of necrotic and infected wounds. The varidase solution (100 000 IU streptokinase and 25 000 IU streptodornase dissolved in 20 ml sterile isotonic saline solution; Lederle Laboratories) was applied on a sterile gauze compress. Varidase was changed twice daily according to manufacturer's	Outcome 1: Median percentage reduction in ulcer area Outcome 2: Proportion of patient with infection Outcome 3: Proportion of patient with skin reaction	Group 1: 2.4 Group 2: -18.7 Group 1: 0/14 Group 2: 1/14 Group 1: 0/14 Group 2: 1/14	Funding: / Limitations: sequence generation by matched pairs; no report on allocation concealment; no blinding of patients and nurses; small sample size; no information on PU classification or grades Additional outcomes: Disappearance of necrotic tissue occurred in 7 (50%) patient (4 women) treated with zinc and in 6 (43%) patients (5 women) treated with Varidase; The sequential analysis revealed a non-significant difference between

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: The statistical test was performed at 5% level. The authors tested whether the probability of the patient being assessed as successful was the same for zinc and the Varidase group. For the statistical test the result was measured as successful or unsuccessful. A sequential test procedure was used to minimize expected sample size. Baseline differences: The two groups were comparable with respect to age, sex, having diabetes mellitus, site of ulcer and initial ulcer area (cm²). Study power/sample size: The statistical test was designed to have the power of 0.95 to detect a 75% success rate in one group and a 25% success rate in the other. If a statistical	Group 2 Randomised N: 14 Completed N:14 Dropouts: 0 Age (mean years): 86 Gender (m/f): (3/11) Diabetes: 4 PU location: Trochanter major: 1 Ischial tuberosity: 1 Lower leg: 2 Malleolus: 1 Heel: 7 Lateral edge foot: 1 Sole: 1 Initial ulcer area (median cm²; range): 4.2; 1.2-18.2 Inclusion criteria: Geriatric patients with one or more necrotic PUs Exclusion criteria: /	recommendations. Both groups: Dressings were secured with porous acrylic-based tapes. Before the study began, loosely attached necrotic material was removed, but ulcers were not surgically debrided subsequently. No patients were given antibiotics. Nursing care followed the standard routine of the department.			the two treatments. The initial ulcer area was larger in the zinc group than in the Varidase group. The ulcers which were cleansed were on average half the size of the non-cleansed ulcers for both treatments. The median time to desloughing was 23 days (rage 7-56 days) for the zinc and 21 (range 7-42) days for the Varidase treated ulcers. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
non-significant difference was found it is reasonable to conclude that there is no large difference between the treatments. The number of patients needed with a conventional test (McNemar's Test) to achieve this power was too great to be practicable. A sequential test procedure was used to minimize expected sample size. Setting: Hospitalized and outpatients Length of study: 8 weeks of treatment Assessment of PUs: The ulcers were photographed and the area was determined with a planimeter from in situ tracings made by one of the authors at weekly intervals. An independent surgeon from another hospital assessed the result of therapy from					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
photographs of the ulcers. It was judged successful if the ulcer was free of necrotic tissue within 8 weeks – otherwise it was classified as unsuccessful. Classification of PUs: not reported. Multiple ulcers: In case of multiple necrotic ulcers, these were treated uniformly, but only the largest was monitored.					

Table 170: Alm 1989[8]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Alm (1989) **Title**: Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze compresses. **Journal:** Acta Dermato-Venereologica, 149; 1-10 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: stratified allocation based on Norton score Blinding: blinding of outcome assessor. Addressing incomplete outcome data: intention-to-treat analysis except the patients in which protocol was violated, died in wash-out period, missing case-record and	Patient group: Long stay patients PUs. All patients Randomised N: 50 patients and 56 PUs Completed N: 50 PUs for efficacy analysis and 51 PUs for safety analysis Drop-outs: 6 PUs for efficacy analysis (1 drop-out for unknown reason, 1 missing case report, 1 died during wash-out period, 2 in which protocol was violated, and 1 incomplete data)) and 5PUs for the safety analysis (1 drop-out for unknown reason, 1 missing case report, 1 died during wash-out period, and 2 in which protocol was violated) Gender (m/f) (patients): ±6/44 Group 1 Randomised N: 31 PUs Completed N: 29 PUs for the safety analysis and 28	Group 1: Hydrocolloid dressing: sheet, paste and powder (Comfeel®, Coloplast A/S, Espergaerde, Denmerk). The dressing was changed when necessary. Th sheet is used solely or on top of the filled ulcer. Six ulcers were filled with paste and one with both paste and powder during the treatment period. Comfeel® sheet: consists of sodium carboxymethylcellulose particles embedded in an adhesive, elastic mass. The side which faces away from the ulcer is covered with a 0.3mm polyurethane film. Comfeel® paste: consists of sodium carboxymethylcellulose particles and guar cellulose particles suspended in a paste basis from vaseline, liquid paraffin and cetanol. Comfeel® powder: a dry mixture of sodium carboxymethylcellulose, guar cellulose and xanthan cellulose. Group 2: wet saline gauze dressings which was changed twice daily.	Outcome 1: Relative median percentage decrease in ulcer area by 6 weeks Outcome 2: Median percentage decrease in ulcer area by 8 weeks Outcome 3: Median ulcer depth at week 4 Outcome 4: Healing distribution function Outcome 5: proportion of patient reporting pain at dressing change	Group 1: 100.0 Group 2: 69.0 P value: 0.016 Group 1: figure unclear; not reported Group 2: figure unclear; not reported P value: 0.047 P value: 0.15 Treatment with hydrocolloid needed to be stopped in one patient (n=1/49) due to great pain.	Funding: / Limitations: no report on sequence allocation; allocation concealment by stratification; drop-outs unclear; partial statistical measure of difference between groups; no blinding of patients and nurses; no information on classification of PU and unclear if grade I PUs were included; information on pain unclear; no report on preventive measures or debridement. Additional outcomes: Granulation tissue was larger in G1 than G2

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
drop-out for unknown reason. Those were excluded. Statistical analysis: Mean values, standard deviations and t-test were used when the values were apparently normally distributed. When values were normally distributed, median values and lower and upper hinges were calculated. The Mann-Whitney U-test was then used for probability evaluations. The statistical analysis was performed by means of the software package SYSTAT (Systat Inc., Illinois, USA). The healing outcome was analysed by means of the lifetest program SAS (SAS institute Inc., Cary, USA) The statistical analysis was performed by means of the software package SYSTAT (Systat Inc., Illinois, USA). The probability	or 29 PUs for the efficacy analysis (latter unclear). Dropouts: 2 for the safety analysis and 2 or 3 for the efficacy analysis (latter unclear). Age (mean years (SD)): 83.6 (9.2) Norton score (mean (SD)): 12 (2) Duration PU (mean months (SD)): 4.6 (10.9) Ulcer location: Heel: n=11 Sacrum: n=8 Malleolus: n=4 Gluteal region: n=3 Hip: n=4 Other: n=1 Ulcer depth (median mm (IQR)): 1.75 (0.30-3.00) Ulcer area (median cm² (IQR)): 2.02 (0.95-3.10) Granulated area (median cm² (IQR)): 0.32 (0.051-1.68) Group 2 Randomised N: 25 PUs Completed N: 22 PUs for the safety analysis and 21	Both groups: after randomization all ulcers were dressed with wet saline gauze dressings for one week (wash-out period).			Nursing time: G1 versus G2, p<0.0001 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcomes was analysed by the log rank test. A two-tailed p-value of ≤ 0.05 was accepted as statistical significance. Baseline differences: Difference was not measured statistically except for ulcer depth, ulcer area and granulated area, which were not significantly different. Groups were comparable based on the average. Study power/sample size: No a priory sample size calculation. Setting: Long-term ward. Length of study: six weeks of treatment and follow-up for a further 3 to 6 weeks Assessment of PUs: Ulcer were photographed once a week. The area of the ulcer which was not covered with epithelium was determined after projection of the slide from below onto a	or 22 PUs for the efficacy analysis (latter unclear). Dropouts: 3 for the safety analysis and 3 or 4 for the efficacy analysis (latter unclear). Age (mean years (SD)): 83.4 (9.4) Norton score (mean (SD)): 13 (3) Duration PU (mean months (SD)): 4.8 (6.4) Ulcer location: Heel: n=8 Sacrum: n=9 Malleolus: n=3 Gluteal region: n=2 Hip: n=1 Other: n=2 Ulcer depth (median mm (IQR)): 2.00 (1.00-5.00) Ulcer area (median cm² (IQR)): 2.44 (0.97-3.24) Granulated area (median cm² (IQR)): 0.25 (0.079-0.70) Inclusion criteria: having a PU. Exclusion criteria: Norton score <7				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
horizontal glass plate which was covered with matt drawing foil. The relevant area was measured on the image which appeared on the matt foil, suing a Haff digital planimeter type 320 E (Haff, Pfronten, GFR) and the real area was then calculated, taking the degree of magnification into consideration. The depth and degree of cleanness and the extent and intensity of maceration were assessed and classified on rating scales. Classification of PUs: not reported. Multiple ulcers: 50 patients with 56 ulcers. Ulcers are unit of analysis and randomization.					

Table 171: Chang 1998[47]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Chang (1998) **Title**: Pressure ulcers-randomised controlled trial comparing hydrocolloid and saline gauze dressings. **Journal:** The Medical Journal of Malaysia, 53 (4); 428-431. **Study type**: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported. Blinding: no blinding. Addressing incomplete outcome data: no drop-out. Statistical analysis: Overall performance, pain, adherence, comfort, ease of removal was analysed by Wilcoxon Rank Sum Test. Rates of wound healing was analysed by Analysis	Patient group: Patients aged 18 years and older with a grade II or III PU. All patients Randomised N: 34 Completed N: 34 Drop-outs: 0 Age (mean years; range): 57.6; 20-85 Incontinence: Urine: n=5 Faecal: n=16 Both: n=4 Ulcer grade: Grade II: n=21 Grade III: n=13 Duration of PU (mean days; range): 33; 4-274 Ulcer location: Sacrum: n=30 Ilium: n=3 Greater trochanter: n=1 Group 1 Randomised N: 17 Completed N: 17 Dropouts: 0	Group 1: Hydrocolloid dressing (DuoDermCGF®). Dressings were changed every seven days or when leakage occurred. Cavity were filled with hydrocolloid gel (DuoDerm Hydroactive Gel®). DuoDermCGF®: occlusive dressing, which is under the influence of wound exudate and provides a moist wound environment. The outer later is made of polyurethane foam which is impermeable. Group 2: Wet soaked saline gauze dressing. The saline dressing was covered with a Gamgee® pack. Dressings were changed once a day or when exudate is visible through the second dressing. Both groups: /	Outcome 1: Mean reduction (%) in ulcer area Outcome 2: percentage of patients reporting a dressing as uncomfortable Outcome 3: percentage of patients reporting moderate/severe pain during dressing removal Outcome 4: proportion of patients reporting with an infection	Group 1: 34 Group 2: -9 P value: 0.23 Group 1: 0 Group 2: 50 P value: <0.01 Group 1: 0 Group 2: 44 P value: <0.01 Group 1: 0/17 Group 2: 0/17	Funding: funded by a grant from 3M company Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no a priory sample size calculation; difference between groups concerning PU location at baseline; no report on drop-out and number of patient completing the study Additional outcomes: Ease of use (G1: 62% vs G2: 19; p<0.01) Cost per subject (mean dressing time and mean nursing cost): G1:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
of Variance Test. Baseline differences: No statistical difference between groups except ulcer location. Study power/sample size: No a priory sample size calculation. Setting: University hospital Kuala Lumpur. Length of study: 8 weeks of treatment or until complete healing. Assessment of PUs: Wound tracings of ulcer perimeter were made at each dressing change by moulding a piece of clear plastic food wrap over the ulcer and into the ulcer cavity. The tracings were then transferred onto acetate transparencies using an Optomax Image Analyzer. Colour photographs were also taken. Assessments were done weekly. Classification of PUs: not reported.	Ulcer grade: Grade II: n=11 Grade III: n=6 Group 2 Randomised N: 17 Completed N: 17 Dropouts: 0 Ulcer grade: (3 missing) Grade II: n=7 Grade III: n=7 Inclusion criteria: Grade II or III PU; at least 18 years of age; provide written informed consent Exclusion criteria: Immunocompromised; infected PU; known sensitivity to the study dressings				RM 45.89 vs G2: RM105.30; p=0.025 Cost per subject (mean dressing time, mean nursing cost, and total cost material): G1: RM 271.45 vs G2: RM 173.05; p=0.12 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: only one PU per patient was eligible for study entry.					

Table 172: Chuangsuwanich 2011[49]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Chuansuwanich (2011) **Title**: The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers. **Journal:** Journal of the Medical Association of Thailand, 94 (5); 559-565 Type of study: randomized controlled trial Sequence generation: randomly by computer Allocation concealment: not reported. Blinding: no blinding. Addressing incomplete outcome data: no missing reported	Patient group: In- and out-patients with a grade III or IV PU (according to the NPUAP 1989 classification). All patients Randomised N: 40 Completed N: 40 Drop-outs: 0 Group 1 Randomised N: 20 Completed N: 20 Dropouts: 0 Age (mean years (SD)): 62.60 (20.59) Gender (m/f): 8/12 Duration of PU (mean days (SD)): 232.00 (180.52) Ulcer location: Sacrum: n=16	Group 1: Silver mesh dressing (Tegaderm® Ag Mesh dressing) after wound bed cleansing. Cotton gauze was used as outer dressing. Dressings were changed every three days. Group 2: Silver sulfadiazine cream after wound bed cleansing. Cotton gauze was used as outer dressing. Dressings were changed twice a day. Both groups: Wounds were debrided as necessary.	Outcome 1: mean healing rate (%) at eight weeks Outcome 2: percentage reduction in PUSH score at eight weeks Outcome 3: complications	Group 1: 36.95 Group 2: 25.06 P value: 0.507 Group 1: 28.15 Group 2: 34.51 P value: 0.473 Group 1: 0/20 Group 2: 0/20	Funding: / Limitations: no report on allocation concealment; no blinding; no a priory sample size calculation and small sample size Additional outcomes: cost was calculated (drug cost + outer dressing cost x time of dressing change/20). G1: 263 USD per patient; G2: 1812 USD per patient; p=0.00 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: All data analysis was performed using SPSS 13.0. Data were expressed as mean ± standard deviation (SD). Comparison of the mean between two groups of all parameters was evaluated for the significance by non-parametric Mann-Whitney U-test before treatment and at eight week of treatment. A p-value of less than 0.05 was considered significant. Baseline differences: no statistical difference between groups. Study power/sample size: No a priory sample size calculation. Setting: Siriraj Hospital Length of study: eight weeks Assessment of PUs: Ulcer size was determined by using VISITRAKR Wound	Greater trochanter: n=1 Ischium: n=3 Surface area (mean cm² (SD)): 12.17 Group 2 Randomised N: 20 Completed N: 20 Dropouts: 20 Age (mean years (SD)): 69.10 (16.02) Gender (m/f): 9/11 Duration of PU (mean days (SD)): 197.40 (131.65) Ulcer location: Sacrum: n=14 Greater trochanter: n=5 Ischium: n=1 Surface area (mean cm² (SD)): 22.82 Inclusion criteria: Grade III or grade IV Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
measurement system and wound photography at the beginning en very two weeks. The PUSH score was assessed every two weeks. Classification of PUs: NPUAP classification (1989). Multiple ulcers: not reported					

Table 173: Gerding 1993[82]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gerding (1993) **Title**: Oxyquinoline-containing ointment vs standard therapy for grade I and grade II skin lesions. **Journal:** Dermatology Nursing, 4 (5): 389-398. Type of study: Randomized controlled trial Sequence generation: a random allocation list	Patient group: Palliative care patients with a grade II or III PU (according to the NPUAP classification). All patients Randomised N: 74 patients and 137 ulcers Completed N: 74 patients and 137 ulcers Drop-outs: 0 Group 1	Group 1: Oxyquinoline-containing ointment (DermaMentTM). Ulcers were cleansed with soap and water. Afterwards the ointment was applied at least three times a day or whenever cleansing the area. DermaMentTM: is a bactericide, fungicide and trichomonicide. Group 2: A&DTM ointment. Ulcers were cleansed with soap and water. Afterwards the ointment was applied at least	Outcome 1: Proportion of ulcers completely healed Outcome 2: Proportion of grade I ulcers completely healed Outcome 3: Proportion of grade II ulcers completely healed	Group 1: 43/86 Group 2: 21/51 Group 1: 23/41 Group 2: 16/28 Group 1: 20/45 Group 2: 5/23	Funding: Grant from InnoVisions, Inc. Dublin, OH Limitations: no report on allocation concealment; only blinding of outcome assessor; no report on baseline characteristics; no a priory sample size calculation; little

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
maintained at each central nursing office was used. Allocation concealment: not reported Blinding: outcome assessors was blinded. Addressing incomplete outcome data: no drop outs Statistical analysis: Statistical analysis of the responses to the two different treatments included use of the 'fisher t-test' and chi-square analysis. No study controls were used for pressure relief, incontinence, or nutritional. Baseline differences: baseline characteristics were not reported. Study power/sample size: No a priory sample size calculation. Setting: three long-term care facilities Length of study: 28 days of treatment or until complete healing	Randomised N: 86 Completed N: 86 Dropouts: 0 Ulcers grade: Grade I: 41 Grade II: 45 Group 2 Randomised N: 51 Completed N: 51 Dropouts: 0 Ulcers grade: Grade I: 28 Grade II: 23 Inclusion criteria: newly diagnosed grade I or II PU; treatment with an emollient ordered by the attending physician Exclusion criteria: /	three times a day or whenever cleansing the area. Both groups: /	Outcome 4: Proportion of grade I ulcers improved on day 15 Outcome 5: Proportion of grade II ulcers improved on day 22 Outcome 6: Proportion of grade I ulcers not changed on day 15 Outcome 7: Proportion of grade II ulcers not changed on day 22 Outcome 8: Proportion of grade I ulcers worsened on day 15 Outcome 9: Proportion of grade II ulcers worsened on day 22	Group 1: 15/41 Group 2: 6/28 Group 1: 19/45 Group 2: 8/23 Group 1: 4/41 Group 2: 4/28 Group 1: 5/45 Group 2: 7/23 Group 1: 0/41 Group 2: 2/28	information on ulcer assessment; no report on preventive measures Additional outcomes: preference of treatment rated by nursing staff not blinded to the treatment Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Lesions were assessed on a daily basis. Progression of healing was evaluated on the basis of change in lesion size intensity, and extend of surrounding erythema, presence /absence of drainage, and presence/absence of granulation tissue. Classification of PUs: NPUAP classification (1989). Multiple ulcers: 74 patients with 137 ulcers. Ulcer was unit of analysis and randomization			Outcome 10: Mean days to complete healing Outcome 11: Mean days to complete healing of grade I ulcers Outcome 12: Mean days to complete healing of grade II ulcers	Group 1: 1/45 Group 2: 3/23 Group 1: 7.23 (4.15) Group 2: 8.62 (5.16) Group 1: 6.75 (3.90) Group 2: 7.25 (4.80) Group 1: 7.80 (4.47) Group 2: 13.0 (3.94) P-value: p<0.05	

Table 174: Günes 2007[92]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Günes (2007) **Title**: Effectiveness of a honey dressing for healing pressure ulcers. **Journal:** Journal of Wound, Ostomy and Continence Nursing, 34 (2); 184-190. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: no blinding. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis: Data are analysed using the Statistical Package for the Social Sciences (Version 11.0 for Windows). PUSH scores were used to characterize PU healing. Chi-square analysis was conducted to compare	Patient group: Hospitalized patients aged 18 years and older with grade II or III PUs (according to the US Agency for Health Care Research and Quality's PU Guideline Panel classification). All patients Randomised N: 27 patients Completed N: 26 patients and 50 ulcers Drop-outs: 1 (died) Ulcer grade: Grade II: n=2 Grade III: n=48 Group 1 Randomised N: 15 patients and 25 ulcers Completed N: 15 patients and 25 ulcers Dropouts: 0 Age (mean years (SD)): 65.80 (6.30) Gender (m/f): 9/6 BMI (mean kg/m² (SD)):	Group 1: Honey dressing (3.8% concentration, and sterilized at 25kGy Gamma irradiation). Ulcers were irrigated with NaCl0.9% at each dressing change. A gauze dressing impregnated with honey (20ml) was used as a primary dressing. A semipermeable adhesive dressing was used as secondary dressing to prevent leakage of honey. Dressings were changed once daily or when contaminated with urine or faeces. Group 2: Ethoxydiaminoacridine and nitrofurazone dressing. Ulcers were cleaned with ethoxydiaminoacridine solution (0.1%) and a nitrofurazone cream was spread to the surface of the wound. A gauze dressing soaked with ethoxydiaminoacridine covered the ulcer. A semipermeable adhesive dressing was used as secondary dressing. Dressings were changed once daily or when contaminated with urine or faeces.	Outcome 1: Mean percentage decrease in PUSH score Outcome 2: Mean percentage reduction in ulcer size Outcome 3: Proportion of ulcers completely healed Outcome 4: Proportion of patients with adverse events attributed to the treatment	Group 1: 56.3 Group 2: 12.9 P value: < 0.001 Group 1: 56 Group 2: 13 P value: < 0.001 Group 1: 5/25 Group 2: 0/25 P value: < 0.001 Group 1: 0/15 Group 2: 0/11	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priory sample size calculation Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
wound and patient demographics by groups. Repeated anova were calculated to compare PU healing in both groups. Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample size calculation. Setting: one university hospital in Izmir Length of study: maximum five weeks of treatment or until complete healing. Assessment of PUs: Ulcer tracings were made by standard acetate hand tracing. Ulcer characteristics were documented via the PUSH instrument. Measurement was carried out at baseline and on each weekly visit. The total score ranged from 0 to 17, with 0 representing a healed wound.	27.2 (1.38) Mobility level (mean score (SD)); score 1 to 4, with 1 greater impairment: 1.20 (0.40) Group 2 Randomised N: 12 patients Completed N: 11 patients and 25 ulcers Dropouts: 1 (died) Age (mean years (SD)): 66.56 (5.53) Gender (m/f): 8/3 BMI (mean kg/m² (SD)): 26.4 (1.40) Mobility level (mean score (SD)); score 1 to 4, with 1 greater impairment: 1.32 (0.47) Inclusion criteria: Older than 18; life expectancy > 2 months Exclusion criteria: diabetes mellitus	Both groups: all patients received preventive skin regimen (a turning and repositioning program and a pressure relieving mattress)			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: Agency Health Care Research and Quality's Pressure Ulcer Guideline Panel classification (1994) Multiple ulcers: 26 patients with 50 ulcers were included.					

Table 175: Hirshberg 2003[98]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Hirshberg (2003) **Title**: TGF-beta3 in the treatment of pressure ulcers: a preliminary report. **Journal:** Advances IN Skin and Wound Care, 14 (2); 91-95 Type of study: randomized controlled trial (subset analysis) Sequence generation: not reported Allocation concealment: not reported Blinding: blinding, no	Patient group: Hospitalized patients aged 18 years and older with a grade III or IV PU (according to the NPUAP 1992 classification). All patients Randomised N: 14 Completed N: 8 Drop-outs: 6 (1 died, 2 developed osteomyelitis, 1 was non-compliant to pressure relief protocol, 1 had an unsatisfactory therapeutic effect, 1 had an aspiration pneumonia)	Group 1: Topical agent: 1.0µg/cm² transforming growth factor beta 3. After 15 minutes the wound was cleaned with saline and loosely packed with saline-moistened gauze. Group 2: Topical agent: 2.5µg/cm² transforming growth factor beta 3. After 15 minutes the wound was cleaned with saline and loosely packed with saline-moistened gauze. Group 3: placebo gel Both groups: All patients received standardized wound	Outcome 1: proportion of patients completely healed Outcome 2: Mean relative reduction surface area (%) at termination Outcome 3: Mean relative reduction in volume (%) at termination	Group 1: 0/4 Group 2: 1/5 Group 2: 0/5 Group 1: 70 Group 2: 60 Group 3: 30 Group 1: 75 Group 2: 60 Group 3: 20	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; blinding, but no information; no a priory sample size calculation; no statistical measure of difference between groups; very small sample size and high drop-out

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
further information. Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: The Bonferroni adjustment (Dunn) t test, a 1-way analysis of variance, was performed on the data at visits 4, 10, and 16 at the .05 level of significance. The relative PU volume and relative PU bed surface area were defined as the size at a particular visit divided by the baseline size. Thus, the reduction in size of the PU was evaluated relative to the original ulcer size. Baseline differences: Difference not statistically measured. No clinically important differences were observed between groups Study power/sample size: No a priory sample size calculation. Setting: University wound care centre,	Group 1 Randomised N: 4 Completed N: 3 Dropouts: 1 (1 died) Age (mean years (SD)): 51.0 (7.9) Gender (m/f): 1/3 Duration of PU (mean weeks (SD)): 45 (28) Surface area (mean cm² (SD)): 45.1 (25.2) Ulcer volume (mean cm³ (SD)): 32.6 (29.2) Group 2 Randomised N: 5 Completed N: 2 Dropouts: 3 (2 developed osteomyelitis, and 1 was non-compliant to pressure relief protocol) Age (mean years (SD)): 34.0 (16.2) Gender (m/f): 4/1 Duration of PU (mean weeks (SD)): 43 (17) Surface area (mean cm² (SD)): 46.6 (13.1) Ulcer volume (mean cm³ (SD)): 31.5 (14.2)	care: all target ulcers were debrided before randomization, gentle cleansing of the wound bed with saline, maintenance of a moist wound environment, recognition and treatment of infection, off-loading of pressure from the affected area using low-air-low surfaces, and nutritional support.			Additional outcomes: /. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Michigan Length of study: 16 weeks or until ulcer healed, whichever occurred first. Assessment of PUs: Surface area site was measured by planimetry. A calcium alginate mould was made to measure the volume of the ulcer. The area of the PU bed was calculated using a dosage determination chart that converted area volume to ulcer bed area. If the volume was less than 10cm², the calculation was not done and the ulcer bed area was considered equal to ulcer surface area. Classification of PUs: NPUAP (1992). Multiple ulcers: patients had between one and three ulcers. If more than 1 full-thickness PU was present, the PU closest to a volume of 40 cm3 was designated	Group 3 Randomised N: 5 Completed N: 3 Dropouts: 2 (1 had an unsatisfactory therapeutic effect, and 1 had an aspiration pneumonia) Age (mean years (SD)): 48.0 (21.0) Gender (m/f): 3/2 Duration of PU (mean weeks (SD)): 44 (23) Surface area (mean cm² (SD)): 43.2 (14.1) Ulcer volume (mean cm³ (SD)): 28.1 (14.7) Inclusion criteria: Older than 18; PU surface area between 15 cm2 and 120 cm2 and the calcium alginate mould weight had to be 10 grams or more, following debridement at the baseline visit; ulcer present for at least 4 weeks; a serum albumin concentration of 2.5 grams/dL or more;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
as the target ulcer.	bacterial counts of less than 105 per gram of tissue and no evidence of [beta]-hemolytic streptococci or malignancy. Exclusion criteria: osteomyelitis, determined by clinical evaluation, [chi]-ray, and/or bone biopsy; calcium alginate mold weight was 10 grams or less after debridement; topical antibiotics or disinfectants were applied to the target ulcer during cleansing; autolytic or enzymatic debriding agents were used on the target ulcer; an experimental, non-approved, or investigational drug was used within the past month or during the trial; malignancy at any PU site; administration of systemic corticosteroids of more than 20 mg per day, or administration of other immunosuppressive therapy; target ulcer failed to heal with				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	previous cytokine therapy; patients received radiation therapy at the target ulcer site; women who were pregnant, nursing, or of childbearing age and not using an accepted method of birth control				

Table 176: Hollisaz 2004[99]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Hollisaz (2004) **Title**: A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings for the treatment of pressure ulcers [ISRCTN33429693]. **Journal:** BMC Dermatology, 4 (1); 18-26 Type of study: randomized controlled trial Sequence generation: random number table	Patient group: Patients with a spinal cord injury and a grade I or II PU (according to the NPUAP or Shea classification) All patients Randomised N: 83 patients with 91 ulcers Completed N: 83 patients with 91 ulcers Drop-outs: 0 Group 1 Randomised N: 28 patients with 31 ulcers Completed N: 28 patients with 31 ulcers	Group 1: Hydrocolloid adhesive dressing was used after cleaning and washing (3 times with normal saline) of the ulcer. The adhesive dressing was changed twice a week. Group 2: Phenytoin cream was used after cleaning and washing (3 times with normal saline) of the ulcer. A thin layer was applied to the ulcer before the dressing was performed. The dressing was changed daily. Group 3: Simple dressing was used after cleaning, washing (3 times with normal saline) and drying of the ulcer with a sterile gauze. The ulcer was	Outcome 1: proportion of ulcers complete healed after eight weeks (all grades; all sites) Outcome 2: proportion of ulcers complete healed after eight weeks (grade I; all sites) Outcome 3: proportion of ulcers complete healed after eight weeks (grade II; all	Group 1: 23/31 Group 2: 12/30 Group 3: 8/30 P value G1 vs G2: <0.01 P value G1 vs G3: <0.005 Group 1: 11/13 Group 2: 2/9 Group 3: 5/11 P value G1 vs G2: <0.005 P value G1 vs G3: <0.05 Group 1: 12/18 Group 2: 10/21 Group 3: 3/19	Funding: The study was supported by the Jaonbazan Medical and Engineering Research Center, the medical and research section of the official governmental body responsible for SCI war victims. Limitations: no blinding of patients and nurses; sample size lower than calculated sample size

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
was used. The statistician in the team generated the random allocation sequence. Allocation concealment: stratified randomization (ulcers grade and location) was used. The statistician delivered the treatment category in an opaque sealed envelope bearing only the number of the patient. Blinding: outcome assessor blinding. Addressing incomplete outcome data: no drop-out. Statistical analysis: All the data collected from the patients' preliminary and complementary questionnaires were analysed by SPSS software using ANOVA and Chi square tests, and P-values of <0.05 were assumed significant. The 95% confidence intervals were also calculated	Dropouts: 0 Age (mean years (SD)): 36.81 (6.71) Gender (m/f): 28/0 Duration of PU (mean weeks (SD)): 7.63 (5.59) Ulcer grade: Grade I: n=13 Grade II: n=18 Ulcer location: Gluteal: n=6 Ischial: n=18 Sacral: n=7 Surface area (mean cm² (SD)): 7.26 (15.4) Group 2 Randomised N: 28 patients with 30 ulcers Completed N: 28 patients with 30 ulcers Dropouts: 0 Age (mean years (SD)): 36.5 (4.99) Gender (m/f): 28/0 Duration of PU (mean weeks (SD)): 5.84 (8.04) Ulcer grade: Grade I: n=9 Grade II: n=21	covered with wet saline gauze dressing and was changed twice a day. Both groups: all ulcers were debrided before treatment. No concomitant topical or systematic antibiotic, glucocorticoid or immunosuppressive agent were allowed during the treatment.	sites) Outcome 4: proportion of ulcers complete healed after eight weeks (all grades; gluteal) Outcome 5: proportion of ulcers complete healed after eight weeks (all grades; ischial) Outcome 6: proportion of ulcers complete healed after eight weeks (all grades; sacral) Outcome 7: proportion of ulcers partially healed after eight weeks Outcome 8: proportion of ulcers worsened	P value G1 vs G2: >0.05 P value G1 vs G3: <0.005 Group 1: 6/6 Group 2: 2/7 Group 3: 1/8 P value G1 vs G2: <0.005 P value G1 vs G3: <0.001 Group 1: 13/18 Group 2: 8/18 Group 3: 3/14 P value G1 vs G2: <0.1 P value G1 vs G3: <0.005 Group 1: 4/7 Group 2: 2/5 Group 3: 4/8 P value G1 vs G2: >0.35 P value G1 vs G3: >0.20 Group 1: 4/31 Group 2: 4/30 Group 3: 5/30	Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and reported. For rare events (more than 20 percent of cross tabulation cells had values less than 5), Fisher's exact test was used. Based on grade and location of ulcers, subgroup analyses were performed using the same statistical tests. Baseline differences: no statistical difference between groups. Study power/sample size: A response rate of 30%, 40% and 80%w was assumed for SD, PC and HD, respectively. Based on a 40% difference, power of 0.85, 95% confidence level and estimated follow-up loss of 10%, 29 patients were required for each study group. Final sample size lower than calculated. Setting: home care and long-term care centres Length of study: 8 weeks of treatment	Ulcer location: Gluteal: n=7 Ischial: n=18 Sacral: n=5 Surface area (mean cm² (SD)): 5.12 (3.63) Group 3 Randomised N: 27 patients with 30 ulcers Completed N: 27 patients with 30 ulcers Dropouts: 0 Age (mean years (SD)): 36.6 (6.17) Gender (m/f): 27/0 Duration of PU (mean weeks (SD)): 5.25 (5.39) Ulcer grade: Grade I: n=11 Grade II: n=19 Ulcer location: Gluteal: n=8 Ischial: n=14 Sacral: n=8 Surface area (mean cm² (SD)): 10.27 (15.32) Inclusion criteria: Paraplegia caused by		after eight weeks Outcome 9: proportion of patients completely healed after eight weeks (one ulcer per patient randomly drawn)	Group 1: 2/31 Group 2: 2/30 Group 3: 9/30 Group 1: 20/28 Group 2: 11/28 Group 3: 8/27 P value G1 vs G2: <0.01 P value G1 vs G3: <0.005	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: The general practitioner filled in a questionnaire on ulcer status every two weeks. Completely healed ulcer patients were followed up by monthly visits from GP for further 4 months after end of trial. One of the authors assesses complete/partial/without/worsening healing at the end of the study. Ulcer surface area was measured by tracing on an paper overly, which was scanned, redrawn and measured by AutoCAD 2000 Classification of PUs: NPUAP (1989) and Shea (1975) classification. Multiple ulcers: if a patient had more than one ulcer, all ulcers were treated by the same method. Ulcers were the unit of analysis.	spinal cord injury; PU grade I or II according to Shea or NPUAP classification; informed consent; smoothness of ulcer area to establish whether adhesive could be used at the site Exclusion criteria: Addiction; heavy smoking (more than 20 cigarettes a day or more than 10 packs per year; concomitant chronic disease (e.g. diabetes mellitus or frank vascular disease such as Buerger's disease).				

Table 177: Kaya 2005[111]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kaya (2005) **Title**: The effectiveness of a hydrogel dressing compared with standard management of pressure ulcers. **Journal:** Journal of Wound Care, 14 (1); 42-44 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: not reported. Statistical analysis: The Mann-Whitney U test was used to compare arithmetic means and differences between groups. All statistical analyses were performed using SPSS	Patient group: Hospitalized patients with a spinal cord injury and with PUs (according to the NPUAP classification) All patients Randomised N: 27 patients and 49 ulcers Completed N: not reported Drop-outs: not reported Gender (m/f): 24/3 Group 1 Randomised N: 15 patients and 25 ulcers Completed N: not reported Dropouts: not reported Age (mean years (SD); range): 35.27 (14.57; 16-56) Ulcer grade: Grade I: 6 Grade II: 17 Grade III: 2 Ulcer location: Sacral: n=7	Group 1: Hydrogel dressing (Elasto-GelTM, South-West Technologies, North Kansas City, Missouri, USA). Dressings were changed every four days, or more if membrane became contaminated or non-occlusive. Group 2: Povidone-iodine soaked gauze dressings which were changed every daily. Both groups: necrotic areas were mechanically debrided	Outcome 1: Mean healing rate (cm²/day; range)	Group 1: 0.12 (0.16); 0.02-0.36 Group 2: 0.09 (0.05); 0.03-0.23 P value: 0.97	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no report on drop-outs; no report on blinding; little information on ulcer assessment and statistical analysis; no information on preventive measures. Additional outcomes: Treatment time (mean days (SD); range): G1: 51.56 (20.07); 15-91; G2: 51.54 (23.69); 16-106 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample size calculation. Setting: Hospital. Length of study: Not reported Assessment of PUs: Ulcers were measured in cm². The surface area was evaluated every four days until epithelisation was complete. Classification of PUs: NPUAP classification. Multiple ulcers: 27 patients with 49 ulcers.	Ischia: n=6 Heel: n=6 Greater trochanter: n=3 Knee: n=1 Lateral malleolus: n=2 Ulcer area (mean cm² (SD); range): 4.13 (2.73) Group 2 Randomised N: 12 patients and 24 ulcers Completed N: not reported Dropouts: not reported Age (mean years (SD); range): 29.67 (6.41); 17-39 Ulcer grade: Grade I: 6 Grade II: 17 Grade III: 1 Ulcer location: Sacral: n=6 Ischia: n=3 Heel: n=2 Greater trochanter: n=4 Iliac cest: n=4 Knee: n=2 Fibula: n=2				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Foot: n=1 Ulcer area (mean cm² (SD); range): 6.45 (6.88); 2-35 Inclusion criteria: SCI patient; PU Exclusion criteria: /				

Table 178: Kim 1996[116]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kim (1996) **Title**: Efficacy of hydrocolloid occlusive dressing technique in decubitus ulcer treatment: a comparative study. **Journal:** Yonsei Medical Journal, 37 (3); 181-185 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported	Patient group: Patients with a grade I or II PU (according to the NPUAP classification). All patients Randomised N: 44 Completed N: 44 Drop-outs: 0 Group 1 Randomised N: 26 Completed N: 26 Dropouts: 0 Age (mean years (SD)): 50.5 (18.3) Gender (m/f): 23/3	Group 1: Hydrocolloid occlusive dressing (DuoDerm®, Squib, Princeton, NJ). Ulcers were cleaned with saline irrigation and boric solution prior to application of the dressing. Dressings were changed every 4-5 days. Group 2: Wet-to-dry dressing. Ulcers were cleaned with saline irrigation and boric solution prior to application of the povidone soaked wet gauze. Dressings were changed three times a day. Both groups: All ulcers were debrided prior to application of the dressing. All patients	Outcome 1: Healing rate (%) Outcome 2: Mean healing speed (mm²/day) Outcome 3: Proportion of patients with complete healing Outcome 4: Proportion of patients with hypergranulation	Group 1: 80.8 Group 2: 77.8 P value: > 0.05 Group 1: 9.1 (5.4) Group 2: 7.9 (4.7) P value: > 0.05 Group 1: 21/26 Group 2: 14/18 Group 1: 3/26 Group 2: 0/18	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priory sample size calculation; no report on multiple ulcers Additional outcomes: cost (won): G1: 8204 (2664) versus G2: 14571 (6700)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: not reported. Addressing incomplete outcome data: no missing data reported Statistical analysis: The chi-square and t-test were used for the statistical analysis. Baseline differences: No statistical difference between groups Study power/sample size: No a priory sample size calculation. Setting: department of rehabilitation medicine Length of study: mean treatment duration was 18.9 (8.2) days in G1 and 24.3 (11.2) days in G2 Assessment of PUs: Ulcer size was estimated by measuring the longest diameters and the longest diameter perpendicular to it. Other measured variables were ulcer site, size and degree, presence of necrotic tissue, exudate, serum albumin level,	Incontinence: Urine: n=19 Faecal: n=10 Ulcer grade: Grade I: n=6 Grade II: n=20 Ulcer location: Sacrum: n=7 Pelvic girdle: n=7 Other: n=12 Surface area (mean cm²): unclear Group 2 Randomised N: 18 Completed N: 18 Dropouts: 0 Age (mean years (SD)): 46.9 (16.8) Gender (m/f): 13/5 Incontinence: Urine: n=12 Faecal: n=7 Ulcer grade: Grade I: n=6 Grade II: n=12 Ulcer location: Sacrum: n=4 Pelvic girdle: n=7	received position change to relieve the pressure to the ulcer site.			Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
hemoglobin level and urinary and faecal incontinence. Classification of PUs: NPUAP classification (1989). Multiple ulcers: not reported.	Other: n=7 Surface area (mean cm²): unclear Inclusion criteria: PUs grade I or II Exclusion criteria: PU grade III or IV; systemic infection, endocrinological disorder, difficulty keeping pressure relieving positions; aggravated general condition due to other factors				

Table 179: Knudsen 1982[119]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Knudsen (1982) **Title**: The use of a haemodialysate in the treatment of decubital ulcer: A double-blind randomized clinical study. **Journal:** Current Therapeutic Research, 32 (3); 498-504 Type of study:	Patient group: Patients with a spinal cord injury and a PU. All patients Randomised N: 16 Completed N: 8 Drop-outs: 8 (3 underwent plastic surgery, 3 fistels and sinuses broke through, 2 transferred)	Group 1: Dialysate (Solcoseryl®, Solco Basle Ltd., Basle, Switzerland). Jelly was used for the ulcer crater and ointment was used for the ulcer edges and zones where epithelialization occurred. The edges were covered with Melolin bandage. The bandages were changed and fresh jelly and ointment was applied three times a day during the first week and twice	Outcome 1: Mean ml decrease in ulcer size Outcome 2: Mean percentage decrease in ulcer size at day 10 Outcome 3: Mean percentage decrease in ulcer size at day 20	Group 1: 13.4 (10.02) Group 2: 6.57 (4.88) Group 1: 39 Group 2: 28 Group 1: 80 Group 2: 59	Funding: Solco Bazle Ltd. provided the test drug Limitations: no report on sequence generation; concealment no report on allocation concealment; double-blind no further

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
randomized controlled trial Sequence generation: a not reported Allocation concealment: not reported Blinding: double blind, no further information Addressing incomplete outcome data: drop-outs were excluded Statistical analysis: The student t-test was used for analysis of the differences between the regression coefficients for the active and the placebo treatments. Baseline differences: Difference was not measured statistically. Study power/sample size: No a priory sample size calculation. Setting: hospital Length of study: three weeks of treatment. Assessment of PUs: Ulcers were measured 9 times and loss of substance 5 times. The logarithm of the product	Group 1 Randomised N: not reported Completed N: 5 Dropouts: not reported Characteristics of completed N Age (mean years (SD); range): 33.6 (8.17); 22-40 Gender (m/f): 3/2 Ulcer size (mean ml (SD); range): 17.44 (13.88); 7.6-40.9 Ulcer location: sacral area Group 2 Randomised N: not reported Completed N: 3 Dropouts: not reported Characteristics of completed N Age (mean years (SD); range): 42 (19.47); 20-57 Gender (m/f): 2/1 Ulcer size (mean ml (SD); range): 14.1 (8.16); 5.7-22.0 Ulcer location: sacral area	a day during the following two weeks. Solcoseryl®: a protein-free dialysate of calf blood Group 2: Placebo. Jelly was used for the ulcer crater and ointment was used for the ulcer edges and zones where epithelialization occurred. The edges were covered with Melolin bandage. The bandages were changed and fresh jelly and ointment was applied three times a day during the first week and twice a day during the following two weeks. Both groups: all patients were placed on water mattresses. Patients were turned 10 times at regular intervals over 24 hours. Systemic and local antibiotics were stopped at least one week prior to the start of the study.	Outcome 4: Mean healing half-time (days) Outcome 5: Side effects	Group 1: 8.52 (2.36) Group 2: 24.0 (18.43) P-value: p<0.05 (favour G1) Group 1: 0/5 Group 2: 0/3	information; no ITT analysis; no a priory sample size calculation; small sample size and high dropout; no classification of PU; no information on number of randomized patients per group; no characteristics on patients who dropped out; no statistical measurement of differences between groups Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
length, width and depth of the ulcer was used as one parameter for the ulcer size. In addition, the exact volume of lost substance was measured by filling the ulcer crater with placebo gel to skin level using a syringe. Ulcers were photographed in color 4 times under standardized conditions during the course of treatment. Classification of PUs: not reported. Multiple ulcers: not reported	Inclusion criteria: Para-tetraplegic patients; decubital ulcer with a size which could be measured in three dimensions and with a measurable loss of substance of at least 1 ml Exclusion criteria: > 60 years; diabetes mellitus; cardiac and/or peripheral vascular disease				

Table 180: Kraft 1993[123]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kraft (1993) **Title**: A comparison of Epi-Lock and saline dressings in the treatment of pressure ulcers. **Journal:** Decubitus, 6	Patient group: Male veterans with a grade II or III PU (according to the Enterstomal Therapy definition). All patients Randomised N: 34	Group 1: foam dressing (Epi-LockTM). Epi-LockTM: a sterile, non-adherent, semi-occlusive polyurethane foam wound dressing with an adhesive cover. Group 2: saline moistened gauze dressing.	Outcome 1: Proportion of patients/ulcers completely healed	Group 1: 10/24 Group 2: 3/14	Funding: funding by Calgon Vestal Labaratories Limitations: no report on sequence allocation; no report on allocation

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(6); 42-48 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: intention-to-treat analysis Statistical analysis: Not reported except for correlation between determined variables and ulcer healing. Data were analysed using regression analysis. Baseline differences: Difference was not statistically measured. Study power/sample size: Unclear if a priory sample size calculation was performed. Sample size was targeted to allow for drop-outs. The sample size was adequate to permit	Completed N: 17 Drop-outs: 17 (2 died, 2 withdrew, staff requested withdrawal for 6 patients, 1 had surgery, 1 had special bed treatment, 5 had a reaction to RX) Age (mean years; range): 56; 28-78 Gender (m/f): 38/0 Spinal cord injury: 33 Ulcer grade: Grade II: n=22 Grade III: n=16 Ulcer duration: range: new to five years ≤ 2 months: n=20 > 2 months: n=14 Group 1 Randomised N: 24 Completed N: 11 Dropouts: 13 (1 withdrew, staff requested withdrawal for 5 patients, 1 had special bed treatment, 4 had a reaction to RX) Group 2	Both groups: Standardized dressing procedures were performed in all patients.			concealment; no report on blinding; a priory sample size calculation unclear; small sample size and high drop-out (ITT); no measurement of statistical difference between groups at baseline; no information on statistical analysis; no information on ulcer assessment; little information on dressing and standardized procedure. Additional outcomes: Cost (nursing time and dressing cost): G1: $20.48 versus G2: $74.97 Correlation (variables: medication, cultures, age, smoking, serum albumin, TIBC, CBC, fasting blood sugar,

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistical analysis to detect difference in healing between groups, grades and over time. Setting: tertiary care veteran's hospital in the Midwest consisting of a spinal cord injury centre and an extended care centre. Length of study: 24 days of treatment Assessment of PUs: All subjects were assessed by the same rater who noted grade, tissue color, drainage, odour and condition of the skin surrounding the ulcer. Classification of PUs: Enterstomal Therapy definition (1987). Multiple ulcers: Indirect: one ulcer per patient.	Randomised N: 14 Completed N: 6 Dropouts: 8 (2 died, 1 withdrew, staff requested withdrawal for 1 patients, 1 had surgery, 1 had a reaction to RX) Inclusion criteria: / Exclusion criteria: PU grade I or IV; clinically infected ulcer; patient on special bed; unstable insulin-dependent diabetes; serum albumin < 2gm; hemoglobin < 12gm; class IV congestive heart failure; chronic renal insufficiency; documented severe peripheral vascular disease; documented COPD				electrolytes, CO2 levels): serum albumin was inversely related to patients age Notes: /

Table 181: Kucan 1981[124]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kucan (1981) **Title**: Comparison of silver sulfadiazine, povidone-iodine and physiologic saline in the treatment of chronic pressure ulcers. **Journal:** Journal of the American geriatric Society, 29 (5); 232-235 Type of study: randomized controlled trial Sequence generation: a computer-generated randomized table was used Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded Statistical analysis: Not reported. Baseline differences: No	Patient group: Hospitalized patients with an infected PU. All patients Randomised N: 45 Completed N: 40 Drop-outs: 5 (reason not reported) Age (range years): 16-102 Group 1 Randomised N: not reported Completed N: 15 Dropouts: not reported Group 2 Randomised N: not reported Completed N: 11 Dropouts: not reported Group 3 Randomised N: not reported Completed N: 14	Group 1: Silver sulfazidine cream 1% (Silvadene® cream). Ulcers were cleansed with a sterile saline solution. The cream was applied to the ulcer every eight hours with a gloved hand and worked into the crypts and crevices. The ulcer was then covered with two layers of fine mesh gauze. Group 2: Povidone-iodine solution (Betadine®). Ulcers were cleansed with a sterile saline solution. The ulcers were dressed with a coarse-mesh gauze fluffed dressing saturated with the solution. The dressing was changed every six hours. Group 3: Physiologic saline 0.9% NaCl. Ulcers were cleansed with a sterile saline solution. The ulcers were dressed with a coarse-mesh gauze fluffed dressing saturated with the saline. The dressing was changed every four hours.	Outcome 1: Proportion of patient clinically responding within three weeks Outcome 2: Mean values of bacterial levels	P value G1 versus G2: ≤ 0.022 P value G1 versus G2: < 0.01 P value G1 versus G3: < 0.10	Funding: / Limitations: no report on allocation concealment; no report on blinding; no ITT analysis; no report on statistical analysis; no a priory sample size calculation. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistical difference between groups. Study power/sample size: No a priory sample size calculation. Setting: hospital Length of study: three weeks of treatment or until the ulcer was deemed microbiologically clean, clinically ready for closure or the medical regimen was considered a failure. Assessment of PUs: Ulcers were clinically and microbiologically evaluated. The microbiologic examination was conducted as described by Robson and Heggers (1969 and 1970). A reduction in total microbial count per gram of tissue to 105 or fewer and the absence of β-hemolytic streptococci. The clinical evaluation was based on the investigators judgment.	Dropouts: not reported Inclusion criteria: Infected PU (bacterial count >105 bacteria per gram tissue); no sensitivity to sulfa or iodine preparations; not pregnant; no severe concomitant systemic disease; no severe concomitant infection outside the ulcer; no acute cellulitis in the area surrounding the ulcer; no radiographic bone involvement beneath the ulcer Exclusion criteria: /	Both groups: Debridement of the necrotic tissue was performed was indicated. Systemic antibiotic therapy was started only for the treatment of intercurrent infections. No other topical agents were applied on the ulcers. All patients received supportive treatment consisting of nutritional, postural, surgical and nursing care.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: not reported. Multiple ulcers: Only one ulcer per patient was evaluated.					

Table 182: Kuflik 2001[125]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kuflik (2001) **Title**: Petrolatum versus Resurfix® ointment in the treatment of pressure ulcers. **Journal:** Ostomy/wound Management, 47 (2); 52-56 Type of study: randomized controlled trial Sequence generation: tubes were randomly numbered Allocation concealment: not reported Blinding: patients, physicians and nursing staff were blinded. Blinding of outcome	Patient group: Elderly patients with a grade I or II PU (according to the AHCPR classification). All patients Randomised N: 19 patient with 20 ulcers Completed N: 15 patients with 16 ulcers Drop-outs: 4 patients with 4 ulcers (1 medical condition, 1 non-improvement, 2 worsening) Group 1 Randomised N: 10 patients with 11 ulcers Completed N: 8 patients with 9 ulcers	Group 1: Ointment (Resurfix®, Topix Pharamceuticals Inc., North Amityville, NY). Treatment was applied twice-daily. Resurfix®: contains petrolatum, live yeast cell derivates, shark liver oil, catechins in green tea extract and vitamin E, benzyl alcohol, ceramides and yucca extract. Group 2: Base component petrolatum. Treatment was applied twice-daily. Both groups: No patient received a pressure-reducing device (was judged as not necessary by the investigator). All patients received adequate nutrition. No other treatments or	Outcome 1: Proportion of ulcers completely healed (all grades) Outcome 2: Proportion of ulcers completely healed (grade I) Outcome 3: Proportion of ulcers completely healed (grade II) Outcome 4: Proportion of ulcers improved (all grades) Outcome 5: Proportion of	Group 1: 5/10 Group 2: 2/9 Group 1: 4/5 Group 2: 2/7 Group 1: 1/5 Group 2: 0/2 Group 1: 4/10 Group 2: 0/9	Funding: Funded by Topix Pharmaceuticals, Inc. Limitations: insufficient information on sequence generation; no report on allocation concealment; no blinding of outcome assessor; no report on statistical analysis; little information on baseline characteristics and difference not measured statistically; no a

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assessor (investigator) was not reported. Addressing incomplete outcome data: not reported Statistical analysis: Not reported. Baseline differences: No baseline characteristics reported except for ulcer grade and - size. No statistical measurement of differences between groups. Study power/sample size: No a priory sample size calculation. Setting: not reported Length of study: six weeks of treatment. Assessment of PUs: Ulcers area was measured using standard metric measurements and tested by the investigators. Before and after photographs were taken. Classification of PUs: Agency for Healthcare	Dropouts: 2 patients with 2 ulcers (1 medical condition, 1 non-improvement) Ulcer grade (randomised pressure ulcers): Grade I: 6 Grade II: 5 Ulcer size (mean cm (SD); range): 1.69 (1.01) Group 2 Randomised N: 9 patients with 9 ulcers Completed N: 7 patients with 7 ulcers Dropouts: 7 patients with 7 ulcers (2 worsening) Ulcer grade: Grade I: 6 Grade II: 3 Ulcer size (mean cm (SD); range): 1.2 (1.13) Inclusion criteria: Grade I and II PU; Exclusion criteria: complex underlying etiologies such as venous stasis and severe diabetes	dressings could be used	ulcers improved (grade I) Outcome 6: Proportion of ulcers improved (grade II) Outcome 7: Proportion of ulcers not changed (all grades) Outcome 8: Proportion of ulcers not changed (grade I) Outcome 9: Proportion of ulcers not changed (grade II) Outcome 10: Proportion of ulcers worsened (all grades) Outcome 11: Proportion of ulcers worsened	Group 1: 1/5 Group 2: 0/6 Group 1: 3/5 Group 2: 0/3 Group 1: 1/10 Group 2: 1/9 Group 1: 0/5 Group 2: 1/6 Group 1: 1/5 Group 2: 0/3 Group 1: 0/10 Group 2: 6/9	priory sample size calculation; small sample size; no report on setting; little information on ulcer assessment. Additional outcomes: change in erythema Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Policy and Research Guidelines (1992). Multiple ulcers: One patient had two ulcers. Ulcer was unit of analysis.			(grade I) Outcome 12: Proportion of ulcers worsened (grade II)	Group 1: 0/5 Group 2: 3/6 Group 1: 0/5 Group 2: 3/3	

Table 183: Landi 2003[127]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Landi (2003) **Title**: Topical Treatment of Pressure Ulcers with Nerve Growth Factor: A Randomized Clinical Trial. **Journal:** Annals of Internal Medicine, 139 (8); 635-642. Type of study: randomized controlled trial	Patient group: Nursing home patients a grade II or V PU to the foot (according to the Yarkony-Kirk classification). All patients Randomised N: 38 Completed N: 36 Drop-outs: 2 (1 died, and 1 lost to follow up) Group 1	Group 1: topical nerve growth factor (2.5 S murine nerve growth factor). One mg of nerve growth factor was dissolved in 20 ml of balanced salt solution, with a final concentration of 50 μg/ml. The nerve growth factor solution was dropped daily on the lesion and allowed to dry for 2 to 3 minutes. Group 2: Balanced salt solution. The solution was dropped daily on the lesion and	Outcome 1: Proportion of patients completely healed Outcome 2: Improvement by 3 or more grades Outcome 3: Improvement by 2 grades Outcome 4:	Group 1: 8/18 Group 2: 1/18 P value: 0.009 Group 1: 5/18 Group 2: 0/18 P value: < 0.001 Group 1: 14/18 Group 2: 2/18 P value: < 0.001	Funding: Grant from the Progetto Finalizzato Invecchiamento of the Italian National Research Council. Support was also provided by interRAI, an international group of clinicians and researchers who collaborate to promote research

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: a computer-generated list was used. Allocation concealment: randomly stratified according to age group, sex, and ulcer surface area Blinding: double blind, nurses and outcome assessor Addressing incomplete outcome data: unclear Statistical analysis: Quantitative variables are presented as mean values (±SD). Differences in baseline characteristics between patients in the control and treatment groups were analysed in several ways. Quantitative outcomes were tested by using the Student t-test after a pre-test for homogeneity of variance. The Mann–Whitney test was used for cases in which the normality	Randomised N: 19 Completed N: 18 Dropouts: 1 (died) Age (mean years (SD); range): 80.2 (3.0); 75-85 Gender (m/f): 5/13 BMI (mean kg/m²): 24.0 (1.4) Duration of PU (mean days (SD)): 13 (4) Ulcer grade: Grade II: n=3 Grade III: n=9 Grade IV: n=5 Grade V: n=1 Ulcer location: Heel: n=14 Lateral malleolus: n=4 Surface area (mean mm² (SD)): 1012 (633) Group 2 Randomised N: 19 Completed N: 18 Dropouts: 1 (lost to follow-up) Age (mean years (SD); range): 80.2 (4.7); 73-93 Gender (m/f): 5/13 BMI (mean kg/m²): 23.8	allowed to dry for 2 to 3 minutes. Both groups: All ulcers received daily local care: irrigation with normal saline, use of debriding enzymes, and application of opaque hydrocolloid occlusive barriers. Al patient received the same preventive skin regimen (turning, repositioning and use of pressure relieving mattress)	Improvement by 1 grade Outcome 5: Reduction in ulcer area (mm²) Outcome 6: Reduction in ulcer area (mm²) (adjusted for baseline ulcer area, location and duration) Outcome 7: Proportion of patients with adverse events	Group 1: 18/18 Group 2: 8/18 P value: < 0.001 Group 1: 738 (393) Group 2: 485 (384) P value: < 0.034 Group 1: 6.5 (0.3) Group 2: 5.9 (0.3) P value: < 0.001 Group 1: 0/18 Group 2: 0/18	on resident assessment instruments and quality outcomes for elderly persons. Dr. Aloe (co-author) was supported by a grant from the Italian National Institute of Health (ICG 120/4RA00-90) and by a grant from the Italian National Research Council, FISR/ Neurobiotechnolog y (192/03). Limitations:; inadequate allocation concealment; no patient blinding; no a priory sample size calculation; no ITT. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assumption was not reasonable. Categorical variables were analyzed by using the Fisher exact test. Analysis of covariance was used to compare reduction in pressure ulcer area from baseline to 6-week follow-up after adjustment for baseline ulcer area, location, and duration. Because the distribution of reduction in pressure ulcer area was not normal, this analysis was performed after natural log transformation of this variable. Statistical analyses were performed by using SPSS, version 10.0 (SPSS Inc., Chicago, Illinois). Baseline differences: No statistical differences between group according to a p <0.2. Study power/sample size: No a priory sample size calculation.	(1.4) Duration of PU (mean days (SD)): 12 (5) Ulcer grade: Grade II: n=3 Grade III: n=13 Grade IV: n=1 Grade V: n=1 Ulcer location: Heel: n=15 Lateral malleolus: n=3 Surface area (mean mm² (SD)): 1012 (655) Inclusion criteria: PU of the foot that ranged from 1 cm2 to 30 cm2 in total area Exclusion criteria: developed the lesion more than 1 month before admission; terminal illnesses; diabetes; peripheral vascular diseases				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: teaching nursing home of Catholic University of the Sacred Heart, Fontecchio, Italy. Length of study: 6 weeks of treatment or until completely healed Assessment of PUs: The ulcer perimeter was traced onto sterile, transparent block paper and the blocks were counted. Digital photographs were taken at baseline and every week during the follow-up period. Classification of PUs: Yarkony-Kirk classification (1990). Multiple ulcers: indirect: one ulcer per patient					

Table 184: Ljungberg 2009[134]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ljungberg (1998) **Title**: Comparison of dextranomer paste and saline dressings for management of decubital ulcers. **Journal:** Clinical Therapeutics, 20 (4); 737-743. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: intention to treat analysis Statistical analysis: Treatment comparisons were based on the change from study entry to day 15 or the end of the study (end point)	Patient group: Male patients with a spinal cord injury, aged 18 years and older, and with exudative PUs (according to the Eltorai classification). All patients Randomised N: 23 patients with 30 ulcers Completed N: not reported Drop-outs: not reported Age (range years): 23-73 Gender (m/f): 23/0 Group 1 Randomised N: 15 ulcers Completed N: not reported Dropouts: not reported Duration of PU (mean months; median months; range): 4.2; 4; 0.5-12 Ulcer grade: Grade II: n=10 Grade III: n=4	Group 1: Dextranomer paste (Debrisan®, Pharmacia Pharmaceuticals, AB, Uppsala, Sweden). Ulcers were cleaned with mild soap and water and rinsed with saline solution. Paste was applied on the wet ulcer and was covered with a dry sterile dressing. Debrisan®: contained 64% dextranomer, 30.5% polyethylene glycol 600 and 5.5% distilled water Group 2: Saline dressing. Ulcers were cleaned with mild soap and water and rinsed with saline solution. The saline soaked dressing was applied on the wet ulcer and was covered with a dry sterile dressing. Both groups: All ulcers were surgically debrided before application of the dressing.	Outcome 1: Proportion of ulcer improved with 25% Outcome 2: Proportion of ulcers with granulation after 15 days Outcome 3: Proportion of ulcers with epithelialization after 15 days Outcome 4: Proportion of patients with adverse events	Group 1: 11/15 Group 2: 2/15 P value: < 0.01 Group 1: 10/15 Group 2: 8/15 P value: > 0.05 Group 1: 7/15 Group 2: 4/15 P value: > 0.05 Group 1 and 2: 0/23	Funding: Grant from Pharmacia Pharmaceuticals AB, Sweden. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priory sample size calculation; no measurement of statistical difference between groups; little information on ulcer assessment; no information on number of patients per group. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and using the chi-square test. The level of significance for all tests was $p < 0.05$. Baseline differences: Difference not statistically measured. Groups were comparable. Study power/sample size: No a priory sample size calculation. Setting: Spinal cord injury service, Long Beach Veterans Administration Hospital, Long Beach, California. Length of study: 15 days of treatment. Assessment of PUs: Qualitative assessment of the ulcers was conducted with the aid of photographs. The extent of granulation was measured on a six-point scale. Ulcers were assessed each time the nurse changed the dressing. Classification of PUs: Eltorai classification.	Grade IV: n=1 Ulcer location: Ischium: n=6 Sacrum: n=3 Hips: n=4 Ankle: n=2 Other: n=0 Infected ulcers: 6 Group 2 Randomised N: 15 ulcers Completed N: not reported Dropouts: not reported Duration of PU (mean months; median months; range): 4.3; 4; 0.5-10 Ulcer grade: Grade II: n=12 Grade III: n=3 Grade IV: n=0 Ulcer location: Ischium: n=5 Sacrum: n=3 Hips: n=3 Ankle: n=1 Other: n=3 Infected ulcers: 9				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: 30 ulcers in 23 patients. Ulcers were the unit of analysis.	Inclusion criteria: Aged 18 years and older; exudative PU Exclusion criteria: PU involving the bone				

Table 185: Matzen 1999[138]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Matzen (1999) **Title**: A new amorphous hydrocolloid for the treatment of pressure sores: A randomised controlled study. **Journal:** Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery, 33 (1); 13-15. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported	Patient group: Patients older than 18 years with a grade III or IV PU (according to the Lowthian classification). All patients Randomised N: 32 Completed N: 6 Drop-outs: 20 (8 had other illnesses, 3 died, 1 had a missing schedule, 2 withdrew, 6 had insufficient effect of the treatment). Ulcer location: Sacrum: n=21 Trochanter: n=11 Group 1 Randomised N: 17	Group 1: Hydrocolloid dressing (Hydrogel®, Coloplast A/S, Denmark). The dressing was covered with a transparent hydrocolloid dressing (Comfeel®, Coloplast A/S, Denmark). The ulcers were cleaned and changed daily. Group 2: Saline gauze compresses. The dressing was covered with a transparent hydrocolloid dressing (Comfeel®, Coloplast A/S, Denmark). The ulcers were cleaned and changed daily. Both groups: All ulcers were debrided before application of the dressing as necessary.	Outcome 1: Mean relative volume reduction (%) Outcome 2: Proportion of patients completely healed Outcome 3: Median (range) pain during treatment Outcome 4: Median (range) smell during treatment Outcome 5: Median (range)	Group 1: 26 (20) Group 2: 64 (16) P value: < 0.02 Group 1: 5/17 Group 2: 0/15 Group 1: 2 (1-4) Group 2: 2 (1-3) Group 1: 2 (1-4) Group 2: 2 (1-3)	Funding: /. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priory sample size calculation; no measurement of statistical difference between groups; setting not reported; little information on ulcer assessment, pain, smell, comfort Additional

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: The data were skewed and therefore assessed by the nonparametric Mann-Whitney test. Differences were accepted as significant if the probability was less than 0.05. Baseline differences: Difference not statistically measured. Study power/sample size: No a priory sample size calculation. Setting: not reported. Length of study: 12 weeks of treatment or until complete healing. Assessment of PUs: Healing of ulcers was estimated by measuring the amount of water needed to fill the cavity. Classification of PUs: Lowthian classification (1994). Multiple ulcers: not reported	Completed N: 8 Dropouts: 9 (5 had other illnesses, 2 died, 1 had a missing schedule, 1 withdrew) Age (mean years range): 82; 32-97 Gender (m/f): 2/15 Group 2 Randomised N: 15 Completed N: 4 Dropouts: 11 (3 had other illnesses, 1 died, 1 had a missing schedule, 1 withdrew, 6 had insufficient effect of the treatment) Age (mean years range): 84; 46-89 Gender (m/f): 3/12 Inclusion criteria: Grade III or IV PU; non-infected PU located in the sacral or trochanteric areas. Exclusion criteria: Patients with diseases or taking drugs known to impair healing		comfort during treatment	Group 1: 4 (3-4) Group 2: 3 (2-4)	outcomes: Length of time dressing required (days) Notes: /

Table 186: Moberg 1983[147]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Moberg (1983) **Title**: A randomized trial of Cadexomer Iodine in Decubitus Ulcers. **Journal:** Journal of the American geriatric Society, 31 (8); 462-465. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded Statistical analysis: Change of ulcer area and change of pain, pus and debris scores were evaluated suing the t-test. Nominal response categories were evaluated using fisher's exact probability test. Baseline differences:	Patient group: Hospitalized patients with an deep or superficial PU. All patients Randomised N: 38 Completed N: 34 Drop-outs: 4 (2 worsened, 1 skin irritation and oedema, 1 transferred) Group 1 Randomised N: 19 Completed N: 16 Dropouts: 3 (2 worsened and 1 skin irritation and oedema) Characteristics for completed N Age (mean years (SD); range): 72.6 (3.3); 52-90 Gender (m/f): 3/13 Ulcer duration (mean months (SD)): 6.2 (2.5) Depth of ulcer: Deep: 10 Superficial: 6 Ulcer area (mean cm² (SEM)): 9.6 (1.8)	Group 1: Cadexomer iodine. The iodine was applied daily to the ulcer in a layer approximately 3mm thick and was removed after 24 hours under stream of water or saline or with a wet swab. Cadexomer iodine: a dry powder consisting of spherical microbeads that range in diameter from 100 to 315µm. Each microbead is a highly hydrophilic, three dimensional network of a modified starch polymer containing iodine, which is physically immobilized within the matrix at a concentration of 0.9%. One gram of powder can absorb as much as 7ml of fluid. Group 2: standard treatment. Individualized and depending on appearance of ulcer and surrounding skin. It included saline dressings, enzyme-based debriding agents, and nonadhesive dressings. Both groups: All patients received attention to nutrition, improvement of hygiene and removal of localized pressure	Outcome 1: Proportion of ulcers reduced with 50% after three weeks Outcome 2: Mean cm² (SEM) decrease in ulcer area after three weeks. Outcome 3: Mean percentage (SEM) decrease in ulcer area of three weeks.	Group 1: 8/16 Group 2: 1/18 P-value: <0.01 Group 1: 2.9 (1.3) Group 2: 2.5 (1.1) P-value: <0.05 Group 1: 30.9 (11.5) Group 2: 19.6 (7.4) P-value: <0.02	Funding: / Limitations: no report on sequence generation; no report on allocation concealment; no report on blinding; no ITT analysis; baseline difference not measured statistically; no a priory sample size calculation. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical difference between groups was not measured. Groups were comparable. Study power/sample size: No a priory sample size calculation. Setting: hospital Length of study: First, three weeks of treatment. If the ulcers were clearly not abating or were getting worse the patient could be switched to the other treatment group for a period of five weeks. If a positive response was observed during the first three weeks, treatment was continued until the ulcers healed or for five weeks, whichever occurred first. Assessment of PUs: Ulcer area was measured by planimetry performed on a tracing of the outline of the ulcer and by measurement of the longest diameter. Pain was assessed by a	Group 2 Randomised N: 19 Completed N: 18 Dropouts: 1 (transferred) Characteristics for completed N Age (mean years (SD); range): 80.1 (2.9); 52-97 Gender (m/f): 5/13 Ulcer duration (mean months (SD)): 6.2 (2.8) Depth of ulcer: Deep: 8 Superficial: 10 Ulcer area (mean cm² (SEM)): 12.4 (4.3) Inclusion criteria: PU Exclusion criteria: be moribund; have a malignancy; history of iodine sensitivity; psychiatric illness; other condition that might make them unable to give informed consent: otherwise unsuitable for the clinical trial	by use of decubitus mattress, turning of the patient every two to three hours and optimal mobilization			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
10cm vas scale (0 (painless) to 100 (extremely painful)). Classification of PUs: classified as deep or superficial. Multiple ulcers: not reported.					

Table 187: Mustoe 1994[156]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Mustoe (1994) **Title**: A phase II study to evaluate recombinant platelet-derived growth factor- BB in the treatment of grade 3 and 4 pressure ulcers. **Journal:** Archives of Surgery, 129; 213-219. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: double blind,	Patient group: Patients with a grade III or IV PU. All patients Randomised N: 52 Completed N: 41 Drop-outs: 11 (3 illness unrelated to the study, 2 died, 1 non-compliant to study, 1 infection, 1 physician required withdrawal, 2 missing data on day 29, 1 not reported) Group 1 Randomised N: unclear Completed N: 15	Group 1: Growth factor rPDGF-BB (100μg/ml). Ulcers were dressed daily with moist saline gauze dressings. Group 2: Growth factor rPDGF-BB (300μg/ml). Ulcers were dressed daily with moist saline gauze dressings. Group 3: placebo Both groups: All patients were mechanically debrided as necessary. Intermittent pressure relief wads obtained through turning regimes according the routines. No specialized pressure-reducing mattress and beds were used in the study	Outcome 1: Proportion of patients completely healed by 29 days Outcome 2: Proportion of patients completely healed by 5 months Outcome 3: Ulcer volume (g) at 29 days (adjusted for initial volume)	Group 1: 2/16 Group 2: 0/14 Group 2: 1/14 Group 1: 6/16 Group 2: 3/12 Group 2: 2/14 Group 1: 1.75 Group 2: 2.00 Group 2: 3.50 P-value: 0.056 P-value G1&2 vs G3: 0.009	Funding: Supported by Amgen Inc, Thousand Oaks, Calif. Limitations:; no report on sequence allocation; no report on allocation concealment; double blinding, no additional information; no a priory sample size calculation; small sample size; no ITT analysis; no information on PU classification; no

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
no further information Addressing incomplete outcome data: drop-out excluded. Statistical analysis: Patient characteristics, ulcer size and depth, and grade were compared among groups using analysis of variance. The Tukey test was used to make pairwise comparisons among treatment means. The Kruskal-Wallis anova was used to compare initial ulcer volume, and duration of the ulcer prior to onset of treatment among groups. On day 29, ulcer volume was compared among the groups using ancova with the baseline volume as covariate. Ulcer volume was transformed using log10 transformation prior to analysis. Groups were compared using single linear contrast by a two tailed t-test. Actual life table analysis was used	Dropouts: unclear Age (mean years (SD)): 73.5 (15.0) Gender (m/f): 4/11 Duration of PU (median months; range): 5.2; 1.7-56.7 Ulcer grade: Grade III: n=4 Grade IV: n=11 Ulcer location: Ischium: n=3 Sacrum: n=5 Trochanter: n=4 Other: n=3 Ulcer volume (mean cm² (SD)): 5.5 (6.1) Group 2 Randomised N: unclear Completed N: 12 Dropouts: unclear Age (mean years (SD)): 67.5 (17.7) Gender (m/f): 5/7 Duration of PU (median months; range): 3.9; 0.3-10.0 Ulcer grade: Grade III: n=3				information on multiple ulcers Additional outcomes: Cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
to summarize the time to 50% healing for each group. The Tarone-Ware test was used to compare the time to 50% healing Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample size calculation Setting: Three centers: nursing homes and hospitals Length of study: 29 days of treatment and up to 5 months of follow-up. Assessment of PUs: Ulcers were evaluated by serial photographs. Volume measurements were obtained from weighting alginate casts of the wounds. The area of the ulcer opening was measured by planimetry. Classification of PUs: not reported. Multiple ulcers: not reported	Grade IV: n=9 Ulcer location: Ischium: n=2 Sacrum: n=5 Trochanter: n=2 Other: n=3 Ulcer volume (mean cm² (SD)): 7.1 (8.8) Group 3 Randomised N: unclear Completed N: 14 Dropouts: unclear Age (mean years (SD)): 73.4 (17.7) Gender (m/f): 5/9 Duration of PU (median months; range): 2.0; 0.3-29.9 Ulcer grade: Grade III: n=3 Grade IV: n=11 Ulcer location: Ischium: n=4 Sacrum: n=6 Trochanter: n=3 Other: n=1 Ulcer volume (mean cm² (SD)): 10.8 (13.2)				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Inclusion criteria: Grade III or IV PU; ulcer surface between 4 and 100 cm²; no evidence of cellulites; malignancy in the ulcer area Exclusion criteria: venous or arterial disorder directly implicated n the cause of the ulcer; existing endocrine disease; immunosuppressive disease, sepsis; pregnancy or lactation; active abuse of alcohol or drugs; unstable renal, hepatic, hematologic or cardiac disease; use of immunotherapy, cytotoxic chemotherapy or investigational drugs.				

Table 188: Nasar 1982[157]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Nasar (1982) **Title**: Cost effectiveness in treating deep pressure sores and	Patient group: Elderly patients with a deep pressure ulcer. All patients	Group 1: Debrisan - dextranomer. The Debrisan was applied in a stiff paste (four parts of Debrisan mixed with one part glycerol), twice daily for the first three days	Outcome 1: Time (days) to healing (defined as granulating and < 25% of original surface area)	Group 1: 39.3 (17.67) Group 2: 61.8 (13.86)	Funding: / Limitations: no report on sequence allocation, on

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ulcers. **Journal:** Practice of Medicine, 226; 307-310. Type of study: randomized controlled trial Sequence generation: treatment was selected on a random basis. Allocation concealment: not reported. Blinding: not reported. Addressing incomplete outcome data: drop-out were excluded Statistical analysis: Not reported. Baseline differences: Not reported. Study power/sample size: No a priory sample size calculation. Setting: Not reported. Length of study: Until complete healing. Assessment of PUs: Ulcers were measured with celluloid squares and photographed. Ulcers were measured	Randomised N: 12 patients and 18 ulcers, however unclear in text it seems 16 ulcers were included Completed N: 11 ulcers Drop-outs: 5 (1 patient discontinued due to pain, 1 died, 3 switched to other treatment) Group 1 Randomised N: 8 ulcers Completed N: 6 ulcers Dropouts: 2 (1 patient discontinued due to pain, 1 died) Characteristics of completed N Age (mean years (SD)): 83.17 (7.86) Group 2 Randomised N: 8 ulcers Completed N: 5 ulcers Dropouts: 3 (switched to other treatment) Characteristics of completed N Age (mean years (SD)): 79.8 (3.27)	and daily thereafter. Group 2: Chlorinated lime solutions (Eusol) and paraffin packs. The solution was applied trice daily for the first three days and thereafter twice daily until the wounds healed. Melolin were used throughout and these were held in place with micropore tape. A Salvon sachet was used each time the dressing was changed. Both groups: Anaemia, hypoalbuminea, hypo vitaminosis and high blood urea were corrected if present. Scrupulous control of diabetic patients was ensured. Systematic antibiotics were only administered for organisms such as staphylococcus aureus and β haemolytic streptococci and no local antibiotic creams or lotions were applied. Patients with urinary incontinent were catheterized during the study period. Hardened sloughs were cut off at an early grade.	Outcome 2: Proportion of patients with pain	Group 1: 1/? Group 2: 3/?	allocation concealment, blinding, statistical analysis, PU classification, setting; no ITT analysis; no a priory sample size calculation; number of patients randomized and included unclear. Additional outcomes: cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
every third day by an independent observer. Pain was recorded as yes or no. Classification of PUs: not reported. Multiple ulcers: 12 patients with 18 ulcers were included. Ulcer was unit of analysis.	Inclusion criteria: Patients with deep PUs. Exclusion criteria: Patients with an urinary tract infection.	All patients were nursed on a large cell ripple mattress. Concurrent therapy: ultraviolet light.			

Table 189: Neill 1989[158]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Neill (1989) **Title**: Pressure Sore Response to a New Hydrocolloid Dressing. **Journal:** Wounds: A compendium of Clinical Research and Practice, 1 (3); 173-185. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported	Patient group: Patients 18 years and older with grade II or III PUs (according to the Shea classification). All patients Randomised N: 100 ulcers Completed N: 65 patients and 87 ulcers Drop-outs: 13 ulcers (11 intercurrent medical events and 2 violated protocol) Group 1 Randomised N: not	Group 1: Hydrocolloid dressing (TegasorbTM). Ulcers (free of debris) were irrigated with 50cc of a 1:1 solution of 3% hydrogen peroxide and sterile normal saline followed by 50cc saline rinse. Ulcers (with necrotic tissue, debris or faeces) were irrigated with 50cc of a 1:1 solution of 1% povidone-iodine and sterile saline solution between the hydrogen peroxide solution and the saline rinse. The skin was dried and the dressing was applied and changed every 7 days unless eschar was present (every three days), or the	Outcome 1: Proportion of ulcers completely healed Outcome 2: Proportion of ulcers completely healed (grade II PUs) Outcome 3: Proportion of ulcers enlarged (grade II PUs) Outcome 4:	Group 1: 13/42 Group 2: 10/45 Group 1: 11/25 Group 2: 9/34 P value: > 0.05 Group 1: 7/25 Group 2: 11/34 P value: > 0.05	Funding: Funded by the 3M Company, Medical-Surgical Division. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priory sample size calculation; no ITT analysis; no information on PU classification

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: not reported Addressing incomplete outcome data: drop-out excluded. Statistical analysis: Nonparametric test was used to compare distribution of healing between groups. Anova with PU grade, treatment group, and interaction as factor in the model was applied to the data after transformation of the data into ranks. A p value less than 0.05 was considered significant. A logistic regression model was used to look at covariates of healing. Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample size calculation. Setting: A tertiary care facility and its affiliated nursing home Length of study: eight weeks of treatment.	reported Completed N: 42 ulcers Dropouts: not reported Ulcer grade: Grade II: n=25 Grade III: n=17 Ulcer volume (mean cm² (SD); range): 8.3 (9.9); 0.43-43.93 Presence of necrosis: 34 Ulcers on hip, heel, or sacrum: 31 Group 2 Randomised N: not reported Completed N: 45 ulcers Dropouts: not reported Ulcer grade: Grade II: n=34 Grade III: n=11 Ulcer volume (mean cm² (SD); range): 7.6 (8.6); 0.23-35.16 Presence of necrosis: 28 Ulcers on hip, heel, or sacrum: 34 Inclusion criteria: 18 years and older; ulcer <	dressing became non-adherent or leaked. TegasorbTM: contains polysaccharide, gelatine, pectin, and polyisobutylene. It consists of a flexible oval mass with an adherent hydrocolloid inner face, and an outer water and bacteria impermeable, adhesive-coated, polyurethane film. Group 2: Wet to damp saline gauze dressing. Ulcers (free of debris) were irrigated with 50cc of a 1:1 solution of 3% hydrogen peroxide and sterile normal saline followed by 50cc saline rinse. Ulcers (with necrotic tissue, debris or faeces) were irrigated with 50cc of a 1:1 solution of 1% povidone-iodine and sterile saline solution between the hydrogen peroxide solution and the saline rinse. After an open wide mesh gauze pad was moistened with sterile gauze and applied to the ulcer. A sterile gauze was applied as second dressing and secured with paper tape. The dressing was changed every eight hours	Proportion of ulcers completely healed (grade III PUs) Outcome 5: Proportion of ulcers enlarged (grade III PUs) Outcome 6: Median percentage reduction in size (grade II PUs) Outcome 7: Median percentage reduction in size (grade III PUs) Outcome 8: Proportion of patients with adverse events	Group 1: 2/17 Group 2: 1/11 P value: > 0.05 Group 1: 7/17 Group 2: 4/11 P value: > 0.05 Group 1: 91 Group 2: 48 P value: > 0.05 Group 1: 0.3 Group 2: 30 P value: > 0.05 Group 1: 9/50 (skin irritation) Group 2: 1/50 (ulcer worsened P value: < 0.06	Additional outcomes: Nursing time; Organism growth Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Ulcers edges were traced onto transparencies and photographs beside a metric ruler were taken using a Minolta Maxxum 7000 with a 50mm macro lens and a 80PX ring light with automated exposure. A Zeiss IBAS Image Analyzer was used to calculate the ulcer surface area. Classification of PUs: Shea classification Multiple ulcers: A maximum of 2 PU per patients were included. The second ulcer received the alternate therapy	1.5cm in depth, <5.6cm by 10cm in width and length; Grade II or III Exclusion criteria: inability of patient or guardian to give informed consent; presence of diabetes mellitus; history of skin hypersensitivity, skin disease, allergies to tape or adhesives; concurrent radiotherapy to PU area; medical condition that could interfere with study controls; pre-existing skin disease around the PU; clinical infection associated with PU; peripheral vascular ulcers evidenced by a Brachial Ankle Index ≤ 0.6; scars, contusions, abrasions, or open skin in the immediate PU area.	Both groups: All subject received standard treatment for PUs: a pressure-reducing air mattress, and air-fluidized bed or a low air loss bed; an eggcrate wheelchair; turning and repositioning et least every two hours; control of incontinence with an external urine catheter and fecal incontinence collector.			

Table 190: Olekse 1986[168]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Oleske (1986) **Title**: A randomized	Patient group: Patients older than 21 years with grade I or II PUs	Group 1: Polyurethane self-adhesive dressing. Cleansing of the ulcer and application of the	Outcome 1: Proportion of ulcers completely	Group 1: 1/9 Group 2: 0/10	Funding: the study was sponsored by the Department of

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
clinical trial of two dressing methods for the treatment of low-grade pressure ulcers. **Journal:** Journal of Enterostomal Therapy, 13 (3); 90-98. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: drop-out was excluded. Statistical analysis: One-way analysis of variance was used to compare the two treatments. A paired t test was used to compare the largest axis and surface area changes within treatment group. A standard chi-square test was used to compare the PU grades before and after therapy end to	(according to the Enis and Sarmiento classification). All patients Randomised N: 16 patients Completed N: 15 patients and 19 ulcers Drop-outs: 1 (unanticipated transfer to nursing home). Age (mean years (SD); range): 69 (6); 52-93 Ulcer location: Gluteal and coccyx area Group 1 Randomised N: not reported Completed N: 7 patients and 9 ulcers Dropouts: not reported Ulcer grade: Grade I: n=2 Grade II: n=7 Ulcer area (mean cm² (SD): 3.5 (1.2) Group 2 Randomised N: not	dressing was according to a standardized protocol. The dressing was changed if it dislodged from the ulcer site. Group 2: Saline dressing. Cleansing of the ulcer and application of the dressing was according to a standardized protocol. The dressing was changed every four hours around the clock Both groups: All patients received the standardized nursing skin care: repositioning every 3 hours, daily administration of multivitamin tablets, use of a convoluted foam mattress (without sleeves)	healed Outcome 2: Proportion of ulcers worsened Outcome 3: Mean percentage surface area reduction	Group 1: 1/9 Group 2: 2/10 Group 1: 42.9 Group 2: 2.5	Medical Nursing, Rush-Presbyterian-St.Luke's Medical Centre and the Chicago Community trust. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priory sample size calculation; small sample size Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
compare the two treatment groups. The significance of the calculated statistics was determined by a two-tailed test with the level of alpha = 0.05 Baseline differences: No statistical difference in terms of age, sex and race. Study power/sample size: No a priory sample size calculation. Setting: inpatient medicine unit. Length of study: 10 days of treatment. Assessment of PUs: Wound healing was evaluated: ulcer grade, longest wound axis, total wound surface area. A transparent rule was used to measure the longest wound axis. Tracings of the ulcer surface were made onto sterile plastic sheets. Surface area were than computed by means of compensating polar	reported Completed N: 8 patients and 10 ulcers Dropouts: not reported Ulcer grade: Grade I: n=5 Grade II: n=5 Ulcer area (mean cm² (SD): 7.7 (8.6) Inclusion criteria: Adults (21 years of age or over) with a PU grade I or II; afebrile (< 100°F orally or < 101°F rectally); confined to bed, wheelchair, or chair and expected to be so for at least two weeks: expected hospitalization of two weeks; ulcer caused by pressure; ulcer of at least 2cm diameter; not contained in an area currently being irradiated; no evidence of infection; hemoglobin level > 10g/dL Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
planimeter. Classification of PUs Enis and Sarmiento classification (1973). Multiple ulcers: 15 patients with 19 ulcers					

Table 191: Payne 2001[175]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Payne (2001) **Title**: Long-term outcome study of growth factor-treated pressure ulcers. **Journal:** The American Journal of Surgery, 181 (1); 81-86. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: double blind, only blinding of assessor reported. Addressing incomplete	Patient group: Inpatients with a grade III or IV PU. All patients Randomised N: 61 Completed N: 54 Drop-outs: 7 (4 died and 3 were lost to follow-up). Group 1 Randomised N: 15 Completed N: 14 Dropouts: 1 (lost to follow-up) Age (mean years (SD)): 18.8 (11.8) Ulcer duration (mean months (SD)): 6.8 (6.1) Ulcer volume (mean cm^3 (SD)): 32.77 (21.06)	Group 1: Growth factor: rhuGM-CSF (2.0μg/cm^2) was topically applied. After 15 minutes of air-drying, the wounds were dressed with a non-adherent dressing next to the wound surface and dry gauze to fill the wound. Group 2: Growth factor: rhubFGF (5.0μg/cm^2) was topically applied. After 15 minutes of air-drying, the wounds were dressed with a non-adherent dressing next to the wound surface and dry gauze to fill the wound. Group 3: Growth factor: rhuGM-CSF/rhubFGF (2.0μg/cm^2 GM-CSF for 10 days and 5.0μg/cm^2 bFGF the following 25 days) was topically applied. After 15 minutes of	Outcome 1: Proportion of patients completely healed after 1 year Outcome 1: Proportion of patients which worsened at 1 year	Group 1: 8/14 Group 2: 10/14 Group 3: 9/13 Group 4: 10/13 Group 1: 2/14 Group 2: 4/14 Group 3: 1/13 Group 4: 0/13	Funding: grant from the National Institutes of Health (ROI-AR42967). Schering-Plough Research Institute and Scios, Inc. provided the cytokines used in this study Limitations:; no report on sequence allocation; no report on allocation concealment; no blinding of patient and nurses; missing data were excluded; no a

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: excluded. Statistical analysis: Differences amongst various groups in the time to achieve complete healing during the follow-up phase were determined by survival analyses using the Kaplan-Meier method. Significances of differences in time to reach 100% closure was determined by the log-rank and Wilcoxon P values derived from the Kaplan-Meier method. All survival analyses were done using JMP software (SAS Institute, Inc., Cary, NC). Chi-square and Fisher exact analyses were used to compare proportions of various groups of patients healed. All proportion analyses were performed using SigmaStat software (SPSS, Inc., Chicago, IL). Baseline differences: No	Group 2 Randomised N: 15 Completed N: 14 Dropouts: 1 (lost to follow-up) Age (mean years (SD)): 18.8 (11.8) Ulcer duration (mean months (SD)): 6.8 (6.1) Ulcer volume (mean cm³ (SD)): 33.81 (26.12) Group 3 Randomised N: 16 Completed N: 13 Dropouts: 3 (died) Age (mean years (SD)): 51.3 (11.2) Ulcer duration (mean months (SD)): 12.1 (14.6) Ulcer volume (mean cm³ (SD)): 38.16 (38.3) Group 4 Randomised N: 15 Completed N: 13 Dropouts: 2 (1 died and 1 lost to follow-up) Age (mean years (SD)):	air-drying, the wounds were dressed with a nonadherent dressing next to the wound surface and dry gauze to fill the wound. Group 4: Placebo. After 15 minutes of air-drying, the wounds were dressed with a nonadherent dressing next to the wound surface and dry gauze to fill the wound. All groups: All ulcers were sharp debrided before application of the dressing as necessary. Initial drug administration was delayed for at least 24 hours after debridement. All patients were kept on pressure-relief surfaces			priory sample size calculation; little information on setting; little information on ulcer assessment; no report on multiple ulcers; PU classification not reported Additional outcomes: / Notes: This study is a follow-up (1 year) study from the study of Robson (2000). General information on the study are provided in the study by Robson (2000). Outcomes are different and are reported in the study by Payne (2001).

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistical difference between groups for age, ethnicity, smoking status, and duration of PU. Study power/sample size: No a priory sample size calculation. Setting: inpatients. Length of study: 35 days of treatment and 1 year of follow-up. Assessment of PUs: The PUs was measured on day 0 and weekly for 5 weeks. After that they were seen at 3 weeks, 6 weeks, 3 months, 6 months and 1 year. The planimetry was used to determine the ulcer opening and volume using alginate moulds. At each follow-up visit the wounds were assesses as to whether they had achieved complete healing, were still less than 100% healed, or had recurred after a time of 100% closure	47.1 (10.8) Ulcer duration (mean months (SD)): 13.1 (14.2) Ulcer volume (mean cm^3 (SD)): 45.19 (34.79) Inclusion criteria: Age 28-70 years; PU on truncal area; PU grade III/IV; ulcer duration > 8 weeks; initial ulcer volume 10-200cm^3 Exclusion criteria: Significant diabetes mellitus, renal insufficiency, vasculitis, or hepatic, immunologic, cardiac, or hemorrhagic disease; Malignant or neoplastic disease, except for adequately treated skin cancers; Significant malnutrition, systemic steroidal therapy, immunotherapy, or chemotherapy; Cytokine therapy within 90 days or investigational drug study within 30 days				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: not reported. Grade III/IV PU were seen as PU involving any tissue from a bony prominence to the subcutaneous tissue. Multiple ulcers: not reported					

Table 192: Payne 2009[176]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Payne (2009) **Title**: A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of grade II pressure ulcers. **Journal:** Ostomy/wound management 55(2); 50-55. Type of study: randomized controlled trial	Patient group: Patients 18 years and older with a grade II PU (according to the NPUAP classification). All patients Randomised N: 36 Completed N: 27 Drop-outs: 9 (5 died, 1 ulcer infection, 1 abscess unrelated to study ulcer, 1 became ineligible, 1 discharged) Group 1 Randomised N: 20 Completed N: 14	Group 1: Polyurethane self-adhesive foam dressing (Allevyn® Thin, Smith & Nephew Inc, Largo, Fl). Ulcers were cleansed and dried. Ulcers were dressed with the dressing without secondary dressing or fixation. Dressings were changed determined by clinician. Group 2: Saline-soaked gauze dressing. Ulcers were cleansed and dried. Ulcers were dressed with the dressing and with a secondary dry sterile gauze pad held in place with tape. Dressings were changed determined by clinician.	Outcome 1: Proportion of patients completely healed Outcome 2: Median (days) time to healing (time at which 50% of the patients achieved complete healing)	Group 1: 10/20 Group 2: 6/16 Group 1: 28 Group 2: 28	Funding: travel grand and funding from Smith & Nephew Limitations: no report on sequence allocation; no report on allocation concealment; no report on blinding; no measurement of statistical difference between groups; no information on use of preventive measures.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: not reported. Allocation concealment: not reported. Blinding: not reported. Addressing incomplete outcome data: intention to treat analysis for all analysis except cost-effectiveness. Statistical analysis: An accelerated failure time model was used to test for differences between groups for time of healing after adjustment for study center, baseline ulcer area, and duration. Kaplan-Meier methods were used to estimate the median time to healing. Baseline differences: No calculation of the statistical difference between groups. Study power/sample size: To detect a $10 per week difference in cost of dressing and other materials between	Dropouts: 6 (3 died, 1 ulcer infection, 1 abscess unrelated to study ulcer, 1 became ineligible) Age (mean years (SD); median years): 72.5 (14.3); 74.0 Gender (m/f): 13/7 Ulcer duration (mean weeks (SD); median weeks): 56.1 (219.6); 3.5 Ulcer area (mean cm² (SD); median cm²): 5.6 (11.3); 1.8 Ulcer location: Hips/buttocks: n=7 Sacrum: n=8 Upper leg: n=1 Ankle/foot: n=4 Lower leg: n=0 Group 2 Randomised N: 16 Completed N: 13 Dropouts: 3 (2 died, 1 became ineligible) Age (mean years (SD); median years): 73.3 (12.4); 71.5 Gender (m/f): 9/7 Ulcer duration (mean	All groups: /			Additional outcomes: cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
groups assuming a standard deviation of $9.80. This was based on a two-sided unpaired t-test at the 5% level of significance and 80% power. A sample size of 19 patients per groups are required. Setting: three hospital wards, one outpatient hospital clinic, one long-term residential care, one community care clinic. Length of study: four weeks of treatment or until complete healed, whichever came first. Assessment of PUs: Ulcers were measured at baseline and weekly using Visitrak (Smith&Nephew Inc. Largo, FL). Classification of PUs: NPUAP classification. Multiple ulcers: the largest ulcer was included in the study treatment.	weeks (SD); median weeks): 7.0 (9.4); 2.0 Ulcer area (mean cm² (SD); median cm²): 6.2 (7.2); 1.4 Ulcer location: Hips/buttocks: n=7 Sacrum: n=7 Upper leg: n=0 Ankle/foot: n=1 Lower leg: n=1 Inclusion criteria: 18 years and older; not pregnant or using contraception; grade II PU with light to moderate exudate. Exclusion criteria: Known history of poor compliance; presence of clinical infection in wound; previous participation in the evaluation				

Table 193: Rees 1999[180]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Rees (1999) **Title**: Becaplermin gel in the treatment of pressure ulcers: A phase II randomized, double-blind, placebo-controlled study. **Journal:** Wound Repair and Regeneration, 7; 141-147. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported. Blinding: double blind; no further information. Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: The primary endpoint, incidence of complete healing, was analyzed using the Cochran-Mantel Haenszel test,	Patient group: Patients 18 years and older with a grade III or IV PU (according to the NPUAP classification). All patients Randomised N: 124 Completed N: unclear if patients with adverse events dropped the study Drop-outs: unclear Group 1 Randomised N: 31 Completed N: unclear Dropouts: unclear Age (mean years (SD)): 48 (13.1) Gender (m/f): 26/5 Ulcer duration (median weeks (IQR)): 22 (32) Ulcer volume (median ml (IQR)): 16.6 (15.1) Group 2 Randomised N: 32 Completed N: unclear Dropouts: unclear	Group 1: Becaplermin gel (100 µg/g recombinant human PDGF-BB) (Regranex®) applied once daily alternated with placebo every 12 hours. A thin layer of study drug was placed on the entire ulcer and the ulcer was packed with saline-moistened gauze. The second daily dressing was applied in a similar fashion after gently rinsing the wound surface with saline or water. Group 2: Becaplermin gel (300 µg/g recombinant human PDGF-BB) (Regranex®) applied once daily alternated with placebo every 12 hours. A thin layer of study drug was placed on the entire ulcer and the ulcer was packed with saline-moistened gauze. The second daily dressing was applied in a similar fashion after gently rinsing the wound surface with saline or water. Group 3: Becaplermin gel (100 µg/g recombinant human PDGF-BB) (Regranex®) applied twice daily. A thin layer of study drug was	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of patients healed ≥ 90% Outcome 3: Median percentage (range) reduction in ulcer volume Outcome 4: Proportion of patients with non-treatment related adverse events Outcome 5: Proportion of patients with condition	Group 1: 7/31 Group 2: 6/32 Group 3: 1/30 Group 4: 0/31 P value G1 vs G4: 0.005 P value G2 vs G4: 0.008 Group 1: 18/31 Group 2: 19/32 Group 3: 12/30 Group 4: 9/31 P value G1 vs G4: 0.021 P value G2 vs G4: 0.014 Group 1: 99.6 Group 2: 99.7 Group 3: 98.6 Group 4: 99.1 P value G1 vs G4: 0.013 P value G2 vs G4: 0.011 Group 1: 2/31 Group 2: 6/32 Group 3: 9/30 Group 4: 4/31 Group 1: 0/31	Funding: sponsored by Office of Research and Development, Department of Veterans Affairs, Ann Arbor, MI. Funding from Johnson & Johnson, Inc.. Limitations: no report on sequence allocation; no report on allocation concealment; insufficient information on blinding; no a priory sample size calculation; drop-out unclear; no measurement of statistical difference between groups; no information on setting; no information on use of preventive measures.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
which evaluated the association between the response variable and treatments, while adjusting for the effects of study center. Because the incidence of complete healing in the control group was 0, the incidence of and time to 90% ulcer closure were also analyzed. The incidence of 90% closure was analyzed using the Cochran-Mantel Haenszel test, and the significance of differences in time to 90% closure was assessed using the Cox proportional hazards model with baseline ulcer volume as a covariate. The relative ulcer volume, defined as the ulcer volume at the end of the study divided by the ulcer volume at baseline, was analysed using an analysis of covariance model with terms for	Age (mean years (SD)): 49 (12.5) Gender (m/f): 27/5 Ulcer duration (median weeks (IQR)): 33 (40) Ulcer volume (median ml (IQR)): 17.2 (19.7) Group 3 Randomised N: 30 Completed N: unclear Dropouts: unclear Age (mean years (SD)): 51 (18.3) Gender (m/f): 26/4 Ulcer duration (median weeks (IQR)): 22 (52) Ulcer volume (median ml (IQR)): 17.6 (33.8) Group 4 Randomised N: 31 Completed N: unclear Dropouts: unclear Age (mean years (SD)): 50 (13.6) Gender (m/f): 25/6 Ulcer duration (median weeks (IQR)): 30 (43) Ulcer volume (median ml	placed on the entire ulcer and the ulcer was packed with saline-moistened gauze. The second daily dressing was applied in a similar fashion after gently rinsing the wound surface with saline or water. Group 4: Placebo twice daily. All groups: Ulcers were debrided prior to randomization and when necessary.	aggravated Outcome 6: Proportion of patients with osteomyelitis Outcome 7: Proportion of patients with infection Outcome 8: Proportion of patients with sepsis Outcome 9: Proportion of patients with other adverse events	Group 2: 1/32 Group 3: 1/30 Group 4: 0/31 Group 1: 2/31 Group 2: 1/32 Group 3: 0/30 Group 4: 1/31 Group 1: 0/31 Group 2: 0/32 Group 3: 1/30 Group 4: 1/31 Group 1: 0/31 Group 2: 1/32 Group 3: 0/30 Group 4: 0/31 Group 1: 2/31 Group 2: 3/32 Group 3: 2/30 Group 4: 2/31	Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
treatment effect, center effect, and baseline ulcer volume effect, with tests for the relevant interactions. All hypotheses regarding interactions were tested at a significance level of 0.10. All hypotheses regarding comparisons of the active treatment to the vehicle control were 2-sided, performed at the 0.05 level of significance. To ascertain the dose–response relationship, the Cochran-Armitage trend test was used for complete and 90% wound closure parameters. The trend test was one-sided at the 0.025 level against the alternative of a linearly increasing dose-response. Baseline differences: No calculation of the statistical difference only calculated. Groups	(IQR)): 19.6 (21.9) Inclusion criteria: Age > 18 years; having between one and three chronic full thickness (grade III or IV) Pus; target ulcer was the ulcer with the longest time to heal; primary or recurrent PU not involving the bone tissue; ulcer with a volume between 10ml and 150ml, following debridement at baseline; ulcer present for at least 4 weeks; ulcer located where pressure could be off-loaded; albumin concentration > 2.5g/dl, total lymphocyte count > 1000; normal range for vitamin A and C. Exclusion criteria: Osteomyelitis affecting the area of the target ulcer was present; after debridement, a target ulcer volume (measured by Jeltrate mold) of < 10 ml or > 150 ml; topical antibiotics, antiseptics,				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
were comparable. Study power/sample size: No a priory sample size calculation. Setting: not reported. Length of study: 16 weeks of treatment or until complete healed, whichever came first.. Assessment of PUs: Ulcers were assessed for complete healing (completely healed or < completely healed, scored as 1 or 2, respectively). Ulcer volume was measured (determined by Jeltrate mold) and ulcer area was measured (determined by planimetric analyses of acetate tracings). Classification of PUs: NPUAP classification (1989). Multiple ulcers: target ulcer was the ulcer needing the longest tile to heal.	enzymatic debriding agents, or other agents that would interfere with study evaluations had been used within the 7 days preceding randomization; patients with ulcers resulting from electrical, chemical, or radiation insult; patients with cancer; concomitant diseases (e.g., connective tissue disease); treatment (e.g., radiation therapy); medication (e.g., corticosteroids, chemotherapy, or immunosuppressive agents); pregnant, nursing, childbearing potential woman, not using acceptable method of birth control.				

Table 194: Rhodes 2001[182]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Rhodes (2001) **Title**: Topical phenytoin treatment of grade II decubitus ulcers in the elderly. **Journal:** The Annals of Pharmacotherapy, 35 (6); 675-681. Type of study: randomized controlled trial Sequence generation: Patients were matched for age, gender, size and severity of the ulcers and were placed in one of the three groups based on the treatment preference of the randomly assigned physician prescribing the treatment plan. Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis:	Patient group: Nursing home patients with a grade II PU (according to the AHCPR classification). All patients Randomised N: 47 Completed N: 39 Drop-outs: 8 (1 continually recurrent ulcers, 5 died, 2 were discharged) Group 1 Randomised N: 18 Completed N: 15 Dropouts: 3 (1 continually recurrent ulcers, 2 died) Age (mean years): 75.5 Gender (m/f): 16/2 Group 2 Randomised N: 16 Completed N: 13 Dropouts: 3 (2 died, 1 was discharged) Age (mean years): 78.7 Gender (m/f): 15/1	Group 1: Phenytoin. Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with 100mg phenytoin suspension daily. A sterile gauze was soaked in the suspension and placed on the ulcer, followed by a layer of dry sterile gauze. Phenytoin suspension: a single 100 mg phenytoin cup containing 5ml of sterile NaCl 0.9% to form a suspension. Group 2: Hydrocolloid dressing (DuoDerm®). Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with dressing with the edges extending 1¼ inch beyond the wound. The dressing was changed every seven days or when it became uncomfortable, leaked, or the presence of infection signs. Group 3: Triple antibiotic ointment. Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with a layer of TAO. Followed a sterile gauze was applied as cover. The dressing was changed every day.	Outcome 1: Mean time (days; range) to healing Outcome 2: Proportion of patients with treatment related adverse events Outcome 2: Proportion of patients pain	Group 1: 35.3 (14.3); 15-64 Group 2: 51.8 (19.6); 27-90 Group 3: 53.8 (8.5); 42-67 P-value G1 vs G2: 0.020 P-value G1 vs G3: 0.011 Group 1: 0/15 Group 2: 0/13 Group 3: 0/11 Minimal pain was reported in all groups	Funding: / Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priory sample size calculation; small sample size; little information on setting; little information on statistical analysis; no report on multiple ulcers Additional outcomes: / Notes: Hydrocolloid dressings was defined as a collagen dressing in this article

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis included the Levine test for homogeneity of variance, anova, and a post hoc Bonferroni adjustment for multiple pairs. Baseline differences: Difference was not statistically different. Study power/sample size: No a priory sample size calculation. Setting: veteran administration nursing home. Length of study: not reported Assessment of PUs: Ulcers were measured with a MediRule, which was centred over the area to be measured. This transparent, disposable ruler consists of concentric circles measured in centimetres around a cross hair ruled in millimetres. Photographs using a Polaroid Spectra AF were taken once weekly.	Group 3 Randomised N: 13 Completed N: 11 Dropouts: 2 (1 died, 1 was discharged) Age (mean years): 76.5 Gender (m/f): 12/1 Inclusion criteria: Age > 60 years; grade II PU Exclusion criteria: signs and symptoms of ulcer infection; anaemia; malnutrition; folate deficiency; chronic use of immunosuppressive treatment; immobility; those receiving oral phenytoin; history of adverse events caused by phenytoin.	All groups: All ulcers were surgically debrided as necessary. All patients received preventive measures such as maximum mobilisation, adequate nutrition and hydration, and incontinence care.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Two light beams were placed at eight inches from the object. Classification of PUs: Agency Health Care Research and Quality's Pressure Ulcer Guideline Panel classification (1992). Multiple ulcers: not reported					

Table 195: Robson 1992a[186]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Robson (1992a) **Title**: The safety and effect of topically applied recombinant basic fibroblast growth factor on the healing of chronic pressure sores. **Journal:** Annals of surgery, 216 (4); 401-406. Type of study: randomized controlled trial Sequence generation:	Patient group: Hospitalized patients denervated in the ulcer area (congenital or acquired spinal cord pathology) with a grade III or IV PU. All patients Randomised N: 50 Completed N: 49 Drop-outs: 1 (removed due to suspicion of cancer) Group 1	Group 1: Growth factor: bFGF (1.0µg/cm2) Administration schedule were: (1) 1.0 µg/cm2 bFGF administered on days 1 and 13. Placebo on day 4, 7 and 10. No treatment on day 16, 19, and 22. (2) 1.0 µg/cm2 bFGF administered on days 1, 4, 7, 10, and 13. No treatment on day 16, 19, and 22. (3) 1.0 µg/cm2 bFGF administered on days 1, 4, 7, 10, 13, 16, 19, and 22. (4) 10.0 µg/cm2 bFGF	Outcome 1: Change in volume (cc) (regression curve) Outcome 2: Mean percentage decrease in volume Outcome 3: Proportion of patients >70% decrease in 30 days	Group 1: / Group 2: / P value: <0.05 Group 1: 69 Group 2: 59 Group 1: 21/35 Group 2: 4/14 P value: 0.047	Funding: grant from California Biotechnology, Inc. Limitations:; no report on sequence allocation; inadequate allocation; no blinding of patient and nurses; missing data were excluded; no a priory sample size calculation; no information on setting; no report

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not reported. Allocation concealment: not reported; unequal allocation to different schedules. Blinding: blinding of observer. Addressing incomplete outcome data: not reported. Statistical analysis: Descriptive statistics were computed for demographic characteristics such as age, gender, ethnicity, and pressure sore duration. The patients' ages and sore durations were compared using the Wilcoxon two-sample test, whereas gender and ethnicity were compared using the Fisher's exact test. Both parametric and nonparametric analyses were used to determine efficacy of bFGF, depending on the apparent normality of the data. Percentage decrease in volume over	Randomised N: 35 Completed N: 35 Dropouts: 0 Age (mean years (SD)): 37.8 (13.2) Gender (m/f): 30/5 Ulcer duration (mean months (SD)): 17.7 (21.6) Group 2 Randomised N: 15 Completed N: 14 Dropouts: 1 (removed due to suspicion of cancer) Age (mean years (SD)): 37.9 (12.8) Ulcer duration (mean months (SD)): 25.9 (46.3) Inclusion criteria: Age 28-65 years; initial ulcer volume 10-200cm³ measured by alginate mold; hospitalized; mechanical debridement (at least 24 hours before initiation of treatment); normal or clinically insignificant laboratory findings.	administered on days 1 and 13. Placebo on day 4, 7 and 10. No treatment on day 16, 19, and 22. (5) 10.0 μg/cm2 bFGF administered on days 1, 4, 7, 10, and 13. No treatment on day 16, 19, and 22. (6) 10.0 μg/cm2 bFGF administered on days 1, 4, 7, 10, 13, 16, 19, and 22. (7) 5.0 μg/cm2 bFGF administered daily for 21 days. (8) 5.0 μg/cm2 administered on days 1-5, 7, 14, and 21. Group 2: Placebo Administration schedule were: (1) placebo on days 1, 4, 7, 10, and 13. (2) placebo daily for 21 days. (3) placebo on days 1-5, 7, 14, and 21. All groups: All ulcers were sharp debrided before application of the dressing as necessary. Initial drug administration was delayed for at least 24 hours after debridement. Pressure-relieving devices were			on multiple ulcers; PU classification not reported Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
30 days was compared in each bFGF dosage regimen patient group with the placebo-treated patients, using analysis of variance. To assess for response rate relationships to initial pressure sore size, actual decrease in volume was compared with initial wound size and regression analyses were performed. The slopes of the regression curves then were compared with the F test. Because previous trials with the pressure sore model used in this study showed a placebo response of up to 50% decrease in volume, and a topical antimicrobial response of 60% reduction over a 4-week period,'4 an arbitrary response rate of 70% wound closure over 30 days was chosen as indicative of a responder. Categorical	Exclusion criteria: Arterial or venous disorder, or vasculitis as cause for ulcerated wound; clinically significant systemic disease; significant malnutrition; recent use of steroidal therapy; penicillin allergy	used as appropriate. Patients not on air-fluidized beds were repositioned rigorously at 2-hour intervals throughout the treatment period.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
responders by this definition were compared between bFGF treated patients and placebo-treated patients using analysis of variance. Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample size calculation. Setting: not reported. Length of study: 30 days of treatment and 5 months of follow up. Assessment of PUs: The PUs was measured on day 0, 8, 16, 23 and 30 using planimetry; maximum perpendicular diameters of the surface opening and maximum depth of the crater; volume determination using alginate molds; color photography of the ulcer at a set focal distance; quantitative and qualitative					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
microbiology of wound tissue biopsies; and histologic analyses of wound tissue. Classification of PUs: not reported. Grade III/IV PU were seen as PU extending from the bone to the subcutaneous tissue. Multiple ulcers: not reported					

Table 196: Robson 1992b[187]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Robson (1992b) **Title**: Recombinant human platelet-derived growth factor-BB for the treatment of chronic pressure ulcers. **Journal:** Annals of Plastic Surgery, 29 (3); 193-201. Type of study: randomized controlled trial Sequence generation:	Patient group: Hospitalized patients denervated in the ulcer area (congenital or acquired spinal cord pathology) with a grade III or IV PU. All patients Randomised N: 20 Completed N: 20 Drop-outs: 0 Group 1 Randomised N: 4	Group 1: Growth factor: rPDGF-BB (1.0 μg/ml). Wound were cleansed with saline and then bottled dry with sterile gauze, before application of the GF. After application the wound was left open for 15 minutes to permit absorption of the GF. The ulcer crater was packed with fresh sterile gauze and sealed closed with Biobrane attached to the healthy surface of the wound margins. Group 2: Growth factor: rPDGF-BB (10.0 μg/ml). Wound were cleansed with saline and then	Outcome 1: Mean percentage (SEM) change in ulcer depth at day 29 Outcome 2: Mean percentage (SEM) change in ulcer volume at day 29 Outcome 3:	Group 1: not reported; figure unclear Group 2: not reported; figure unclear Group 3: 85.9 (7.4) Group 4: 65.1 (6.7) Group 1: not reported; figure unclear Group 2: not reported; figure unclear Group 3: 93.6 (4.0) Group 4: 78.2 (5.6)	Funding: / Limitations:; no report on sequence allocation; inadequate allocation; no blinding of nurses; no a priory sample size calculation; small sample size; no information on setting; no report on multiple ulcers; PU classification not reported

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not reported; unequal allocation to different schedules. Allocation concealment: not reported Blinding: blinding of patients and investigator Addressing incomplete outcome data: no drop out. Statistical analysis: The primary endpoints were evaluated as a percentage of initial wound size to adjust for differences in baseline ulcer sizes. A two-way analysis of variance with repeated measures was performed to compare healing among treatment groups over time. Significant anova effects were further analyzed using the Tukey-Kramer multiple comparisons procedure (alpha 0.05, two tailed). Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample	Completed N: 4 Dropouts: 0 Age (mean years (SD); range): 37.8 (13.2); 21-56 Ulcer duration (mean months (SD); range): 11.6 (5.5); 3-27 Ulcer depth (mean cm (SD); range): 1.7 (0.5); 0.5-2.7 Ulcer volume (mean cm³ (SD); range): 13.8 (4.8); 5-26 Group 2 Randomised N: 4 Completed N: 4 Dropouts: 0 Age (mean years (SD); range): 43 (5); 32-54 Ulcer duration (mean months (SD); range): 16.0 (7.1); 4-36 Ulcer depth (mean cm (SD); range): 1.6 (0.6); 0.8-3.5 Ulcer volume (mean cm³ (SD); range): 15.8 (4.0); 9-28 Group 3	bottled dry with sterile gauze, before application of the GF. After application the wound was left open for 15 minutes to permit absorption of the GF. The ulcer crater was packed with fresh sterile gauze and sealed closed with Biobrane attached to the healthy surface of the wound margins. Group 3: Growth factor: rPDGF-BB (100.0 μg/ml). Wound were cleansed with saline and then bottled dry with sterile gauze, before application of the GF. After application the wound was left open for 15 minutes to permit absorption of the GF. The ulcer crater was packed with fresh sterile gauze and sealed closed with Biobrane attached to the healthy surface of the wound margins. Group 4: Placebo. All groups: All ulcers were sharp debrided if necessary. Initial drug administration was delayed for at least 24 hours after debridement. Pressure-relieving devices were used as appropriate. Patients were repositioned rigorously at	Proportion of patients with invasive infections Outcome 3: Proportion of patients completely healed	P value: 0.16 Group 1: 0/4 Group 2: 0/4 Group 3: 0/5 Group 4: 0/7 Group 1: 0/4 Group 2: 0/4 Group 3: 2/5 Group 4: 0/7	Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size calculation. Setting: hospital. Length of study: 4 weeks of treatment and 5 months of follow-up. Assessment of PUs: Measurements of PU were perfomed on days 0, 7, 14, 21, and 29 using (1) maximum perpendicalr diameters of the surface and maximum depth of the crater (Kudin wound gauge), (2) volume determination using alginate mold weight, and volumetric displacement, and (3) color photography of the ulcer at a set focal distance. The ulcer area opening was quantitated from the tracing using a macrolens and digitized planimetry. Classification of PUs: not reported. Grade III/IV PU were seen as PU through the subcutaneous tissue. Multiple ulcers: not	Randomised N: 5 Completed N: 5 Dropouts: 0 Age (mean years (SD); range): 29 (4); 21-45 Ulcer duration (mean months (SD); range): 17.3 (12.4); 4-67 Ulcer depth (mean cm (SD); range): 2.8 (1.0); 1.6-6.8 Ulcer volume (mean cm³ (SD); range): 11.6 (5.5); 4-33 Group 4 Randomised N: 7 Completed N: 7 Dropouts: 0 Age (mean years (SD); range): 27 (2); 22-35 Ulcer duration (mean months (SD); range): 14.2 (6.2); 1-37 Ulcer depth (mean cm (SD); range): 2.8 (0.4); 1.5-5.2 Ulcer volume (mean cm³ (SD); range): 12.9 (3.8); 5-33	2-hour intervals throughout the treatment period.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reported	Inclusion criteria: PU surface area between 25 and 95 cm² if grade III or IV); no past/present malignancy; mechanical debridement of necrotic tissue at least 2 days before initiation of treatment; normal or clinically insignificant laboratory results Exclusion criteria: Arterial or venous disorder cause for ulcerated wound; clinically significant systemic disease; significant malnutrition; recent use of steroidal therapy, immunotherapy or cytotoxic chemotherapy				

Table 197: Robson 1994[184]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Robson (1994) **Title**: Safety and effect of topical recombinant human interleukin-1	Patient group: Hospitalized patients denervated in the ulcer area (congenital or acquired spinal cord pathology) with a grade III	Group 1: Topical recombinant human IL-1β (0.01 μg/cm2/day – 1.0 μg/ml). Wound were cleansed with normal saline and then bottled spray with the IL-1β. After application the	Outcome 1: Proportion of patients completely healed	Group 1: 0/6 Group 2: 0/6 Group 3: 0/6 Group 4: 0/6	Funding: Grant from Immunex Corportation, Seattle Wahsington

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
beta in the management of pressure sores. **Journal:** Wound Repair and Regeneration, 2; 177-181. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: double blinding; no further information Addressing incomplete outcome data: two patients were excluded. Statistical analysis: The Cochrane-Mantel Haenszel to compare baseline difference between groups. Percentage of change between the groups was compared by means of an analysis of variance model with factors for the group only and adjusted for percentage change.	or IV PU. All patients Randomised N: 24 Completed N: 22 Drop-outs: 2 (1 was discharge, 1 had osteomyelitis) Group 1 Randomised N: 6 Completed N: 5 Dropouts: 1 (discharged) Group 2 Randomised N: 6 Completed N: 6 Dropouts: 0 Group 3 Randomised N: 6 Completed N: 5 Dropouts: 1 (osteomyelitis) Group 4 Randomised N: 5 Completed N: 5 Dropouts: 0	wound was left open for 20 minutes to permit absorption of the GF. Then a saline solution-moistened gauze dressing was applied. The gauze dressing was changed 12 hours later. Group 2: Topical recombinant human IL-1β (0.1 μg/cm2/day – 10.0 μg/ml). Wound were cleansed with normal saline and then bottled spray with the IL-1β. After application the wound was left open for 20 minutes to permit absorption of the GF. Then a saline solution-moistened gauze dressing was applied. The gauze dressing was changed 12 hours later. Group 3: Topical recombinant human IL-1β (1.0 μg/cm2/day – 100.0 μg/ml). Wound were cleansed with normal saline and then bottled spray with the IL-1β. After application the wound was left open for 20 minutes to permit absorption of the GF. Then a saline solution-moistened gauze dressing was applied. The gauze dressing was changed 12 hours later.	Outcome 2: Percentage reduction in wound size at 29 days	Group 1: not reported; figure unclear Group 2: not reported; figure unclear Group 3: not reported; figure unclear Group 4: not reported; figure unclear	Limitations:; no report on sequence allocation; no report on allocation concealment; no information on blinding; no a priory sample size calculation; small sample size; no information on setting; no report on multiple ulcers; PU classification not reported Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: hospital. Length of study: 28 days of treatment and 3 months of follow-up. Assessment of PUs: Measurements of PU were performed on days 0, 7, 14, 29, and 1 and 3 months after drug application using (1) color photography of the ulcer at a set focal distance, (2) maximum length, width and depth crater diameter, (3) planimetry of the ulcer opening, and (4) volume determination Classification of PUs: not reported. Grade III/IV PU were seen as PU from the bone to the subcutaneous tissue. Multiple ulcers: not reported	Inclusion criteria: Men, non-pregnant, non-lactating women; 18 years and older; 28 days of hospitalization; wound volume ranging from 10 to 100 cm^3 or to the bone prominence; PU located on the sacrum, ischium or trochanter; PU grade III or IV. Exclusion criteria: Arterial or venous disorder cause for ulcerated wound; significant endocrine disease such as diabetes mellitus; systemic sepsis from the PU; lack of cooperation or unsuitability; inability o provide informed consent; whirlpool therapy requirements; testing positive for HIV; use of investigational drugs within 1 month before study entry; treatment of the target ulcer with cytokines within 3 months before study entry.	Group 4: Placebo All groups: All ulcers were sharp debrided before application of the dressing as necessary. Initial drug administration was delayed for at least 24 hours after debridement. Pressure-relieving devices were used as appropriate. Patients not on air-fluidized beds were repositioned rigorously at 2-hour Intervals.			

Table 198: Robson 2000[185]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Robson (2000) **Title**: Sequential cytokine therapy for pressure ulcers: Clinical and mechanistic response. **Journal:** Annals of surgery, 231 (4); 600-611. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: double blind, only blinding of assessor reported. Addressing incomplete outcome data: excluded. Statistical analysis: Descriptive statistics were computed for demographic characteristics such as age, ethnicity, smoking status, and pressure	Patient group: Inpatients with a grade III or IV PU. All patients Randomised N: 61 Completed N: 61 Drop-outs: 0 Group 1 Randomised N: 15 Completed N: 15 Dropouts: 0 Age (mean years range): 18.8 (11.8) Ulcer duration (mean months (SD)): 6.8 (6.1) Ulcer volume (mean cm^3 (SD)): 32.77 (21.06) Group 2 Randomised N: 15 Completed N: 15 Dropouts: 0 Age (mean years range): 18.8 (11.8) Ulcer duration (mean months (SD)): 6.8 (6.1) Ulcer volume (mean cm^3 (SD)): 33.81 (26.12)	Group 1: Growth factor: rhuGM-CSF (2.0μg/cm^2) was topically applied. After 15 minutes of air-drying, the wounds were dressed with a nonadherent dressing next to the wound surface and dry gauze to fill the wound. Group 2: Growth factor: rhubFGF (5.0μg/cm^2) was topically applied. After 15 minutes of air-drying, the wounds were dressed with a nonadherent dressing next to the wound surface and dry gauze to fill the wound. Group 3: Growth factor: rhuGM-CSF/rhubFGF (2.0μg/cm^2 GM-CSF for 10 days and 5.0μg/cm^2 bFGF the following 25 days) was topically applied. After 15 minutes of air-drying, the wounds were dressed with a nonadherent dressing next to the wound surface and dry gauze to fill the wound. Group 4: Placebo. After 15 minutes of air-drying, the wounds were dressed with a nonadherent dressing next to the wound surface and dry	Outcome 1: Mean percentage wound closure on day 36 Outcome 2: Median (range) percentage wound closure on day 36	Group 1: 67 (24) Group 2: 75 (19) Group 3: 68 (21) Group 4: 71 (11) Group 1: 70 (3-93) Group 2: 79 (42-99) Group 3: 73 (29-98) Group 4: 72 (39-84) P-value: 0.69	Funding: grant from the National Institutes of Health (ROI-AR42967). Schering-Plough Research Institute and Scios, Inc. provided the cytokines used in this study Limitations:; no report on sequence allocation; no report on allocation concealment; no blinding of patient and nurses; missing data were excluded; no a priory sample size calculation; little information on setting; little information on ulcer assessment; no report on multiple ulcers; PU classification not reported

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ulceration duration. The patients' ages and ulcer duration were compared by analysis of variance, whereas ethnicity and smoking status were compared using chi-square analysis (Sigma Stat 2.03, SPSS, Chicago, IL). Both parametric and nonparametric analyses were used to determine the efficacy of GM-CSF treatment alone, bFGF treatment alone, or sequential GM-CSF/bFGF treatment, depending on the apparent normality of the data. The percentage decrease in volume during the 35 days was compared among patient groups using the Kruskal-Wallis method of analysis of variance on ranks (Sigma Stat). Patients achieving various percentages of healing versus time were compared across	Group 3 Randomised N: 16 Completed N: 16 Dropouts: 0 Age (mean years range): 51.3 (11.2) Ulcer duration (mean months (SD)): 12.1 (14.6) Ulcer volume (mean cm^3 (SD)): 38.16 (38.3) Group 4 Randomised N: 15 Completed N: 15 Dropouts: 0 Age (mean years range): 47.1 (10.8) Ulcer duration (mean months (SD)): 13.1 (14.2) Ulcer volume (mean cm^3 (SD)): 45.19 (34.79) Inclusion criteria: Age 28-70 years; PU on truncal area; PU grade III/IV; ulcer duration > 8 weeks; initial ulcer volume 10-200cm^3 Exclusion criteria:	gauze to fill the wound. All groups: All ulcers were sharp debrided before application of the dressing as necessary. Initial drug administration was delayed for at least 24 hours after debridement. All patients were kept on pressure-relief surfaces			Additional outcomes: cost: G1: $2200, G2: $800 to $1000; G3: $1700, G4: $3000 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
treatment groups by Kaplan-Meier survival analysis (JMP software, SAS, Cary, NC). All data obtained longitudinally on ulcer measurements, cytokine levels and changes, and fibroblast activity in FPCLs were evaluated for possible correlations using the Spearman rank order correlation (Sigma Stat). With this test, pairs of variables with positive correlation coefficients and p values , 0.05 tend to increase together. For pairs with negative correlation coefficients and p values , 0.05, one variable tends to decrease while the other increases. Baseline differences: No statistical difference between groups for age, ethnicity, smoking status, and duration of PU. Study power/sample size: No a priory sample	Significant diabetes mellitus, renal insufficiency, vasculitis, or hepatic, immunologic, cardiac, or hemorrhagic disease; Malignant or neoplastic disease, except for adequately treated skin cancers; Significant malnutrition, systemic steroidal therapy, immunotherapy, or chemotherapy; Cytokine therapy within 90 days or investigational drug study within 30 days				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size calculation. Setting: inpatients. Length of study: 35 days of treatment. Assessment of PUs: The PUs was measured on day 0 and weekly for 5 weeks. After that they were seen at 3 weeks, 6 weeks, 3 months, 6 months and 1 year. The planimetry was used to determine the ulcer opening and volume using alginate molds. At each follow-up visit the wounds were assesses as to whether they had achieved complete healing, were still less than 100% healed, or had recurred after a time of 100% closure Classification of PUs: not reported. Grade III/IV PU were seen as PU involving any tissue from a bony prominence to the subcutaneous tissue. Multiple ulcers: not reported					

Table 199: Shamimi 2008[205]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Shamimi (2008) **Title**: Topical application of Semelil (ANGIPARSTM) in treatment of pressure ulcers: a randomized clinical trial. **Journal:** DARU, 16 (Supplement 1); 54-57. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: no drop-outs Statistical analysis: not reported. Baseline differences: No statistical difference between groups. Study power/sample size: No a priory sample size calculation.	Patient group: Hospitalized patients with a PU. All patients Randomised N: 18 Completed N: 18 Drop-outs: 0 Group 1 Randomised N: 9 Completed N: 9 Dropouts: 0 Age (mean years (SD)): 47.9 (21.2) Gender (m/f): 7/2 Ulcer area (mean cm² (SD)): 56.1 (93.3) Number of ulcers (mean number (SD)): 1.2 (0.4) Group 2 Randomised N: 9 Completed N: 9 Dropouts: 0 Age (mean years (SD)): 46.0 (22.7) Gender (m/f): 7/2 Ulcer area (mean cm²	Group 1: Naïve herbal extract (Semelil (AngiparsTM). 3% gel daily. Group 2: conventional treatment Both groups: Debridement if necessary	Outcome 1: Mean cm² decrease in ulcer area Outcome 2: Mean rate of healing (%) Outcome 4: Proportion of patients healed > 80% Outcome 5: Proportion of patients healed 50-80% Outcome 6: Proportion of patients healed 20-50% Outcome 7: Proportion of patients healed < 20% Outcome 8: Proportion of patients with	Group 1: 48.2 (85.3) Group 2: 2.8 (6.2) P-value: 0.000 Group 1: 78.3 (12.5) Group 2: 6.3 (22.7) P-value: 0.000 Group 1: 6/9 Group 2: 0/9 Group 1: 3/9 Group 2: 1/9 Group 1: 0/9 Group 2: 0/9 Group 1: 0/9 Group 2: 8/9	Funding: / Limitations: no report on sequence generation; no report on allocation concealment; no report on blinding; no a priory sample size calculation; no report on PU classification; little information on intervention and comparison Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: Vali-e-Asr hospital, Medical Sciences/University of Tehran (Iran) Length of study: two months Assessment of PUs: Ulcers were photographed and measured to assess the ulcer diameter, steadiness or regression per 2 weeks till 2 months. Classification of PUs: not reported. Multiple ulcers: patients had a mean number of ulcers of 1.2 (0.4) for G1 and 1.2 (0.7) for G2	(SD)): 19.5 (16.1) Number of ulcers (mean number (SD)): 1.2 (0.7) Inclusion criteria: > 18 years; PU resulting from spinal complications, amputation of the lower limbs, chronic diseases like brain vessel disorders or factures due to osteoporosis; ulcer size > 1cm²; occurred within the last 2 weeks Exclusion criteria: acute infection of ulcer; ulcer with bone exposure; disease or situation that impairs ulcer improvement; alcohol or drug abuse; dialysis and renal failure; corticosteroid consumption; use of immune suppressive agents; radiotherapy or chemotherapy; any known drug hypersensitivity		adverse events	Group 1: 0/9 Group 2: 0/9	

Table 200: Sipponen 2008[206]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Sipponen (2008) **Title**: Beneficial effect of resin salve in treatment of severe pressure ulcers: A prospective, randomized and controlled multicentre trial. **Journal:** British Journal of Dermatology, 158 (5); 1055-1062. Type of study: randomized controlled trial Sequence generation: permuted block sizes of four according to a random list designed by a specialist in biometrics. Allocation concealment: closed envelopes Blinding: no blinding Addressing incomplete outcome data: drop-outs were excluded Statistical analysis: Differences between parallel groups were	Patient group: Hospitalized patients with a grade II to IV PU (according to the EPUAP). All patients Randomised N: 37 patients and 45 ulcers Completed N: 22 patients and 29 ulcers Drop-outs: 15 patients and 16 ulcers (7 deaths, 2 operated, 1 allergic skin reaction, 1 misdiagnosed, 4 patients-based refusal) Group 1 Randomised N: 21 patients and 27 ulcers Completed N: 13 patients and 18 ulcers Dropouts: 8 patients and 9 ulcers (3 deaths, 2 operated, 1 allergic skin reaction, 1 misdiagnosed, 1 patients-based refusal) Age (mean years (SD); range): 80 (10); 58-98 Gender (m/f): 6/7 BMI (mean kg/m² (SD);	Group 1: Resin salve (from the Norway spruce (Picea abies). An even layer of resin +/- 1 mm thick was spread between loose sterile cotton gauze. The gauze was placed on both infected and noninfected areas of the pressure ulcer to cover the ulcer area with resin fully. The resin–gauze dressing was changed daily if the ulcer was infected or produced a discharge; if this were not the case, the dressing was changed every third day. Group 2: sodium carboxymethylcellulose hydrocolloid polymer without or with ionic silver (Aquacel® or Aquacel Ag®; ConvaTec Ltd, London, U.K.). The Aquacel–hydrocolloid dressing was changed daily if the ulcer produced excessive discharge, but if there was no secretion the dressing was changed every third day, as for the resin–gauze. Both groups: 3 patients received a pressure ulcer	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of ulcers completely healed Outcome 3: Proportion of ulcers improved Outcome 4: Proportion of ulcers worsened Outcome 5: Mean percentage reduction in ulcer width Outcome 6: Mean percentage reduction in ulcer depth Outcome 7: speed of healing (days)	Group 1: 12/13 Group 2: 4/9 P-value: 0.003 Group 1: 17/18 Group 2: 4/11 P-value: 0.003 Group 1: 18/18 Group 2: 10/11 Group 1: 0/18 Group 2: 1/11 P-value: 0.003 Group 1: 93.75 Group 2: 57.14 Group 1: 88.46 Group 2: -1.89	Funding: grant to A.s. in support of this investigation and the Lappish Resin project Limitations: no blinding; no ITT analysis; final sample size lower than calculated Additional outcomes: bacterial cultures Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
compared with the $\chi 2$ test or Fisher's exact test, as appropriate. Mean and SD were computed for continuous variables and proportions were compared after distribution analysis with the nonparametric Mann–Whitney U-test or Student's t-test, as appropriate. The healing of the ulcers over time was assessed by Kaplan–Meier analysis and the log-rank test was used to estimate the differences in the final outcome and healing time between the parallel groups. P < 0.05 was considered statistically significant. SPSS 14.0 was used for the statistical calculations (SPSS, Chicago, IL, U.S.A.). Baseline differences: No statistical difference between groups. Study power/sample	range): 21.8 (7.1); 15.9-35.5 Diabetes: 6 Ulcer width (mean cm (SD)): 3.2 (2.4) Ulcer depth (mean mm (SD)): 5.2 (10.3) Ulcer location: Calcaneus: 8 Trochanter: 3 Sacrum: 1 Ischium: 1 Other: 5 Ulcer grade: Grade II: 7 Grade III: 9 Grade IV: 2 Group 2 Randomised N: 16 patients and 18 ulcers Completed N: 9 patients and 11 ulcers Dropouts: 7 patients and 7 ulcers (4 deaths, 3 patients-based refusal) Age (mean years (SD); range): 74 (8); 60-88 Gender (m/f): 3/6 BMI (mean kg/m² (SD);	mattress.	(log-rank-test) Outcome 8: Proportion of patients allergic skin reaction	P-value: 0.013 Group 1: 1/21 Group 2: 0/16	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: A two group χ2 test with a 0.05 two-sided significance level will have 80% power to detect the difference between a group 1 proportion of 0.900 and a group 2 proportion of 0.500 (odds ratio 0.111) when the sample size in each group is 20. Setting: 11 primary care hospitals in Finland Length of study: six months Assessment of PUs: Ulcer localization, ulcer grade, color, width and depth were measured at the beginning of the study and thereafter monthly for 6 months. All ulcers were photographed and planimetry analysis was performed. Classification of PUs: EPUAP classification. Multiple ulcers: 37 patients and 45 ulcers	range): 21.9 (6.6); 16.9-34.7 Diabetes: 1 Ulcer width (mean cm (SD)): 4.2 (2.8) Ulcer depth (mean mm (SD)): 5.3 (6.5) Ulcer location: Calcaneus: 2 Trochanter: 1 Sacrum: 2 Ischium: 5 Other: 1 Ulcer grade: Grade II: 5 Grade III: 5 Grade IV: 1 Inclusion criteria: One or several severe PU (grade II to IV); with or without an infection Exclusion criteria: Life expectancy < 6 months; advanced malignant disease				

Table 201: Subbanna 2007[214]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Subbanna (2008) **Title**: Topical phenytoin solution for treating pressure ulcers: A prospective, randomized, double-blind clinical trial. **Journal:** Spinal Cord, 45 (11); 739-743. Type of study: randomized controlled trial Sequence generation: computer-generated randomized list. Allocation concealment: not reported Blinding: nursing staff and outcome assessor were blinded. No report on blinding of patient. Addressing incomplete outcome data: drop-outs were excluded Statistical analysis: Values were expressed as mean+/-SD and number	Patient group: Patients with a spinal cord injury and a grade II PU (according to the NPUAP). All patients Randomised N: 28 Completed N: 26 Drop-outs: 2 (discharged) Group 1 Randomised N: 14 Completed N: 12 Dropouts: 2 (discharged) Age (mean years (SD)): 34.25 (18.12) Gender (m/f): 13/1 Ulcer volume (mean ml (SD)): 3.70 (2.85) Ulcer duration (mean days (SD)): 71.81 (48.12) PUSH score (mean (SD)): 13.5 (1.16) Ulcer location: Gluteal: 2 Trochanter: 2 Sacrum: 9 Lumbar: 1	Group 1: Phenytoin solution. Sterile gauge soaked with phenytoin solution dressing once daily. Injection phenytoin solution (50 mg/ml, Park-Davis) was diluted using normal saline (0.9% NaCl, CMC pharmacy) to prepare phenytoin solution (5 mg/ml). At this concentration the pH was 7.3–7.4. Group 2: Saline solution. Sterile gauge soaked with normal saline once daily. Both groups: /	Outcome 1: Mean percentage reduction in ulcer size Outcome 2: Mean percentage reduction in ulcer volume Outcome 3: Mean percentage reduction in PUSH score Outcome 4: Proportion of patients with adverse events	Group 1: 47.83 (20.94) Group 2: 36.03 (17.63) P-value: 0.132 Group 1: 53.94 (31.20) Group 2: 55.76 (27.75) P-value: 0.777 Group 1: 19.53 (17.70) Group 2: 11.39 (11.09) P-value: 0.261 Group 1: 0/14 Group 2: 0/14	Funding: fund from the CMC fluid research grants committee Limitations: no report on allocation concealment; no report on blinding of the patients; no ITT analysis; no report on the sample size calculation; small sample size; no information on preventive measures Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(percentage) for continuous and categorical variables, respectively. The differences in the PUSH scores, ulcer volume and ulcer size between the two groups were analysed using independent t-test and Mann–Whitney U test (for normally and non-normally distributed data). P-values less than 0.05 were considered statistically significant. All analyses were carried out using Statistical Package for Social Sciences (SPSS version 11.5 Inc., Chicago, IL). Baseline differences: No difference between groups. Unclear if it was measured statistically. Study power/sample size: Sample size was based on the study results form a pilot study with 14 patients. No report on the sample	Group 2 Randomised N: 14 Completed N: 14 Dropouts: 0 Age (mean years (SD)): 31.64 (12.27) Gender (m/f): 12/2 Ulcer volume (mean ml (SD)): 4.85 (3.75) Ulcer duration (mean days (SD)): 68.18 (40.45) PUSH score (mean (SD)): 13.21 (1.42) Ulcer location: Gluteal: 1 Trochanter: 2 Sacrum: 10 Knee: 1 Inclusion criteria: PU grade II without necrotic tissue; paraplegic; age between 10 and 55 Exclusion criteria: anaemia; hypoalbuminemia; elevated serum creatinine; abnormal liver function tests; history of smoking; peripheral				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size calculation. Setting: tertiary care teaching hospital in South India, Department of Physical Medicine and Rehabilitation, Christian Medical College, Vellore. Length of study: 15 days of treatment Assessment of PUs: The ulcer healing rate was assessed using the Pressure Ulcer Scale for Healing (PUSH 3.0). PUSH 3.0 scores pressure ulcers from 0 to 17 based on ulcer surface area (length X width), exudate amount and tissue type. Reduction in PUSH 3.0 indicates ulcer healing. To assess the ulcer size, tracings of ulcer perimeter were taken on transparent sheets. Images were scanned And ulcer size was determined using a computer software developed by the Department of	vascular disease; diabetes mellitus; malignancy; connective tissue disorder; psychiatric illness				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Bioengineering, Christian Medical College, Vellore. To measure ulcer volume, ulcers were initially filled with normal saline up to the brim and then normal saline was withdrawn using a calibrated syringe. PUSH 3.0 scores, ulcer size and volume measurements were estimated on day 1 before starting the treatment and on day 16. Classification of PUs: NPUAP classification (1989). Multiple ulcers: not reported					

Table 202: Thomas 1998[225]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Thomas (1998) **Title**: Acemannan hydrogel	Patient group: Patients older than 18 years with grade II, III or IV PU.	Group 1: Amorphous hydrogel dressing (Carrasyn® gel, Carrington Laboratories, Inc., Irving, TX). Ulcers were	Outcome 1: Proportion of patients completely healed	Group 1: 10/16 Group 2: 9/14 Odds ratio: 0.93 (95% CI: 0.16-5.2)	Funding: grant from Carrington Labaratories, Inc. Irving, Tx.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
dressing versus saline dressing for pressure ulcers. A randomized, controlled trial. **Journal:** Advances in Wound Care, 11 (6); 273-276. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis: Comparison of dichotomous variables was performed by chi-square test. Fischer's exact test was used when a cell value was less than 5. Distributions of continuous variables were compared by the Kruskal-Wallis test for groups. Data were analysed using EPI6..	All patients Randomised N: 41 Completed N: 30 Drop-outs: 11 (6 died, 2 worsened, 2 hospitalized, 1 violated protocol) Age (mean years (SD); range): 77 (12); 35-97 Gender (m/f): 19/22 Ulcer grade: Grade II: 15 Grade III: 20 Grade IV: 6 Group 1 Randomised N: 22 Completed: 16 Dropouts: 6 (4 died, 1 worsened, 1 hospitalized) Characteristics are form completed N Age (mean years (SD)): 79 (9) Gender (m/f): 7/9 Ulcer grade: Grade II: 8 Grade III: 6 Grade IV: 2 Ulcer area (mean cm² (SD)): 8.9 (9.3)	cleansed with saline and gently mechanical wiped with gauze. Ulcers were treated with a 1/8 inch layer of hydrogel and covered with a dry sterile nonwoven gauze, held in place with a thick gauze dressing. Dressings were changed daily. Carrasyn®: the active ingredient is thought to be acemannan, a complex carbohydrate derived from the aloe vera plant. Group 2: Moist saline gauze dressing. Ulcers were cleansed with saline and gently mechanical wiped with gauze. Ulcers were covered with a sterile nonwoven saline soaked gauze and a dry sterile nonwoven gauze, held in place with a thick gauze dressing. Dressings were changed daily. All groups: Pressure relieving devices were used in 26.7% of the patients	Outcome 2: Percentage healing rate Outcome 3: Mean time to healing (weeks) Outcome 4: Proportion of patients worsened	P-value: 0.92 Group 1: 63 Group 2: 64 Group 1: 5.3 (2.3) Group 2: 5.2 (2.4) P-value: 0.87 Group 1: 1/22 Group 2: 1/19	Limitations: no report on sequence generation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priory sample size calculation; no report on classification of PU Additional outcomes: healing rate and subject characteristics (odds ratio's) Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: No statistical difference between groups for the characteristics of the patients after exclusion of drop-outs Study power/sample size: The study had a power of 80% to detect 25% difference at alpha significance 0.05. Unclear if a priory calculation. Setting: skilled nursing facilities and home health care agencies. Length of study: 10 weeks of treatment or until complete healing, whichever came first. Assessment of PUs: Ulcers were photographed and tracing were made. Classification of PUs: not reported. Multiple ulcers: only one ulcer par subject was evaluated	Incontinence: Urine: 9 Faecal: 12 Group 2 Randomised N: 19 Completed N: 14 Drop-outs: 5 (2 died, 1 worsened, 1 hospitalized, 1 violated protocol) Characteristics are form completed N Age (mean years (SD)): 72 (13) Gender (m/f): 9/5 Ulcer grade: Grade II: 6 Grade III: 7 Grade IV: 1 Ulcer area (mean cm² (SD)): 5.9 (6.0) Incontinence: Urine: 7 Faecal: 12 Inclusion criteria: Age 18 years and older; grade II, III or IV PU; ulcer area ≥ 1.0cm²				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Exclusion criteria: venous or arterial insufficiency or other non-pressure etiology; ulcers with sinus tracts and/or undermining greater than 1 cm; clinically infected ulcers; concomitant use of other topical medication or systemic steroid therapy; severe medical condition; estimated survival of less than 6 months ; HIV, currently abusing alcohol or drugs; pregnant, breast feeding or not on acceptable means of anti-contraception; diagnose of cancer; receiving chemotherapy				

Table 203: Van Ort 1976[235]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gerber (1979) **Title**: Topical application of insulin in decubitus ulcers: a pilot study **Journal:** Nursing Research, 25 (1): 9-12.	Patient group: Nursing home patients with a pressure ulcer. All patients Randomised N: 14	Group 1: Insulin (10 units of U-40 regular insulin (U.S.P.). The insulin was dropped from a syringe to the ulcer. The ulcer was then allowed to dry. No dressing was applied. Insulin therapy was applied twice a	Outcome 1: Mean rate of healing	P-value: p=0.05	Funding: funded by the University of Arizona College of Nursing Limitations: a random list was

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: Randomized controlled trial, pilot study Sequence generation: table of random numbers. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: no drop outs Statistical analysis: The t-test was used to determine effect of independent variable on dependent variable. Tests to determine the influences of extraneous variables included the Pearson correlation coefficient and the t-test for difference in means. For the t-test, level of significance was set at 0.05. Baseline differences: Difference in baseline characteristics (age and gender) was not measured statistically.	Completed N: 14 Drop-outs: 0 Age (mean years (SD); median years): 72.5 (20.22); 77.5 Gender (m/f): 12/2 Group 1 Randomised N: 6 Completed N: 6 Dropouts: 0 Age (mean years): 79.83 Group 2 Randomised N: 8 Completed N: 8 Dropouts: 0 Age (mean years): 67.0 Inclusion criteria: as a break in skin continuity as evidenced by epidermal or dermal injury involving erythema, pallor, cyanosis, and superficial erosion; size of the ulcer at time of admission was between 1.0 and 7.0 cm; skin breakdown had been in existence 14 days or less prior to the tie the	day for five days. Group 2: Standard care determined by physician or nursing home standing order. Both groups: All patients received routine supportive nursing care: position change, increased fluid intake, high protein diet, and local massage.			used for sequence generation; no report on allocation concealment; no report n blinding; no a priory sample size calculation; little information of baseline characteristics of individual groups; baseline difference not measured statistically Additional outcomes: / Notes: larger study was reported by Gerber and Van Ort 1979 (no outcome of interest were reported in this study)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: A priory sample size calculation unclear. A sample size of 20 patients was anticipated but not reached Setting: nursing home residents Length of study: 15 days Assessment of PUs: The size of the decubitus was measured using a transparent scale, the B.W.Co.Measure, which was placed on the lesion. Ulcers were also photographed. The ulcer was measured and photographed once a day. Classification of PUs: PU were defined as a break in skin continuity as evidenced by epidermal or dermal injury involving erythema, pallor, cyanosis, and superficial erosion. Multiple ulcers: Patients had multiple ulcers. Mean (SD)	subject was admitted to the study Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
number of ulcers: 1.14 (0.36)					

Table 204: Xakellis 1992[246]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Xakellis (1992) **Title**: Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: A cost-effectiveness analysis. **Journal:** Archives of Physical Medicine and Rehabilitation, 73; 463-469. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: intention to treat analysis Statistical analysis: Two-	Patient group: Patients with a grade II or III PU (according to the Shea classification). All patients Randomised N: 39 Completed N: 34 Drop-outs: 5 (1 hospitalized, 1 withdrawal of consent, 3 died) Group 1 Randomised N: 18 Completed: 16 Dropouts: 2 (1 hospitalized, and 1 withdrawal of consent) Age (mean years (SD)): 77.3 (16.9) Gender (m/f): 2/16 Ulcer location: Sacrum: 6 Pelvic area: 8	Group 1: Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Princeton, NJ). Ulcers were cleansed with normal saline only. The dressing was applied and rimmed with tape. The dressing was changed twice weekly or if non-occlusive. Group 2: Saline wet-to-moist gauze dressing. The gauze consists of a non-sterile eight ply gauze dressing moistened with saline and placed on the ulcer. This was covered with an additional gauze dressing and rimmed with tape. The dressing was remoistened with 3cc saline after four hours and changed after eight hours. All groups: All patients with necrotic tissue were sharp debrided as necessary All patient received routine care: repositioning every two	Outcome 1: Proportion of patients completely healed Outcome 2: Median time to healing (days)	Group 1: 16/18 Group 2: 18/21 Group 1: 9 Group 2: 11 P-value: 0.12	Funding: supported by ConvaTec Princeton, NJ and Family Health Foundation of America. Limitations: no report on sequence generation; no report on blinding; no a priory sample size calculation; small sample size; little information on ulcer assessment Additional outcomes: Cost; multivariate analysis Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
tailed chi-square or Fisher exact tests were performed for all categorical variables. Continuous and ordinal data were analysed with the Wilcoxon rank-sum test using the t-approximation for the significance level. The Cox proportional-hazards regression model for survival data was used to determine the factors related to healing time. Logrank statistics were calculated to test the univariate associations between baseline characteristics and healing time. Multivariate analysis was performed using Cox proportional-hazard regression analysis to determine the factors associated independently and significantly ($p \leq 0.05$) with healing time. Baseline differences: No statistical difference	Other: 4 Ulcer grade: Grade II: 18 Grade III: 0 Ulcer area (mean cm²; range): 0.66; 0.12-13.4 Incontinence: Occasionally: 1 Usually: 5 Urine and faeces: 12 BMI (mean kg/m² (SD)): 20.2 (5) Norton score (mean score (SD)): 11.4 (2.8) Group 2 Randomised N: 21 Completed: 18 Dropouts: 3 (died) Age (mean years (SD)): 83.5 (10.6) Gender (m/f): 1/20 Ulcer location: Sacrum: 8 Pelvic area: 6 Other: 7 Ulcer grade: Grade II: 19	hours, cleaning of incontinence with warm water, placing on an air-mattress and air-filled wheelchair cushion, and record of diet.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
between groups. Study power/sample size: No a priory sample size calculation. Setting: long-term care facility. Length of study: six months of treatment. Assessment of PUs: Ulcer circumference was traced on clear plastic film two times weekly. Classification of PU: Shea classification (1975). Multiple ulcers: only one ulcer determined by coin toss was included in the study	Grade III: 2 Ulcer area (mean cm²; range): 0.38; 0.04-24.6 Incontinence: Occasionally: 0 Usually: 3 Urine and faeces: 13 BMI (mean kg/m² (SD)): 21.1 (5) Norton score (mean score (SD)): 12.8 (3.0) Inclusion criteria: Grade II or III Exclusion criteria: rapidly fatal disease; anticipated discharge within one week: ulcers from other causes than pressure such as venous stasis				

Table 205: Yastrub 2004[248]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Yastrub (2004) **Title**: Relationship between type of treatment and degree of wound healing	Patient group: Patients with a grade II PU (according to the AHCPR classification). All patients	Group 1: Polymeric membrane dressing (Polymen®). Dressing were changed as per protocol. Group 2: Dry clean dressing and antibiotic ointment.	Outcome 1: Proportion of patients improved Outcome 2: Mean PUSH score	Group 1: 18/21 Group 2: 15/23 Group 1: 3.24 Group 2: 1.61	Funding: Partial funding by NPUAP award. Limitations: no report on sequence

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
among institutionalized geriatric patients with grade II pressure ulcers. **Journal:** Care Management Journal, 5 (4); 213-218. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: not reported Statistical analysis: The t-test was used to determine the difference between PUSH scores of the different groups. Descriptive statistics were computed using SPSS. Baseline differences: Baseline characteristics not reported. Study power/sample size: No a priory sample	Randomised N: 50 Completed N: 44 Drop-outs: 6 (reason not reported) - unclear Group 1 Randomised N: 21 Completed: 19 Dropouts: 2 missings Group 2 Randomised N: 23 Completed: 23 Dropouts: 0 Inclusion criteria: > 65 years; limitation in ADL; PU grade II Exclusion criteria: /	All groups: All patient received: nutritional supplements, vitamin C and zinc sulphate, pressure relief mattress, foam cushion and repositioning every 2 hours		P-value: > 0.05	generation; no report on allocation concealment; no report on blinding; ITT analysis unclear; drop-outs unclear; no baseline characteristics reported, comparison between groups unclear; no a priory sample size calculation; little information on ulcer assessment; multiple ulcers not reported; little information on dressings. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size calculation. Setting: long-term care facility in Queens, New York. Length of study: four weeks Assessment of PUs: Ulcer were weekly assessed using the Pressure Ulcer Scale for Healing (PUSH). Classification of PUs: AHCPR classification (1994). Multiple ulcers: not reported					

I.2.8 Dressings

Table 206: Agren 1985[4]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Agren (1985) **Title**: Topical Treatment of Pressure Ulcers **Journal:** Scand J Plast Reconstr Surg, 19: 97-100 Type of study: randomized controlled trial Sequence generation: Patients were consecutively matched in pairs. Each member of the pair was randomly allocated. Allocation concealment: not reported Blinding: an independent surgeon from another hospital assessed the result of therapy from photographs of the ulcers. Addressing incomplete	Patient group: Geriatric patients with necrotic PUs. All patients Randomised N: 28 Completed N: 28 Drop-outs: 0 Group 1 Randomised N: 14 Completed N: 14 Dropouts: 0 Age (mean years; range): 81 (46-92) Gender (m/f): (5/9) Diabetes: 5 PU location: Trochanter major: 1 Ichial tuberosity: 1 Knee: 1 Lower leg: 1 Malleolus: 2 Heel: 7 Base of big toe: 1 Initial ulcer area (median	Group 1: Zinc gauze dressing (400µg ZnO/cm²). Dry, sterile gauze compresses were premedicated with zinc oxide. Zinc dressings were changed once a day according to manufacturer's recommendations. Group 2: Streptokinase-streptodornase (Varidase®) Streptokinase works indirectly by transforming plasminogen into the active proteolytic enzyme plasmin via streptokinase-proactivator complex. Streptodornase dissolves deoxyribonucleoproteins commonly presented in pus (Hellgren). Varidase is believed to be beneficial in the treatment of necrotic and infected wounds. The varidase solution (100 000 IU streptokinase and 25 000 IU streptodornase dissolved in 20 ml sterile isotonic saline solution; Lederle Laboratories) was applied on a sterile gauze compress. Varidase was	Outcome 1: Median percentage reduction in ulcer area Outcome 2: Proportion of patient with infection Outcome 3: Proportion of patient with skin reaction	Group 1: 2.4 Group 2: -18.7 Group 1: 0/14 Group 2: 1/14 Group 1: 0/14 Group 2: 1/14	Funding: / Limitations: sequence generation by matched pairs; no report on allocation concealment; no blinding of patients and nurses; small sample size; no information on PU classification or stages Additional outcomes: Disappearance of necrotic tissue occurred in 7 (50%) patient (4 women) treated with zinc and in 6 (43%) patients (5 women) treated with Varidase; The sequential analysis revealed a

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: Not drop-outs Statistical analysis: The statistical test was performed at 5% level. The authors tested whether the probability of the patient being assessed as successful was the same for zinc and the Varidase group. For the statistical test the result was measured as successful or unsuccessful. A sequential test procedure was used to minimize expected sample size. Baseline differences: The two groups were comparable with respect to age, sex, having diabetes mellitus, site of ulcer and initial ulcer area (cm²). Study power/sample size: The statistical test was designed to have the power of 0.95 to detect a 75% success rate in one group and a 25%	cm²; range): 5.8; 1.2-26.0 Group 2 Randomised N: 14 Completed N:14 Dropouts: 0 Age (mean years): 86 Gender (m/f): (3/11) Diabetes: 4 PU location: Trochanter major: 1 Ichial tuberosity: 1 Lower leg: 2 Malleolus: 1 Heel: 7 Lateral edge foor: 1 Sole: 1 Initial ulcer area (median cm²; range): 4.2; 1.2-18.2 Inclusion criteria: / Exclusion criteria: /	changed twice daily according to manufacturer's recommendations. Both groups: Dressings were secured with porous acrylic-based tapes. Before the study began, loosely attached necrotic material was removed, but ulcers were not surgically debrided subsequently. No patients were given antibiotics. Nursing care followed the standard routine of the department.			non-significant difference between the two treatments. The initial ulcer area was larger in the zinc group than in the Varidase group. The ulcers which were cleansed were on average half the size of the non-cleansed ulcers for both treatments. The median time to desloughing was 23 days (rage 7-56 days) for the zinc and 21 (range 7-42) days for the Varidase treated ulcers. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
success rate in the other. If a statistical non-significant difference was found it is reasonable to conclude that there is no large difference between the treatments. The number of patients needed with a conventional test (McNemar's Test) to achieve this power was too great to be practicable. A sequential test procedure was used to minimize expected sample size. Setting: Hospitalized and outpatients Length of study: 8 weeks of treatment Assessment of PUs: The ulcers were photographed and the area was determined with a planimeter from in situ tracings made by one of the authors at weekly intervals. An independent surgeon					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
from another hospital assessed the result of therapy from photographs of the ulcers. It was judged successful if the ulcer was free of necrotic tissue within 8 weeks – otherwise it was classified as unsuccessful. Classification of PUs: not reported. Multiple ulcers: In case of multiple necrotic ulcers, these were treated uniformly, but only the largest was monitored.					

Table 207: Alm 1989[8]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Alm (1989) **Title**: Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze	Patient group: Long stay patients PUs. All patients Randomised N: 50 patients and 56 PUs Completed N: 50 PUs for efficacy analysis and 51	Group 1: Hydrocolloid dressing: sheet, paste and powder (Comfeel®, Coloplast A/S, Espergaerde, Denmerk). The dressing was changed when necessary. Th sheet is used solely or on top of the filled ulcer. Six ulcers were filled with paste and one with both paste	Outcome 1: Relative median percentage decrease in ulcer area by 6 weeks Outcome 2: Median percentage	Group 1: 100.0 Group 2: 69.0 P value: 0.016 Group 1: figure unclear; not reported	Funding: / Limitations: no report on sequence allocation; allocation concealment by stratification; drop-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
compresses. **Journal:** Acta Dermato-Venereologica, 149; 1-10 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: stratified allocation based on Norton score Blinding: blinding of outcome assessor. Addressing incomplete outcome data: intention-to-treat analysis except the patients in which protocol was violated, died in wash-out period, missing case-record and drop-out for unknown reason. Those were excluded. Statistical analysis: Mean values, standard deviations and t-test were used when the values were apparently,normally	PUs for safety analysis Drop-outs: 6 PUs for efficacy analysis (1 drop-out for unknown reason, 1 missing case report, 1 died during wash-out period, 2 in which protocol was violated, and 1 incomplete data)) and 5PUs for the safety analysis (1 drop-out for unknown reason, 1 missing case report, 1 died during wash-out period, and 2 in which protocol was violated) Gender (m/f) (patients): ±6/44 Group 1 Randomised N: 31 PUs Completed N: 29 PUs for the safety analysis and 28 or 29 PUs for the efficacy analysis (latter unclear). Dropouts: 2 for the safety analysis and 2 or 3 for the efficacy analysis (latter unclear). Age (mean years (SD)): 83.6 (9.2) Norton score (mean (SD)):	and powder during the treatment period. Comfeel® sheet: consists of sodium carboxymethylcellulose particles embedded in an adhesive, elastic mass. The side which faces away from the ulcer is covered with a 0.3mm polyurethane film. Comfeel® paste: consists of sodium carboxymethylcellulose particles and guar cellulose particles suspended in a paste basis from vaseline, liquid paraffin and cetanol. Comfeel® powder: a dry mixture of sodium carboxymethylcellulose, guar cellulose and xanthan cellulose. Group 2: wet saline gauze dressings which was changed twice daily. Both groups: after randomization all ulcers were dressed with wet saline gauze dressings for one week (wash-out period).	decrease in ulcer area by 8 weeks Outcome 3: Median ulcer depth at week 4 Outcome 4: Healing distribution function Outcome 5: proportion of patient reporting pain at dressing change	Group 2: figure unclear; not reported P value: 0.047 P value: 0.15 Treatment with hydrocolloid needed to be stopped in one patient (n=1/49) due to great pain.	outs unclear; partial statistical measure of difference between groups; no blinding of patients and nurses; no information on classification of PU and unclear if grade I PUs were included; information on pain unclear; no report on preventive measures or debridement. Additional outcomes: Granulation tissue was larger in G1 than G2 Nursing time: G1 versus G2, p<0.0001 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
distributed. When values were normally distributed, median values and lower and upper hinges were calculated. The Mann-Whitney U-test was then used for probability evaluations. The statistical analysis was performed by means of the software package SYSTAT (Systat Inc., Illinois, USA). The healing outcome was analysed by means of the lifetest program SAS (SAS institute Inc., Cary, USA) The statistical analysis was performed by means of the software package SYSTAT (Systat Inc., Illinois, USA). The probability outcomes was analysed by the log rank test. A two-tailed p-value of ≤ 0.05 was accepted as statistical significance. Baseline differences: Difference was not measured statistically	12 (2) Duration PU (mean months (SD)): 4.6 (10.9) Ulcer location: Heel: n=11 Sacrum: n=8 Malleolus: n=4 Gluteal region: n=3 Hip: n=4 Other: n=1 Ulcer depth (median mm (IQR)): 1.75 (0.30-3.00) Ulcer area (median cm² (IQR)): 2.02 (0.95-3.10) Granulated area (median cm² (IQR)): 0.32 (0.051-1.68) Group 2 Randomised N: 25 PUs Completed N: 22 PUs for the safety analysis and 21 or 22 PUs for the efficacy analysis (latter unclear). Dropouts: 3 for the safety analysis and 3 or 4 for the efficacy analysis (latter unclear). Age (mean years (SD)): 83.4 (9.4) Norton score (mean (SD)):				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
except for ulcer depth, ulcer area and granulated area, which were not significantly different. Groups were comparable based on the average. Study power/sample size: No a priori sample size calculation. Setting: Long-term ward. Length of study: six weeks of treatment and follow-up for a further 3 to 6 weeks Assessment of PUs: Ulcers were photographed once a week. The area of the ulcer which was not covered with epithelium was determined after projection of the slide from below onto a horizontal glass plate which was covered with matt drawing foil. The relevant area was measured on the image which appeared on the matt foil, suing a Haff digital planimeter type	13 (3) Duration PU (mean months (SD)): 4.8 (6.4) Ulcer location: Heel: n=8 Sacrum: n=9 Malleolus: n=3 Gluteal region: n=2 Hip: n=1 Other: n=2 Ulcer depth (median mm (IQR)): 2.00 (1.00-5.00) Ulcer area (median cm² (IQR)): 2.44 (0.97-3.24) Granulated area (median cm² (IQR)): 0.25 (0.079-0.70) Inclusion criteria: having a PU. Exclusion criteria: Norton score <7				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
320 E (Haff, Pfronten, GFR) and the real area was then calculated, taking the degree of magnification into consideration. The depth and degree of cleanness en the extend and intensity of maceration were assessed and classified on rating scales. Classification of PUs: not reported Multiple ulcers: 50 patients with 56 ulcers. Ulcers are unit of analysis and randomization.					

Table 208: Amione 2005[11]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Amione (2005) **Title**: Comparison of Allevyn Adhesive and Biatain Adhesive in the management of pressure ulcers. **Journal:** Journal of Wound Care, 14 (8);	Patient group: Patients 18 years and older with a grade II or III PU (according to the EPUAP classification). All patients Randomised N: 32	Group 1: Adhesive foam dressing (Allevyn®, Smith & Nephew Medical, Hull, UK). Ulcers were cleansed with sterile water or saline before application of the dressing. Dressings were changed when exudate came within 2cm of the edge, bit was not left in	Outcome 1: Proportion of patient completely healed Outcome 2: Median percentage reduction in ulcer area	Group 1: 11/14 Group 2: 5/18 P value: >0.05 Group 1: 38.2 (-97.6-99.4) Group 2: 45.8 (-56.9-90.0) P value: >0.05	Funding: Funded by Smith & nephew Wound Management Division, Hull, UK Limitations: no report; allocation concealment by

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
365-370. Type of study: randomized controlled trial Sequence generation: block randomization Allocation concealment: stratified allocation based on baseline exudate level and treatment centre. Blinding: open trial Addressing incomplete outcome data: intention to treat analysis for outcomes in interest in this review. Per protocol analysis for some of the additional outcomes (marked with*) Statistical analysis: For outcomes of interest for this review, difference between the two dressings were evaluated using the Mantel-Haenszel test. The level of significance was taken as p<0.05. Baseline differences: Difference was not	Completed N: 28 Drop-outs: 4 (reasons unclearly reported) Group 1 Randomised N: 14 Completed N: 13 Dropouts: 1 (had necrosis) Age (median years; range): 81.8; 31.2-94.8 Gender (m/f): 6/8 Ulcer location: Sacrum: n=8 Trochanter: n=1 Ischium: n=1 Heel: n=3 Other: n=1 Ulcer grade: Grade II: n=8 Grade III: n=6 Incontinence Urine: n=1 Faecal: n=0 Both: n=7 Any: n=8 Ulcer area (median cm²; range): 16.3; 0.7-44.3 Group 2	place for longer than seven days. Allevyn®: adhesive, polyurethane inner layer containing a low-allergy adhesive, hydrophilic, absorbent middle layer, and polyurethane outer layer. Group 2: Adhesive foam dressing (Biatain®, Coloplast, Peterborough, UK). Ulcers were cleansed with sterile water or saline before application of the dressing. Dressings were changed when exudate came within 2cm of the edge, bit was not left in place for longer than seven days. Biatain®: foam layer (with three-dimensional polymer structure), with a hydrocolloid-based adhesive, which is placed directly on the wound. Semipermeable polyurethane film backing. Both groups: /	Outcome 3: Mean (range) patient pain on dressing removal (1: none – 4: severe) Outcome 4: Mean (range) patient comfort on dressing removal (1: very comfortable – 4: very uncomfortable) Outcome 4: Proportion of patients with dressing related adverse events Outcome 4: Proportion of patients with non-dressing related adverse events	Group 1: 1.01 (1.00-1.17) Group 2: 1.10 (1.00-2.17) P value: >0.05 Group 1: 1.84 (1.00-2.25) Group 2: 2.11 (1.00-2.17) P value: 0.006 Group 1: 1/14 (peri-erosion) Group 2: 4/18 (1 non-severe erythema, 2 erosion, 1 severe erythema) Group 1: 2/14 Group 2: 2/18	stratification; insufficient sequence generation; no a priori sample size calculation; small sample size; no statistical measure of difference between groups; no blinding; no information on preventive measures and debridement Additional outcomes: Falling apart of dressing.* Ease of application and removal of dressing, conformability of dressing on application and removal, adherence on application and removal. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
measured statistically. Study power/sample size: No a priori sample size calculation. Setting: four wound care centres. Length of study: seven dressing with a maximum of six weeks of treatment Assessment of PUs: Photographs were taken before and after dressing removal and before and after cleansing. Ulcers were traced after cleansing. Classification of PUs: EPUAP classification. Multiple ulcers: the largest ulcer was used in the study	Randomised N: 18 Completed N: 15 Dropouts: 3 (reason not clearly reported) Age (median years; range): 79.1; 30.1-93.6 Gender (m/f): 8/10 Ulcer location: Sacrum: n=7 Trochanter: n=3 Ischium: n=4 Heel: n=3 Other: n=1 Ulcer grade: Grade II: n=10 Grade III: n=8 Incontinence Urine: n=8 Faecal: n=1 Both: n=4 Any: n=13 Ulcer area (median cm²; range): 9.3 (0.6-80.8) Inclusion criteria: 18 years or older; PU grade II or III; slight to moderate exudate. Exclusion criteria: PU grade 0 (healed), I or IV;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	necrosis > 10%; ulcers caused by rheumatoid vasculitis, diabetes, cancer, venous leg ulceration; active cellulitis being treated with systematic antibiotics; ulcer > 14cm length; ulcer with cavity (as opposed to a crater); surrounding skin on which use of adhesive dressing is inappropriate; participation other trial; hypersensitivity to the dressing				

Table 209: Bale 1997[20]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Bale (1997) **Title**: A comparison of two dressings in pressure sore management. **Journal:** Journal of Wound Care, 6 (10); 463-466. Type of study: randomized controlled trial	Patient group: Patients with a stage II or III PU (according to the Stirling classification). All patients Randomised N: 60 Completed N: 20 Drop-outs: 40 (13 were discharged, 8 died, 5 had an adverse incident, 4 requested withdrawal, 4 had an unsuitable	Group 1: Hydrocolloid dressing (Granuflex®) Group 2: Polyurethane foam dressing (Allevyn®) Both groups: /	Outcome 1: Proportion of patient completely healed Outcome 2: Proportion of patient not changed Outcome 3: Proportion of patient worsened	Group 1: 5/9 Group 2: 7/12 Group 1: 1/31 Group 2: 0/29 Group 1: 2/31	Funding: Funded by Smith & Nephew Limitations: no report on sequence allocation; allocation concealment by open randomisation list; no ITT analysis; no a priori sample size calculation; high

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: not reported. Allocation concealment: open randomisation list. Blinding: not reported. Addressing incomplete outcome data: not reported Statistical analysis: All parameters were assessed using the Mann Whitney test except the comparison of mean dressing wear time, which was analysed using the student t-test. All test were two-sided and the 5% level considered significant. Data were analysed using a statistical analysis system (SAS) Baseline differences: Difference was not measured statistically. Groups were balanced Study power/sample size: No a priori sample size calculation. Setting: five centres. Length of study: 30 days	dressing, 3 had a deteriorating wound, 1 had a lack of progress, 2 had rolling dressings) Group 1 Randomised N: 31 Completed N: 9 Dropouts: 22 (8 were discharged, 2 died, 2 had an adverse incident, 2 requested withdrawal, 3 had an unsuitable dressing, 2 had a deteriorating wound, 1 had a lack of progress, 2 had rolling dressings) Age (median years): 74 Gender (m/f): 15/16 Ulcer location: Sacrum: n=13 Trochanter: n=1 Heel: n=11 Other: n=6 Ulcer stage: Stage II: n=22 Grade III: n=9 Ulcer area (cm²): < 5: n=10 5-9: n=6		Outcome 3: Proportion of patient with adverse events (unknown if dressing related)	Group 2: 1/29 Group 1: 2/31 Group 2: 3/29	dropout; no statistical measure of difference between groups; no report on blinding; no report on multiple ulcers; no information on preventive measures and debridement Additional outcomes: ease of application; absorbency of dressing; mean dressing wear time, ease of removal. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
of treatment or until completely healed. Assessment of PUs: Assessment not reported. Classification of PUs: Stirling classification Multiple ulcers: not reported	10-19: n=9 ≥ 20: n=6 Group 2 Randomised N: 29 Completed N: 11 Dropouts: 18 (5 were discharged, 6 died, 3 had an adverse incident, 2 requested withdrawal, 1 had an unsuitable dressing, 1 had a deteriorating wound) Age (median years): 73 Gender (m/f): 12/17 Ulcer location: Sacrum: n=18 Trochanter: n=1 Heel: n=5 Other: n=5 Ulcer stage: Stage II: n=23 Grade III: n=6 Ulcer area (cm²): < 5: n=14 5-9: n=6 10-19: n=4 ≥ 20: n=5 Inclusion criteria: 18				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	years or older; PU stage II or III with the largest diameter ≤ 11 cm; ulcer with no signs of infection; no history of poor compliance; no previous involvement in the study; not pregnant. Exclusion criteria: /				

Table 210: Bale 1998[19]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Bale (1998) **Title**: A comparison of two amorphous hydrogels in the debridement of pressure sores. **Journal:** Journal of Wound Care, 7 (2); 65-68. Type of study: randomized controlled trial Sequence generation: performed by allocating the next sequential number from a	Patient group: Patients with necrotic PUs. All patients Randomised N: 50 Completed N: 38 Drop-outs: 12 (3 patients in group 1 and 4 in group 2 died of causes unrelated to the study. 2 patients in group 1 were withdrawn from the study, 1 lost to follow-up and 1 requested to withdraw due to reasons unrelated to the study. 3 patients in group 2 were withdrawn because they developed a	Group 1: application of an amorphous hydrogel (Sterigel®) manufactured from corn bran and compose of 2% w/w hemicellulose matrix and 20% propylenen glucol in purified water. Group 2: application of another amorphous hydrogel (Intrasite®) Both groups: A low-adherent dressing (Telfa) and a semipermeable film (Tegaderm) were used as secondary dressings in both groups. The gel was replaced daily in	Outcome 1: Mean size of wounds at day 14 in (cm2; range) Outcome 2: Proportion of patients experiencing no ulcer pain at end of study Outcome 3: Proportion of patients experiencing intermittent ulcer pain at end of	Group 1: 26.8 (21.5-40) Group 2: 8.7 (3-15.7) P value:0.08 Group 1: 10/24 Group 2: 5/23 Relative risk: 1.92 95% CI: 0.77-4.75 Group 1: 13/24 Group 2: 16/23 Relative risk: 0.78 95% CI:0.49-1.23	Funding: study was undertaken with financial support from Seton Healtcare Limitations: Unclear allocation concealment Relatively high drop-out Additional outcomes: In group 1, 14 patients achieved complete debridement of

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
computer-generated random number list. Allocation concealment: open randomisation list. Blinding: an independent assessor confirm or reject the subjective assessment recorded by the nurses not blinded. Addressing incomplete outcome data: not reported Statistical analysis: not reported Baseline differences: None Study power/sample size: With the inclusion of 50 patients, the study had a power of 80% to detect a difference equal to 23% of the standard deviation of the quantitative measurements; for qualitative measurements the study was capable of detecting a 36% difference in response rates at a significance	wound infection) Group 1 Randomised N: 26 Completed N: 21 Dropouts: 5 Age (mean years; range): 78; 20-93 Gender (m/f): 9/17 PU grade: Grade II: 2 Grade III: 20 Grade IV: 2 Waterlow score mean (range): 20.5 (13-35) Ulcer area (mean cm2; range): 14.7; 6.6-49 Ulcer depth (mean mm; range): 5; 1-15 Duration of wound mean (mean months; range): 5.1 months; 5 days- 4 years PU location: Sacrum: 5 Ischial tuberosities: 2 Heel: 14 Foot: 2 Gaiter area: 1 Elbow: 1 Lateral malleolus: 0	order to maximise its debridement capability. All other wound treatment was prohibited during the study	study Outcome 4: Proportion of patients experiencing continuous ulcer pain at end of study Outcome 5: Proportion of patients experiencing no pain on dressing removal at end of the study Outcome 6: Proportion of patients experiencing slight pain on dressing removal at end of the study Outcome 7: Proportion of patients experiencing severe pain on dressing removal at	Group 1: 1/24 Group 2: 2/23 Group 1: 17/22 Group 2: 13/20 Group 1: 5/22 Group 2: 6/20 Relative risk: 0.76 95% CI: 0.27-2.10 P value: 0.73 Group 1: 0/22	their wounds, 10 of these in 21 days or more. Of the 7 remaining wounds 1 deteriorated, 1 remained the same and 5 improved. In group 2, 9 achieved complete debridement, 4 of these in 21 days or more. Of the remaining 8, 1 deteriorated, 3 remained the same and 4 improved. There were no differences in wound odor between the two groups. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
level of 5%. Setting: Hospital and community settings in the UK. Length of study: four weeks or until wound had debrided, whichever was sooner Assessment of PUs: The study nurse was asked at each assessment to assess the percentage of black (representing hard dry eshar), green (infection, yellow (slough) and red (healthy granulation tissue). The nurses unanimously considered that debridement was successful when there was 80% red granulation tissue present and no signs of necrosis. Photographs and tracings were also taken at each assessment. The photographs were sent for computerized wound analysis. Pain was measured by the patient selecting from three options:	Buttock: 1 Group 2 Randomised N: 24 Completed N: 17 Dropouts: 7 Age (mean years; range): 77; 38-99 Gender (m/f): 10/14 PU grade: Grade II: 0 Grade III: 21 Grade IV: 1 Waterlow score (mean; range): 20.4; 9-29 Ulcer area (mean cm2; range): 9.4; 1-36 Ulcer depth (mean mm; range): 4.7; 2-10 Duration of wound (mean months; range): 4.7; 11 days- 4 years PU location: Sacrum: 4 Ischial tuberosities: 0 Heel: 19 Foot: 0 Gaiter area: 0 Elbow: 0 Lateral malleolus: 1		end of the study Outcome 8: Proportion of patients uncomfortable or very uncomfortable with dressing Outcome 9: Proportion of patients experiencing maceration of the skin at the end of the study	Group 2: 1/20 Relative risk: 0.30 95% CI: 0.01-7.07 P value: 0.38 Group 1: 0/22 Group 2: 1/20 Group 1: 8/21 Group 2: 9/17	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
none, intermittent and continuous; no measure of the severity of the pain was undertaken. Pain on removal of dressings was measured at the end of the study using three options: pain, slight pain and severe pain. Classification of PUs: not reported. Multiple ulcers: not reported	Buttock: 0 Inclusion criteria: presence of necrotic pressure ulcers Exclusion criteria: wound diameter > 8cm; disease resulting in immunosuppression; pregnant or nursing mothers; participation in another clinical trial 1 month prior to the study; already participated in the trial				

Table 211: Banks 1994a[21]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Banks (1994a) **Title**: The use of two dressings for moderately exuding pressure sores. **Journal:** Journal of Wound Care, 3 (3); 132-134. Type of study: randomized controlled trial	Patient group: Inpatients with a grade II or III PU. All patients Randomised N: 29 Completed N: 22 Drop-outs: 7 (4 wound deterioration, 2 dressing/wound related problems, 2 were discharged)	Group 1: Semi-permeable polyurethane dressing (Spyrosorb®, C.V. Laboratories Ltd). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge of the dressing and before exudate had leaked, with a maximum of seven days. Spyrosorb®: inner layer consists of porous, hydrophilic, pressure sensitive adhesive wound contact surface, the	Outcome 1: Proportion of patient completely healed Outcome 2: Proportion of patient improved Outcome 3: Time to healing (median days)	Group 1: 10/10 Group 2: 11/12 Group 1: 10/10 Group 2: 12/12 Group 1: 13.36 Group 2: 12.69	Funding: sponsored by C.V. Laboratories Ltd and Calgon Vestal Laboratories Limitations: no report on sequence generation; no report on allocation concealment; no

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: not reported. Allocation concealment: not reported. Blinding: not reported. Addressing incomplete outcome data: drop-out were excluded. Statistical analysis: Survival analysis was used to compare the time of healing. The Mann-Whitney U test was used to compare ease of dressing removal, pain at removal, and comfort of dressings. No Further information. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: single centre, inpatients. Length of study: 6 weeks of treatment or until completely healed. Assessment of PUs:	Group 1 Randomised N: 13 Completed N: 10 Dropouts: 3 (1 wound deterioration, 1 dressing/wound related problems, 1 was discharged) Age (median years; range): 73; 40-88 Gender (m/f): 4/9 Ulcer location: Sacrum: n=4 Buttock: n=8 Other: n=1 Duration PU (median days; range): 7; 2-14 Ulcer area (median cm^2; range): 1.4; 0.5-14.3 Group 2 Randomised N: 16 Completed N: 12 Dropouts: 4 (3 wound deterioration, 1 dressing/wound related problems) Age (median years; range): 74; 40-95 Gender (m/f): 7/9	middle layer consists of an absorbent microporous polyurethane membrane, and the outer layer is vapourpermeable Group 2: Hydrocolloid dressing (GranuflexE®, Convatec). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge and before exudate had leaked, with a maximum of seven days. GranuflexE®: consists of an outer waterproof polyurethane foam bonded to a matrix of hydrocolloid particles and hydrophobic polymer. Both groups: Those patients who were not mobile were given support therapy to prevent additional PU. This included pressure relieving equipment and two to four hour turning schedules.	Outcome 4: Percentage of patient reporting painful removal of dressing Outcome 5: Percentage of patient reporting the dressing as (very) uncomfortable	P value: > 0.05 Group 1: figure unclear Group 2: figure unclear P value: < 0.005 Group 1: figure unclear Group 2: figure unclear P value: > 0.05	ITT analysis; no a priori sample size calculation; small sample size; no report on blinding; no report on multiple ulcers; no report in classification of PUs; little information on ulcer assessment and statistical analysis. Additional outcomes: time to dressing change, and ease of removal. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Wound size were carried out using a structured light method. Assessment took place at each dressing change. Classification of PUs: not reported Multiple ulcers: not reported	Ulcer location: Sacrum: n=6 Buttock: n=9 Other: n=1 Duration PU (median days; range): 5.5; 2-365 Ulcer area (median cm²; range): 2.4; 0.1-25.8 Inclusion criteria: 16 years or older; shallow, moist PU of grade II and III; ulcer could be covered by a single 10x10cm dressing; patients could be managed to prevent further lesions developing. Exclusion criteria: lesions that involved tissues other than skin and subcutaneous fat; grade I, IV and V PU; dry and necrotic lesions, patients could be included after debridement; taking systemic corticosteroids; dressed with either study dressing in the two weeks preceding the study; previous sensitivity reaction to either				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	dressings; infected PU; incapable of giving opinion on the dressing; urine or faecal incontinent with PU on sacrum or other sites likely to be soiled.				

Table 212: Banks 1994b[22]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Banks (1994b) **Title**: Comparing two dressings for exuding pressure sores in community patients. **Journal:** Journal of Wound Care, 3 (4); 175-178. Type of study: randomized controlled trial Sequence generation: computer generated random order. Allocation concealment: not reported. Blinding: not reported. Addressing incomplete	Patient group: Patients with a grade II or III PU. All patients Randomised N: 40 Completed N: 28 Drop-outs: 12 (2 wound deterioration, 2 overgranulation, 2 discomfort, 6 reasons unrelated to wound) Group 1 Randomised N: 20 Completed N: 18 Dropouts: 2 (1 was admitted to hospital, 1 died) Age (median years;	Group 1: Semi-permeable polyurethane dressing (Spyrosorb®, C.V. Laboratories Ltd). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge of the dressing. Spyrosorb®: inner layer consists of non-toxic, pressure sensitive adhesive wound contact surface, the middle layer consists of a microporous polyurethane membrane, and the outer layer is vapourpermeable Group 2: Hydrocolloid dressing (GranuflexE®, Convatec). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge of the dressing.	Outcome 1: Proportion of patient completely healed Outcome 2: Proportion of patient improved Outcome 3: Percentage of patient reporting painful removal of dressing Outcome 4: Percentage of patient reporting the dressing as (very)	Group 1: 12/18 Group 2: 10/10 Group 1: 18/18 Group 2: 10/10 Group 1: figure unclear Group 2: figure unclear P value: 0.129 Group 1: figure unclear Group 2: figure unclear P value: < 0.097	Funding: sponsored by C.V. Laboratories Ltd and Calgon Vestal Laboratories Limitations: no report on allocation concealment; no ITT analysis; no a priori sample size calculation; high dropout; no report on blinding; no report on multiple ulcers; no report in classification of PUs; little information on ulcer assessment

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: drop-out were excluded. Statistical analysis: The Mann-Whitney U test was used to compare ease of dressing removal, pain at removal, and comfort of dressings. No Further information. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: community. Length of study: 6 weeks of treatment or until completely healed. Assessment of PUs: Wound size measured using a structured light method to measure the area of the wound tracing. Classification of PUs: not reported. Multiple ulcers: not reported	range): 71; 40-100 Gender (m/f): 9/11 Ulcer location: Sacrum: n=4 Buttock: n=10 Other: n=6 Duration PU (median days; range): 56; 3-365 Ulcer area (mean cm² (SD); median; range): 1.47 (2.26); 0.67; 0.03-9.7 Group 2 Randomised N: 20 Completed N: 10 Dropouts: 10 (2 wound deterioration, 2 overgranulation, 2 discomfort, 2 died, 2 respite care) Age (median years; range): 73; 46-93 Gender (m/f): 12/8 Ulcer location: Sacrum: n=1 Buttock: n=9 Other: n=10 Duration PU (median days; range): 21; 5-252 Ulcer area (mean cm²	GranuflexE®: consists of a thin polyurethane foam sheet bonded onto a semi-permeable polyurethane film. Both groups: all patients were provided with standard pressure relieving mattresses and cushions appropriate to their needs.	uncomfortable		and statistical analysis. Additional outcomes: time to dressing change, and ease of removal. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	(SD); median; range): 1.51 (1.86); 0.74; 0.16-8.19 Inclusion criteria: 16 years or older; shallow, moist PU of grade II and III; ulcer could be covered by a single 10x10cm dressing; patients could be managed to prevent further lesions developing. Exclusion criteria: lesions that involved tissues other than skin and subcutaneous fat; grade I, IV and V PU; dry and necrotic lesions, patients could be included after debridement; taking systemic corticosteroids; dressed with either study dressing in the two weeks preceding the study; previous sensitivity reaction to either dressings; infected PU; incapable of giving opinion on the dressing; urine or faecal incontinent with PU on sacrum or other sites likely to be soiled.				

Table 213: Belmin 2002[28]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Belmin (2002) **Title**: Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects: A multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid dressings alone **Journal:** Journal of the American Geriatrics Society, 50 (2); 269-274 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: balanced by centre and by blocks of four patients Blinding: patients and nurses were not blinded; assessor was	Patient group: Hospitalized patients aged 65 years and older with a grade III or IV PU (according to the Yarkony's classification) All patients Randomised N: 110 Completed N: 72 Drop-outs: 38 (29 died, 3 transferred to another unit, 1 worsened in health status, 4 hade local adverse events, 6 had PU impairment) Group 1 Randomised N: 57 Completed N: 40 Dropouts: 17 (11 died, 1 transferred to another unit, 1 worsened in health status, 1 hade local adverse events, 3 had PU impairment) Age (mean years (SD)): 84.8 (7.1) Gender (m/f): 15/42 Norton score (mean (SD)):	Group 1: Calcium alginate dressing (UrgoSorb®,Urgo, France) for the first four weeks and hydrocolloid dressing (Algoplaque®HP, Urgo, France for the next four weeks. UrgoSorb®: nonwoven dressing composed of calcium alginate (brown seaweeds) fibres and carboxymethylcellulose. Algoplaque®HP: comprised an outer layer of polyurethane and an inner layer formed by an elastomere matric that included hydrocolloid molecules. In patients with deep PUs a hydrocolloid paste (Algoplaque Pâte) was added to the hydrocolloid dressing, but not to the calcium alginate dressing. Group 2: Hydrocolloid dressing (DuodermE®, Convatec-Bristol Myers Squibb, France) for eight weeks. DuodermE®: comprised an outer layer of polyurethane and an inner layer formed by an elastomere matric that included hydrocolloid	Outcome 1: proportion of patients reaching a 40% surface area reduction at 4 weeks. Outcome 2: proportion of patients reaching a 40% surface area reduction at 8 weeks. Outcome 3: mean cm² surface area reduction at 4 weeks. Outcome 4: mean cm² surface area reduction at 8 weeks. Outcome 5: percentage surface area reduction at 4 weeks. Outcome 6: percentage surface	Group 1: 39/57 Group 2: 12/53 P value: <0.0001 Group 1: 43/57 Group 2: 31/53 P value: <0.0001 Group 1: 7.0 (5.7) Group 2: 1.6 (4.9) P value: <0.001 Group 1: 9.7 (7.1) Group 2: 5.2 (7.2) P value: <0.001 Group 1: 47.3 (30.0) Group 2: 14.6 (39.7) P value: <0.001	Funding: funded by Laboratoires Urgo, Dijon, France Limitations: no report on sequence allocation; allocation concealment by block and centre; no blinding of patients and nurses. Additional outcomes: / Notes: DuodermE® is the same product as DuodermCGF® in the United Stades, Granulflex® in the United Kingdom, and Varihesive® in Germany. Algoplaque® is the same product as Sorbex® in the United Stades.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
blinded. Addressing incomplete outcome data: intention-to-treat analysis Statistical analysis: A comparison between groups were performed using chi-square test for qualitative parameters and the Mann-Whitney U test for quantitative variable. The percentage of patients reaching SAR40 was analysed by the Kaplan-Meier method, and treatment groups were compared using the logrank test. The evolution of SAR during the trial was analysed by repeated-measurement analysis of variance, to investigate the effect of time and treatment. Tests were bilateral, and the significance threshold was fixed at .05 Baseline differences: no statistical difference between groups except	13.2 (3.4) Number of incontinent patients: n=27 Ulcer grade: Grade III: n=40 Grade IV: n=16 Ulcer location: Heel: n=34 Sacrum: n=14 Pelvic: n=5 Other: n=4 Duration (mean weeks (SD)): 7.2 (6.8) Surface area (mean cm² (SD)): 14.7 (10.4) Group 2 Randomised N: 53 Completed N: 37 Dropouts: 16 Age (mean years (SD)): 82.2 (7.9) Gender (m/f): 17/36 Norton score (mean (SD)): 12.6 (3.1) Number of incontinent patients: n=26 Ulcer grade: Grade III: n=43 Grade IV: n=9	molecules. In patients with deep PUs a hydrocolloid paste (DuodermE Pâte) was added to the hydrocolloid dressing, but not to the calcium alginate dressing. Both groups: all ulcers were cleaned with a sterile saline, and the surrounding skin was dried before applying the dressings. General treatment (nutrition, medication, use of mattress and cushion) was decided by each investigator according to their usual procedure of care and the patients' health.	area reduction at 8 weeks. Outcome 7: proportion of patients with an infection Outcome 8: proportion of patients with erythema of the surrounding skin Outcome 9: proportion of patients with hypergranulation Outcome 10: proportion of patients with maceration Outcome 11: proportion of patients with bleeding	Group 1: 69.1 (33.9) Group 2: 42.6 (49.1) P value: <0.001 Group 1: 1/57 Group 2: 0/53 Group 1: 2/57 Group 2: 0/53 Group 1: 1/57 Group 2: 5/53 Group 1: 1/57 Group 2: 0/53	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
for concomitant diseases (diabetes and hypertension) Study power/sample size: The size of the study was designed to allow the detection of 35% difference between the groups, with a 5% alpha risk and an 80% power Setting: 20 French geriatric hospital wards Length of study: eight weeks Assessment of PUs: Ulcer surface area was measured by planimetry after cleansing and drying. A sterile transparent polyurethane film was applied to the target ulcer, and the investigator traced its perimeter with a permanent ultra-fine-tipped marker. A photography of the ulcer was taken. Surface area was measured un triplicate, using a digitalization table and	Ulcer location: Heel: n=37 Sacrum: n=11 Pelvic: n=2 Other: n=3 Duration (mean weeks (SD)): 7.7 (6.6) Surface area (mean cm² (SD)): 12.6 (8.0) Inclusion criteria: 65 years and older; PU that passed the subcutaneous tissue (grade III or IV); PU located on the sacrum, elsewhere on the pelvic girdle, or on the heel; surface area < 50cm²; granulation tissue area not covered > 50% of the ulcer surface; no clinical evidence of active local infection. Exclusion criteria: serum albumin < 25g/L; treated with radiotherapy, cytotoxic drugs or corticosteroids; surgical or palliative care needed.			Group 1: 1/57 Group 2: 0/53	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
computer program, and the mean value was used in the analysis. Classification of PUs: Yarkony's classification. Multiple ulcers: Only one ulcer was selected for the study					

Table 214: Bito 2012[30]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Bito (2012) **Title**: Randomised controlled trial evaluating the efficacy of wrap therapy for wound healing acceleration in patients with NPUAP stage II and III pressure ulcer. **Journal:** BMJ, 2; 1-8 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: an allocation centre	Patient group: Hospitalized patients aged 50 years and older with a stage II or III PU (according to the NPUAP classification) All patients Randomised N: 66 Completed N: 39 Drop-outs: 27 (5 died, 20 withdrew, and two were transferred or discharged; the last two were not included in the analysis) Group 1 Randomised N: 35	Group 1: Wrap therapy (food wraps and perforated polyethylene) was used as dressing. The irrigation and covering process was performed every day. Group 2: treated with methods conform the 'Evidence-based localized pressure ulcer treatment guidelines' issued by the JSPU in 2005 Both groups: /	Outcome 1: mean time (days) until complete healing (all stages) Outcome 2: mean time (days) until complete healing (stage II PUs) Outcome 3: mean time (days) until complete healing (stage III PUs) Outcome 4: mean difference in PUSH score (points)	Group 1: 59.8 (95% CI: 49.7-69.9) Group 2: 57.5 (95% CI: 45.2-69.8) P value: 0.75 Group 1: 18.8 (95% CI: 10.3-27.2) Group 2: 16.0 (95% CI: 8.1-23.9) P value: 0.42 Group 1: 63.2 (95% CI: 53.0-73.4) Group 2: 71.8 (95% CI: 61.4-82.3) P value: 0.42	Funding: This study was supported by Division of the Health for the Elderly at Japanese Ministry of Health, Labour and Welfare. Grant name 'Examination and Research Work into New Pressure Ulcer Treatments for the Care of the Elderly'. Limitations: no report on sequence allocation; allocation

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
located received a fax from the health staff with basic information on the patient. A fax with the allocation result was send back to the facility within 48h. Blinding: patients and nurses were not blinded; assessor was blinded. Addressing incomplete outcome data: intention-to-treat analysis. Two patients were excluded from the analysis after randomization because of early transfer or discharge. Statistical analysis: For the main endpoint comparisons, Kaplan Meier plots were created, and the estimated mean value until the endpoint occurrence and its 95% CI were calculated. The differences in the PUSH scores were calculated from 2 weeks immediately after the	Completed N: 23 Dropouts: 12 (2 died and 10 withdrew) Age (mean years (SD)): 81 (12) Gender (m/f): 16/19 Braden score (mean (SD)): 12.7 (2.8) Number of patients using a pressure relieving mattress: 35 Ulcer stage: Stage II: n=4 Stage III: n=31 PUSH score (mean (SD)): 10.7 (2.7) Surface area (mean cm² (SD)): 15 (25) Group 2 Randomised N: 31 Completed N: 16 Dropouts: 15 (3 died, 10 withdrew and 2 transferred or were discharged; the last 2 were not included in the analysis) Age (mean years (SD)): 82 (10) Gender (m/f): 15/14		Outcome 7: proportion of patients who died Outcome 8: proportion of patients with systemic worsening Outcome 9: proportion of patients with localised adverse events Outcome 10: pain during dressing removal assessed by nurses Outcome 11: strong odor during dressing removal assessed by nurses Outcome 12: mild odor during dressing removal assessed by nurses	Group 1: 0.9 (1.3) Group 2: 1.1 (2.1) P value: 0.73 Group 1: 2/35 Group 2: 3/29 Group 1: 4/35 Group 2: 3/29 Group 1: 6/35 Group 2: 7/29 Group 1: 411/1314 Group 2: 316/887 Group 1: 173/1314 Group 2: 178/887	concealment questionable; no blinding of patients and nurses; sample size lower than calculated sample size; complete healing assessed by clinical, no further information; no report on multiple ulcers Additional outcomes: ease od removal of dressing as assessed by nurses (G1: 1214/1314; G2: 802/887) Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
start of observations, between 2-4 weeks, 4-6 weeks, 6-8 weeks, 8-10 weeks and 10-12 weeks and described the speed of pressure ulcer healing over time for both groups. We used PASW Statistics V.18 (SPSS, Inc) for the statistical analysis. Baseline differences: no statistical difference between groups except for use of ointments or sprays and used dressings at baseline. Study power/sample size: A sample size of 80 patients per group was required at a tolerable threshold difference of 7 days, a 5% significance level and a power of 90%. The final sample size was lower than the calculated sample size. Setting: 15 hospitals in Japan related to the Japanese Society of Pressure Ulcers (JSPU) Length of study: 12	Braden score (mean (SD)): 12.8 (3.5) Number of patients using a pressure relieving mattress: 27 Ulcer stage: Stage II: n=8 Stage III: n=21 PUSH score (mean (SD)): 10.8 (2.6) Surface area (mean cm² (SD)): 14 (21) Inclusion criteria: 50 years and older; NPUAP stage II or III PU on either their torso or trochanter; body temperature of 35.5°C minimum to 37.5°C maximum; 600 kcal or over daily intake; no critical nutritional impairment, renal failure, cirrhosis, immunosuppression, uncontrollable diabetes or malignant tumours according to an examination performed			Group 1: 382/1314 Group 2: 361/887	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weeks or until PU healed Assessment of PUs: . Every ulcer heal was confirmed by supervising physicians using photographs. The PUSH score for the localised status of the PU was measured by using photographs. Classification of PUs: NPUAP classification Multiple ulcers: not reported	within past 4 weeks. Exclusion criteria: Patients with an estimated life expectancy < 3 months				

Table 215: Brod 1990[37]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Brod (1994a) **Title**: A randomized comparison of poly-hema and hydrocolloid dressings for treatment of pressure sores. **Journal:** Archives of Dermatology, 126 (7); 969-970. Type of study:	Patient group: Elderly patients with a grade II or III PU. All patients Randomised N: 43 Completed N: 38 Drop-outs: 5 (3 died, 1 poor response, 1 adverse effect)	Group 1: Polyhydroxyethyl methacrylate (poly-hema) dissolved in polyethylene glycol (Hydron® , Acme/Chaston Division, National Patient Development Corp, Dayville, Conn). Dressing was applied as a paste, which solidified to a flexible dressing countered to the ulcer. Dressings were changed twice weekly. Group 2: Hydrocolloid dressing	Outcome 1: Proprotion of patient completely healed Outcome 2: Median time (days) to complete healing Outcome 3: Absolute rate of	Group 1: 14/27 Group 2: 10/16 P-value: 0.54 Group 1: 32 Group 2: 42 P-value: 0.56 Group 1: 0.18	Funding: supported in part by a grant from Acme/Chaston Division, National Patient Development Corp, Dayville, Conn Limitations: insufficient information on

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
randomized controlled trial Sequence generation: 60:40 to G1 and G2. Allocation concealment: stratified by lesion stage. Blinding: blinding of outcome assessor. Addressing incomplete outcome data: intention-to-treat analysis* Statistical analysis: Not reported. Baseline differences: Difference between groups was measured statistically for ulcer area (not significant) only. Groups were balanced. Study power/sample size: No a priori sample size calculation. Setting: academic skilled nursing facility, the Parker Jewish Geriatric Institute, New Hyde Park, NY. Length of study: 6 weeks of treatment.	Group 1 Randomised N: 27 Completed N: 25 Dropouts: 2 (2 died) Age (median years): 86 Ulcer area (median cm²): 2.5 Group 2 Randomised N: 16 Completed N: 13 Dropouts: 3 (1 died, 1 poor response, 1 adverse effect) Age (median years): 82 Ulcer area (median cm²): 1.9 Inclusion criteria: stage II or III PU; life expectancy > 6 months; normal marrow, hepatic, and renal function. Exclusion criteria: /	(DuoDerm®, Convatec, ER Squibb & Sons, Princeton, NJ). Dressing was applied as a sheet with an adhesive backing. Dressings were changed twice weekly. Both groups: Surgical debridement was performed before randomization.	healing (cm²/week) Outcome 4: Proportion of patients with an adverse effect (unknown if dressing related)	Group 2: 0.10 P value: 0.005 Group 1: 0/27 Group 2: 1/16 P value: < 0.005	sequence generation; insufficient information on allocation concealment; no a priory sample size calculation; small sample size; no blinding of nurses and patients; no report on multiple ulcers; little information on ulcer assessment; no information on statistical analysis; unclear if ITT or PP analysis was used; no information on use of preventive measures Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Stage II/III PU were seen as inflammatory reaction extending through the dermis or into the subcutaneous fate. Ulcers size and condition were evaluated weekly. Classification of PUs: not reported. Multiple ulcers: not reported					

Table 216: Brown-Etris 2008[38]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Brown-Etris (2008) **Title**: A prospective, randomized, multisite clinical evaluation of a transparent absorbent acrylic dressing and a hydrocolloid dressing in the management of Stage II and shallow Stage III pressure ulcers. **Journal:** Advances in skin & wound care, 21 (4); 169-174	Patient group: Patients aged 18 years and older with a stage II or shallow III PU. All patients Randomised N: 72 Completed N: not reported Drop-outs: not reported Group 1 Randomised N: 35 Completed N: not	Group 1: Transparent absorbent acrylic dressing (3M Tegaderm® Absorbant Clear Acrylic Dressing, 3M Company, St Paul, MN) was used and changed on an as-needed basis by the facility staff and once a week by the investigator. Group 2: Hydrocolloid dressing (DuoDermCGF®, ConvaTec, ER Squibb & Sons, Princeton, NJ) was used and changed on an as-needed basis by the facility staff and once a week by the investigator.	Outcome 1: percentage difference in ulcer area Outcome 2: proportion of patients completely healed Outcome 3: linear healing rate (cm/week) Outcome 4:	Group 1: 26.7 Group 2: 23.8 Group 1: 21/35 Group 2: 22/37 P value: 0.963 Group 1: 0.10 (0.205) Group 2: 0.12 (0.136) P value: 0.652	Funding: funded by a grand from 3M company Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priori sample size calculation; difference between

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported. Blinding: no blinding. Addressing incomplete outcome data: not reported. Statistical analysis: Descriptive statistics were calculated for all variables. The Wilcoxon rank-sum test (a nonparametric equivalent to the t test) was used to test for differences between the treatment groups. Significance was assessed at P≤05, and trends toward significance were assessed at P≤10 Baseline differences: no statistical difference between groups except ulcer location. Study power/sample size: No a priori sample	reported Dropouts: not reported Age (mean years (SD)): 78.3 (14.7) Gender (m/f): 13/22 Braden score (mean (SD)): 14.9 (3.38) History of incontinence: n=23 Ulcer stage: Stage II: n=23 Stage III: n=12 Duration of PU (median; range): 21.0; 1-291 Ulcer location: Sacrum: n=15 Buttock: n=2 Ischium: n=5 Heel: n=4 Other: n=9 Surface area (mean cm² (SD)): 1.5 (1.69) Group 2 Randomised N: 37 Completed N: not reported Dropouts: not reported Age (mean years (SD)): 72.7 (18.61)	Both groups: /	adverse events (unrelated to dressing) Outcome 5: overall patient comfort assessed by investigator (points: 1 very poor – 5 very good) Outcome 6: odor assessed by investigator (points: 1 very poor – 5 very good)	Group 1: 10/35 Group 2: 8/37 Group 1: 4.8 (0.34) Group 2: 4.4 (0.66) P value: 0.048 Group 1: 5.0 (0.14) Group 2: 4.8 (0.39) P value: 0.016	groups concerning PU location at baseline; no report on drop-out and number of patient completing the study Additional outcomes: ease of application (G1: 4.7 (0.57); G2: 4.5 (0.51); p=0.122) Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size calculation. Setting: five study sites across extended care facilities, out-patient wound care clinics, and home agencies Length of study: 56 days or until PU healed Assessment of PUs: Ulcers and periwound assessments were performed by the investigator at enrolment and nearly weekly. Photographs and ulcer tracings were obtained at time of enrolment and at dressings changes completed by the investigator. Classification of PUs: not reported. Multiple ulcers: only one ulcer (the ulcer with the highest PU stage or if same stage, the ulcer with the largest surface area) was considered in the study.	Gender (m/f): 19/18 Braden score (mean (SD)): 15.0 (3.42) History of incontinence: n=24 Ulcer stage: Stage II: n=22 Stage III: n=15 Duration of PU (median; range): 32.0; 2-635 Ulcer location: Sacrum: n=7 Buttock: n=12 Ischium: n=7 Heel: n=4 Other: n=7 Surface area (mean cm² (SD)): 2.5 (4.86) Inclusion criteria: Stage II or shallow Stage III, minimally to moderately draining pressure ulcer on any anatomical location that, in the investigator's opinion, could have been treated with an HD; patients with ulcers that could be paired with a size/configuration of study dressings to have a				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	periwound skin margin consistent with the manufacturer's package insert instructions; patients with pressure relief needs that were properly assessed and addressed Exclusion criteria: Patients with skin disease or abnormal conditions on or near the product application site; patients with insulin-dependent diabetes that, in the investigator's opinion, had inadequately controlled blood sugar; patients who were receiving steroid, immunosuppressive therapy, or radiation to the area where the pressure ulcer was located; patients with a history of hypersensitivity to adhesive tapes or adhesive wound dressings; patients who were participating in another clinical research study; wounds with more than 50% necrotic tissue or, in the opinion of the				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	investigator, should have undergone debridement before application of an occlusive or semiocclusive dressing; wounds with greater than 1-cm undermining or tunneling; wounds that required use of a filling or packing material; wounds that required the dressing to be cut to a smaller size or to a specialty shape; wounds that exhibited clinical infection as evidenced by purulent, malodorous, or recent increase in drainage and/or periwound erythema, or elevated temperature, or required treatment with a concomitant medication or product				

Table 217: BurgoS 2000[40]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Burgos, (2000) **Title**: Cost, Efficacy,	Patient group: Patients > 5 years presenting with stage III	Group 1: Collagenase ointment (Iruxol® Mono, Laboratorios Knoll, SA) applied once daily in	Outcome 1: Proportion of PU with reduction in	Group 1: 15/18 (83.3%) Group 2: 14/19 (73.7%)	Funding: this study was supported by Labotorios Knoll,

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Efficiency and Tolerability of Collagenase Ointment versus Hydrocolloid Occlusive Dressing in the Treatment of Pressure Ulcers **Journal:** Clin Drug Invest, 2000; 19 (5): 357-365 Type of study: randomized non-blinded parallel group study Sequence generation: Computer generated randomization list into blocks of 4 patients Allocation concealment: no details Blinding: Blinding of assessor Addressing incomplete outcome data: intention-to –treat analysis a per protocol analysis Statistical analysis: Efficacy analysis ITT was carried out using Student's t-test and the Mann-Whitney U test.	pressure ulcers (skin disruption, tissue damage and exudate, and subcutaneous tissue involvement) All patients Randomised N: 37 Completed N: 23 Drop-outs: 14 Reasons in group 1: unrelated death (N=3); discharge from hospital (N=3); transfer to other centre (N=3); Reasons in group 2: unrelated death (N=1); deterioration of general condition (N=1); discharge from hospital (N=1); protocol violation (N=2); ack of efficacy (N=1) Group 1 Randomised N: 18 Completed N: 9 Dropouts: 9 Age (mean years (SD)): 81.9 + 12.7 Gender (m/f): 8/10 Amell scale score (range):	a 1 to 2 mm thick layer to the ulcer bed Group 2: Hydrocolloid dressing (Varihesive®, Convatec, SA) that was changed every 3 days. If hydrocolloid dressings showed leakage due to excessive exudate, dressings were changed more frequently. Varihesive® paste was applied to deep ulcers or ulcers with a large amount of exudate according to the investigator's judgment. Both groups: /	pressure ulcer area after 12 weeks of treatment Outcome 2: Proportion of PU with complete healing of pressure ulcer after 12 weeks of treatment Outcome 3: Mean reduction in ulcer area after 12 weeks of treatment (cm2) Outcome 4: Pain intensity decrease Outcome 5: Patients with adverse reactions	Relative risk: 1.13 95% CI: 0.81-1.59 P value:0.754 Group 1: 3/18 (16.6%) Group 2: 3/19 (15.8%) Relative risk: 1.06 95% CI: 0.24-4.57 P value:0.451 Group 1: 9.1 + 12.7 Group 2: 6.2 + 9.8 P value:0.369 P value: 0.001 Group 1: 1/18 Group 2: 2/19 Relative risk: 0.53 95% CI: 0.05-5.33	SA, Madrid Limitations: Underpowered Unclear allocation concealment Not all outcome assessors were blinded Relatively high drop-out No baseline differences reported. Additional outcomes: No significant differences were observed in cost and efficiency between collagenase ointment and hydrocolloid dressing in the treatment of pressure ulcers. Granulation tissue formulation increased (p>0.0005) and

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Efficacy analysis PP was carried out using factorial analysis of variance 2X9 with repeated measurements of the last factor. Primary outcome measure, ulcer area decrease in absolute terms expressed in cm2, was obtained by subtracting ulcer area at the end of the study treatment from baseline ulcer area. Similarly, differences in percentages of mean ulcer areas in both treatment groups were calculated according to the formula (σt-σs/σt) x 100, where σt is the mean value obtained from transparent acetate films and σs is the mean value obtained from the slides. The statistics used were the t-test for mean equality. Analysis of ulcer characteristics was carried out using the Friedman test for	17.7 + 3.4 Ulcer age : 3.2 + 2.0 months Previously treated ulcers (No. (%)): 15 (83.33) Localisation (no. (%)): Sacrum: 8 (44.44) Trochanter: 4 (22.22) Heel: 3 (16.66) Other: 3 (16.66) Group 2 Randomised N: 19 Completed N: 13 Dropouts: 6 Age (mean years (SD)): 78.6 + 10.4 Gender (m/f): 9/10 Amell scale score (range): 20.2 + 5.9 Ulcer age (range): 2.6 + 1.9 months Previously treated ulcers (No. (%)): 17 (89.47) Localisation (no. (%)): Sacrum: 7 (36.84) Trochanter: 4 (21.05) Heel: 6 (31.57) Other: 2 (10.53)				exudate production decreased (p>0.0005) in both treatment groups. Odour was not modified throughout the study period.* *no concrete data provided Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
longitudinal analysis and the Mann-Whitney U test for cross-sectional analysis. The number and percentage of patients presenting ulcer bacterial colonization and the location of colonized ulcers were analyzed by chi-square test and Fisher's exact test. Analysis of tolerability was carried out by calculating the relative risk of adverse reaction occurrence. Statistical significance was set at $p<0.05$. Baseline differences: Not reported Study power/sample size: No a priori sample size calculation Setting: 7 hospitals in Spain Length of study: 12 weeks of treatment or until healing of the ulcer, whichever occurred first Assessment of PUs:	Inclusion criteria: 55 y; Stage III ulcer for < 1 year Exclusion criteria: End-stage organ disease; localized or systemic signs or symptoms of infection; hypersensitivity to collagenase				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Indirect procedure: After placing an adhesive identification label at one of its margins, the ulcers were photographed according to a standardized method at 50 cm from the focus. The slide of each ulcer was projected and focused in such a way that the size of the attached label matched the actual label size (2.5 cm x 5 cm), and then the contour of each ulcer was transferred to a transparent acetate film. Direct procedure: Were performed by tracing the outline of each ulcer perimeter onto on adequately labelled transparent acetate film. Total surface area of the ulcers was calculated using planimetry (HAFF-Planimeter no. 315, Gebrüder Haff, Germany, calibrated for measurements in cm2).					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Examinations were made at 1-week intervals. Ulcer characteristics were measured on a 5-point scale and included: Pain (no pain, minimal, bearable,intense, unbearable) % granulation tissue (< 10%, 11 to 30%, 31 to 60%, 61 to 90%, > 90%) Exudate (none, minimal, moderate, intense, excessive) Odour (none, minimal, tolerable, intense, repulsive) Classification of PUs: not reported. Multiple ulcers: No details Unit of analysis is the patient. However no patient had more than one pressure ulcer.					

Table 218: Chang 1998[47]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year:	Patient group: Patients	Group 1: Hydrocolloid dressing	Outcome 1: Mean	Group 1: 34	Funding: funded by

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Chang (1998) **Title**: Pressure ulcers-randomised controlled trial comparing hydrocolloid and saline gauze dressings. **Journal:** The Medical Journal of Malaysia, 53 (4); 428-431. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported. Blinding: no blinding. Addressing incomplete outcome data: no drop-out. Statistical analysis: Overall performance, pain, adherence, comfort, ease of removal was analysed by Wilcoxon Rank Sum Test. Rates of wound healing was analysed by Analysis of Variance Test. Baseline differences: No	aged 18 years and older with a stage II or III PU. All patients Randomised N: 34 Completed N: 34 Drop-outs: 0 Age (mean years; range): 57.6; 20-85 Incontinence: Urine: n=5 Faecal: n=16 Both: n=4 Ulcer stage: Stage II: n=23 Stage III: n=12 Duration of PU (mean days; range): 33; 4-274 Ulcer location: Sacrum: n=30 Ilium: n=3 Greater trochanter: n=1 Group 1 Randomised N: 17 Completed N: 17 Dropouts: 0 Ulcer stage: Stage II: n=11	(DuoDermCGF®). Dressings were changed every seven days or when leakage occurred. Cavity were filled with hydrocolloid gel (DuoDerm Hydroactive Gel®). DuoDermCGF®: occlusive dressing, which is under the influence of wound exudate and provides a moist wound environment. The outer later is made of polyurethane foam which is impermeable. Group 2: Wet soaked saline gauze dressing. The saline dressing was covered with a Gamgee® pack. Dressings were changed once a day or when exudate is visible through the second dressing. Both groups: /	reduction (%) in ulcer area Outcome 2: percentage of patients reporting a dressing as uncomfortable Outcome 3: percentage of patients reporting moderate/severe pain during dressing removal Outcome 4: proportion of patients reporting with an infection	Group 2: -9 P value: 0.23 Group 1: 0 Group 2: 50 P value: <0.01 Group 1: 0 Group 2: 44 P value: <0.01 Group 1: 0/17 Group 2: 1/17	a grand from 3M company Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no a priori sample size calculation; difference between groups concerning PU location at baseline; no report on drop-out and number of patient completing the study Additional outcomes: Ease of use (G1: 62% vs G2: 19; p<0.01) Cost per subject (mean dressing time and mean nursing cost): G1: RM 45.89 vs G2: RM105.30; p=0.025

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistical difference between groups except ulcer location. Study power/sample size: No a priori sample size calculation. Setting: University hospital Kuala Lumpur. Length of study: 8 weeks of treatment or until complete healing. Assessment of PUs: . Wound tracings of ulcer perimeter were made at each dressing change by moulding a piece of clear plastic food wrap over the ulcer and into the ulcer cavity. The tracings were then transferred onto acetate transparencies using an Optomax Image Analyzer. Colour photographs were also taken. Assessments were done weekly. Classification of PUs: not reported Multiple ulcers: only one PU per	Stage III: n=6 Group 2 Randomised N: 17 Completed N: 17 Dropouts: 0 Ulcer stage: (3 missings) Stage II: n=7 Stage III: n=7 Inclusion criteria: Stage II or III PU; at least 18 years of age; provide written informed consent Exclusion criteria: Immunocompromised; infected PU; known sensitivity to the study dressings				Cost per subject (mean dressing time, mean nursing cost, and total cost material): G1: RM 271.45 vs G2: RM 173.05; p=0.12 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
patient was eligible for study entry.					

Table 219: Chuangsuwanich 2011[49]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Chuansuwanich (2011) **Title**: The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers. **Journal:** Journal of the Medical Association of Thailand, 94 (5); 559-565 Type of study: randomized controlled trial Sequence generation: randomly by computer Allocation concealment: not reported. Blinding: no blinding. Addressing incomplete outcome data: no missing reported Statistical analysis: All	Patient group: In- and out-patients with a grade III or IV PU (according to the NPUAP 1989 classification). All patients Randomised N: 40 Completed N: 40 Drop-outs: 0 Group 1 Randomised N: 20 Completed N: 20 Dropouts: 0 Age (mean years (SD)): 62.60 (20.59) Gender (m/f): 8/12 Duration of PU (mean days (SD)): 232.00 (180.52) Ulcer location: Sacrum: n=16 Greater trochanter: n=1	Group 1: Silver mesh dressing (Tegaderm® Ag Mesh dressing) after wound bed cleansing. Cotton gauze was used as outer dressing. Dressings were changed every three days. Group 2: Silver sulfadiazine cream after wound bed cleansing. Cotton gauze was used as outer dressing. Dressings were changed twice a day. Both groups: Wounds were debrided as necessary.	Outcome 1: mean healing rate (%) at eight weeks Outcome 2: percentage reduction in PUSH score at eight weeks Outcome 3: complications	Group 1: 36.95 Group 2: 25.06 P value: 0.507 Group 1: 28.15 Group 2: 34.51 P value: 0.473 Group 1: 0/20 Group 2: 0/20	Funding: / Limitations: no report on allocation concealment; no blinding; no a priori sample size calculation and small sample size Additional outcomes: cost was calculated (drug cost + outer dressing cost x time of dressing change/20). G1: 263 USD per patient; G2: 1812 USD per patient; p=0.00 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
data analysis was performed using SPSS 13.0. Data were expressed as mean ± standard deviation (SD). Comparison of the mean between two groups of all parameters was evaluated for the significance by non-parametric Mann-Whitney U-test before treatment and at eight week of treatment. A p-value of less than 0.05 was considered significant. Baseline differences: no statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: Siriraj Hospital Length of study: eight weeks Assessment of PUs: Ulcer size was determined by using VISITRAKR Wound measurement system	Ischium: n=3 Surface area (mean cm² (SD)): 12.17 Group 2 Randomised N: 20 Completed N: 20 Dropouts: 20 Age (mean years (SD)): 69.10 (16.02) Gender (m/f): 9/11 Duration of PU (mean days (SD)): 197.40 (131.65) Ulcer location: Sacrum: n=14 Greater trochanter: n=5 Ischium: n=1 Surface area (mean cm² (SD)): 22.82 Inclusion criteria: Grade III or grade IV Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and wound photography at the beginning en very two weeks. The PUSH score was assessed every two weeks. Classification of PUs: NPUAP classification (1989). Multiple ulcers: not reported					

Table 220: Colin 1996[51]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Colin (1996) **Title**: Managing sloughy pressure sores. **Journal:** Journal of wound care; 5(10):444-446 Type of study: Open, multicentre, multinational, parallel group, prespective and randomized investigation Sequence generation:	Patient group: Patients were considered eligible for entry into the study if they met strict inclusion and exclusion criteria. All patients Randomised N: 135 Completed N: 96 Drop-outs: 39 (adverse incidents (n=5); patient died (n=4); lost to follow up (n=30))	Group 1: The hydrogel (Intrasite Gel) contains a high proportion of water that has been formulated to allow donation of water molecules to the wound surface in order to rehydrate non-viable tissue and maintain a moist wound environment Group 2: The dextranomer paste product (Debrisan Paste) contains polysaccharide beads that are hydrophilic and draw moisture away from the wound surface by capillary action, and is capable of drawing non-viable debris from the wound	Outcome 1: Reduction in pressure sore area (median and range) Outcome 2: Side effects	Group 1: Day 7: 8% (-100 to 75%) Day 14: 23% (-100 to 83%) Day 21: 35% (-185 to 91%) Group 2: Day 7: 0% (-340 to 92%) Day 14: 5% (-340 to 98%) Day 21: 7% (-340 to 98%) P value: p=0.03 at day 21 Group 1: 1/67 Group 2: 4/68 Relative risk: 3.94 95% CI:0.45-34.35	Funding: / Limitations: No inclusion or exclusion criteria formulated; no blinding or randomization method reported Additional outcomes: The median percentage reduction in non-viable tissue was

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
No details Allocation concealment: No details Blinding: no blinding Addressing incomplete outcome data: Intention to treat analysis Statistical analysis: Wound area (cm²) = maximum length (cm) * maximum width (cm) * π/4; area of non-viable tissue (cm²) = wound area*(% yellow + % black)*1/100. The difference in treatments with respect to the percentage reduction in slough from day zero to day 21 was assessed using the Wilcoxon Rank Sum Test. Baseline differences: The two treatment groups were well matched for age, the median being 79 years. In three of the centres several young patients with spinal injuries were	Group 1 Randomised N: 67 Completed N: 53 Dropouts: 14 (adverse incidents (n=1); patient died (n=2); lost to follow up (n=11)) Age: 79 (25-97) Gender (m/f): (28/39) Other relevant patient characteristics: Duration <1 month (n=24); 1-3 months (n=28); >3 months (n=15) Area <4cm² (n=15); 4-13 cm² (n=25); >13cm² (n=27) Grade 1 (n=0); grade 2 (n=16); grade 3 (n=38); grade 4 (n=13) Non-viable tissue area <3cm² (n=15); 3-9cm² (n=24); <9cm² (n=28) Group 2 Randomised N: 68 Completed N: 43 Dropouts: 25 (adverse incidents (n=4); patient died (n=2); lost to follow	bed. Both groups: Both types of dressings were applied and changed according to manufacturers' instructions. The secondary dressing used for both treatment groups was a non-occlusive absorbent dressing (melolin).		There were a total of five adverse events reported during the clinical investigation, one in the amorphous hydrogel group and four in the dextranomer paste group. The only one that was considered to be dressing-related was pain when the dressing was applied reported by a patient in the dextranomer paste group.	74% in the amorphous hydrogel group compared with 62% in the dextranomer paste group. The difference of 12% between the two median values at day 21 was not statistically significant. In the hydrogel group 19% was fully debrided, 30% between 75 and 99% debrided; 18% between 50 and 74% debrided; 13% between 15-49% debrided; 7% between 0-25% debrided (considered as non-responders) and 12% deteriorated. In the dextranomer paste group 21% was fully debrided, 22% between 75 and 99% debrided; 19% between 50

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
included, resulting in a lower median age for these centres. Patients numbers were approximately equal in all six trial centres. There were slightly more women (54%) then men (46%) treated in the study. Study power/sample size: The sample size was set at 120 patients, based on a requirement to be sensitive to a difference of 25% in absolute two treatment groups. Setting: Six centres Length of study: Patients were treated in the study until the wound was fully cleansed or on completion of 21 days' treatment. Patients could be withdrawn from the study for other reasons, for example, patient choice, investigator's discretion, lost to follow-up,	up (n=19)) Age: 81 (25-98) Gender (m/f): (34-34) Other relevant patient characteristics: Duration <1 month (n=22); 1-3 months (n=35); >3 months (n=11) Area <4cm² (n=18); 4-13 cm² (n=25); >13cm² (n=25) Grade 1 (n=1); grade 2 (n=10); grade 3 (n=45); grade 4 (n=12) Non-viable tissue area <3cm² (n=18); 3-9cm² (n=27);<9cm² (n=23) Inclusion criteria: Not reported Exclusion criteria: Not reported				and 74% debrided; 9% between 15-49% debrided; 10% between 0-25% debrided (considered as non-responders) and 19% deteriorated. Assessments were made at day seven, 14 and 21. At each assessment the amorphous hydrogel was found to be easier to apply and remove than the dextranomer paste and was also found to be associated with less pain. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
adverse events. Assessment of PUs: A formal wound assessment and an evaluation of dressing characteristics was performed every 7 days. Photographs of each sore were taken at the initial and final assessment. Data on patient comfort were assessed subjectively; data on ease of application were assessed subjectively on a four-point scale from "very easy" to "very difficult". Classification of PUs: Agency for Healthcare Policy and Research (1992) and International Association of Exterostomal Therapy (1987). Multiple ulcers: Where patient presented more than one pressure sore, only the largest sore was assessed as part of this study.					

Table 221: Colwell 1993[52]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Colwell (1993) **Title**: A comparison of the efficacy and cost-effectiveness of two methods of managing pressure ulcers. **Journal:** Decubitus, 6 (4); 28-36 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported. Blinding: no blinding. Addressing incomplete outcome data: missing were removed from analysis. Statistical analysis: t-test, chi-square and repeated measure ancova were used. Baseline differences: Statistical difference between groups for ulcer stage.	Patient group: Hospitalized patients aged 18 years and older with a stage II and/or III PU. All patients Randomised N: 94 Completed N: 70 Drop-outs: 24 (12 died, 5 were discharged, 5 were lost to the study, 2 were dropped as they had MRSA, 1 progressed to stage IV PU) Group 1 Randomised N: not reported Completed N: 33 with 48 ulcers Dropouts: not reported; an equivalent number of patients dropped in both groups Age (mean years (SD); range): 68; 18-100 Gender (m/f): 18/15 Number of incontinent patients: Faeces: n=16	Group 1: Hydrocolloid wafer dressing (DuoDerm®CGFTM) was used and changed every four days or as needed. DuoDerm®CGFTM: occlusive, sterile, control gel formula that consists of an outer layer of polyurethane foam and an adhesive inner layer of a hydrocolloid polymer complex. Group 2: moist gauze dressing was used and changed every 6 hours or as needed. Moist gauze dressing: sterile dressing consisting of a layer of fluffed, sterile gauze bandages moistened with 0.9% sodium chloride solution. The dressing was secured with hypoallergenic paper tape. Both groups: Cleansing procedure was the same for both groups and was used at each dressing change. All patients were positioned on a pressure-reducing or -relieving surface (e.g. 4" foam overlay or a low air-loss bed)	Outcome 1: mean difference (cm²) in ulcer area Outcome 2: proportion of ulcers completely healed	Group 1: 0.73 Group 2: -0.67 Group 1: 11/48 Group 2: 1/49 P value: 0.963	Funding: funded by a grand from 3M company Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priori sample size calculation; difference between groups concerning PU stage at baseline; high drop-out; no information on randomized patients and ulcers to the intervention groups Additional outcomes: average cost (supply cost + labour associated with time difference): G1: $53.68 per case

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: No a priori sample size calculation. Setting: a university-affiliated tertiary care centre Length of study: minimum eight days of treatment. Range: 6-56 days. Assessment of PUs: Total healing was assessed as complete covering with epithelial tissue. The size of the ulcer was determined by tracing the outline of the wound perimeter on a transparent acetate film placed over the ulcer perimeter. Wound perimeters were traced every fourth day. The total surface area of the ulcer was calculated using an electronic planimeter, which provided a digital readout. Physical measurements of the width and length	Urine/faeces: n=6 Ulcer stage: Stage II: n=33 Stage III: n=15 Duration of PU (of 46 ulcers; 2 missings): < 1 month: n=25 1-3 months: n=21 Ulcer location: Sacrum/coccyx: n=29 Other: n=19 Surface area (mean cm²): 2.29 Ulcer length (range cm): 1.0-20.6 Ulcer width (range cm): 0.4-9.5 Group 2 Randomised N: not reported Completed N: 37 with 49 ulcers Dropouts: not reported; an equivalent number of patients dropped in both groups Age (mean years (SD); range): 68; 29-92 Gender (m/f): 19/18				versus G2: $176.90 per case Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
of the PU using a centimetre guide were also obtained every fourth day Classification of PUs: not reported. Multiple ulcers: 70 patients had 97 wounds	Number of incontinent patients: Faeces: n=23 Urine/faeces: n=6 Ulcer stage: Stage II: n=21 Stage III: n=28 Duration of PU (of 46 ulcers; 3 missings): < 1 month: n=27 1-3 months: n=19 Ulcer location: Sacrum/coccyx: n=27 Other: n=22 Surface area (mean cm²): 2.37 Ulcer length (range cm): 1.4-12.1 Ulcer width (range cm): 0.6-10.0 Inclusion criteria: non-infected stage II and/or III PU Exclusion criteria: presence of any factor that adversely influence wound healing such as uncontrolled diabetes or radiation therapy; presence of clinical signs				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	and symptoms indicating the PU was clinically infected; stage I or IV PU; PU that could not be accurately staged; minimum of eight days in the study				

Table 222: Darkovich 1990[59]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Darkovic (1990) **Title**: Biofilm hydrogel dressing: a clinical evaluation in the treatment of pressure sores. **Journal:** Ostomy/wound management, 29; 47-60. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: No	Patient group: Patients with a stage I or II PUs (according to the Enis and Sarmienti 1973 classification). All patients Randomised N: 90 patients and 129 ulcers Completed N: not reported Drop-outs: not reported Age (mean years; range): 75; 30-98 Gender (m/f): 35/55 Group 1 Randomised N: 41 patients and 62 ulcers Completed N: not	Group 1: Hydrogel (BioFilmTM, BF Goodrich Company). The ulcers were cleaned with normal saline, the surrounding skin was dried, and the dressing was applied. Dressing were changed based on clinical judgement with an average of every three to four days. Group 2: Hydrocolloid (DuoDerm®, ConvaTec, Division of Bristol-Myers Squibb). The ulcers were cleaned with normal saline, the surrounding skin was dried, and the dressing was applied. Dressing were changed based on clinical judgement with an average of every three to four days. Both groups: All patients were	Outcome 1: Proportion of ulcers completely healed Outcome 2: Proportion of ulcers improved Outcome 3: Proportion of ulcers with no change Outcome 4: Proportion of ulcers worsened Outcome 5: Mean percentage	Group 1: 24/62 Group 2: 12/67 Group 1: 56/62 Group 2: 52/67 Group 1: 5/62 Group 2: 8/67 Group 1: 1/62 Group 2: 7/67	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no a priori sample size calculation; difference between groups not statistically measured; drop-outs and use of ITT unclear; little information on patient characteristics; no report on

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
report on intention to treat analysis. Wounds were treated for a maximum of 60 days, complete healing, discharge or judgement of the clinical to change treatment. No information on the number of patients and wound for the two latter situations. Six patients were eliminated from the analysis, unclear how many wounds this included. Statistical analysis: Two methods of analysis were utilized: student t-test and multiple regression. The student –t-test was used to compare average and standard deviations between groups and considers variation within groups. A t exceeding 2.0 approximates a significant difference at 95% confidence. With multiple regression, algebraic mathematical	reported Drop-outs: not reported Ulcer stage: Stage I: n=27 Stage II: n=35 Surface area (mean cm²): 11.0 Group 2 Randomised N: 49patients and 67 ulcers Completed N: not reported Drop-outs: not reported Ulcer stage: Stage I: n=31 Stage II: n=36 Surface area (mean cm²): 9.2 Inclusion criteria: Stage I or II PU; no venous stasis ulcers or diabetic ulcers; lesions ranging in size from at least 0.2 to 100cm²; PU on sacrum, trochanter, lower extremities, buttocks, scapula, and heels; no radiotherapy; blood sugar level <180mg/dl;	placed on a pressure reducing air mattress (Gaymar SofCare®)	ulcer area reduction in stage I ulcers Outcome 6: Mean percentage ulcer area reduction in stage II ulcers Outcome 7: Mean percentage ulcer area reduction in stage II ulcers and size between 2cm² and 20cm² Outcome 8: Healing rate (percentage/day) in stage II ulcers and size between 2cm² and 20cm² Outcome 9: Mean percentage ulcer area reduction in stage II ulcers and size between 2cm² and 20cm² (acute care	Group 1: 72 Group 2: 44 P value: > 0.05 Group 1: 64 Group 2: 34 P value: <0.01 Group 1: 72.3 Group 2: 38.1 P value: <0.01 Group 1: 8.1 Group 2: 3.1 P value: <0.01 Group 1: 80.0 Group 2: 15.1	debridement of ulcers. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
models are fitted to the results and the coefficients of the models were estimated by least squares. Baseline differences: Difference was not statistically measured. Study power/sample size: No a priori sample size calculation. Setting: two acute care facilities and several nursing homes. Length of study: maximum of 60 days, complete healing, discharge or judgement of the clinical to change treatment. Assessment of PUs: Ulcer tracings were taken and, in some cases, photography was used to supplement the tracing to determine the size of the ulcer. A Kundin gauge or metric ruler was used to measure the depth of the ulcer. Assessment was performed at each dressing change or at	improved nutritional status (receiving oral supplement, enteral feedings, TPN, PPN); no infection, sinus tracts or fistulae in the ulcer Exclusion criteria: /		setting) Outcome 10: Healing rate (percentage/day) in stage II ulcers and size between 2cm² and 20cm² (acute care setting)	P value: <0.0001 Group 1: 10.6 Group 2: 1.3 P value: <0.001	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
least weekly.. Classification of PUs: Enis and Sarmienti's classification (1973). Multiple ulcers: 129 ulcers in 90 patients. Ulcers were unit of analysis.					

Table 223: Day 1995[60]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Day (1995) **Title**: Managing sacral pressure ulcers with hydrocolloid dressings: results of a controlled, clinical study. **Journal:** Ostomy/wound management, 41 (2); 52-65. Type of study: randomized controlled trial Sequence generation: randomized schedule Allocation concealment: not reported Blinding: not reported.	Patient group: Patients with a stage II or III PU to the sacral area (according to the NPUAP 1989 classification). All patients Randomised N: 103 Completed N: 96 Drop-outs: 7 (lost to follow up shortly after study enrolment) Group 1 Randomised N: 52 Completed N: 47 Dropouts: 5 Age (mean years (SD)): 72	Group 1: Hydrocolloid triangular shape (DuoDerm® or DuoDermCGF® for US VarihesiveTM for Canada or GranuflexTM for UK, Bristol-Myers Squibb Company). Ulcers were cleaned with saline and the skin needed to be completely dried prior to application of the dressing. The dressing was applied in rolling motion and had to extend at least 1 inch beyond the wound edge. Group 2: Hydrocolloid oval shape (TegasorbTM, 3M Medical-Surgical Division, St Paul, MN). Ulcers were cleaned with saline and the skin needed to be completely dried prior to	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of patients improved Outcome 3: Proportion of patients with no change Outcome 4: Proportion of patients worsened Outcome 5:	Group 1: 17/47 Group 2: 11/49 Group 1: 41/47 Group 2: 31/49 Group 1: 4/47 Group 2: 3/49 Group 1: 2/47 Group 2: 15/49	Funding: / Limitations: insufficient information on sequence allocation; no report on allocation concealment; no blinding; no a priori sample size calculation; difference between groups not statistically measured except for two variables; no report on debridement of

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Addressing incomplete outcome data: Intention to treat analysis except patients who didn't completed a minimum of two dressings change (n=7; G1: 5 and G2: 2). Statistical analysis: Analysis of variance was utilized to assess variables when responses were normally distributed. Categorical and ordinal data were analyzed using Fischer's exact test respectively and the Wilcoxon Rank Sum test respectively. A aired t-test was utilized to compare change from baseline for ulcer length and width. All tests were performed at the 0.05 level of significance utilizing the Statistical Analysis System (SAS). Baseline differences: Difference was statistically measured for age and height (not significantly different). Study power/sample	(16) Gender (m/f): 27/20 Diabetes: 10 Activity level: Ambulant: n=0 Some ambulant: n=8 Mainly sitting: n=19 Recumbent: n=20 Incontinence: Urine: n=3 Faecal: n=9 Both: n=12 Ulcer stage: Stage II: n=38 Stage III: n=9 Duration of PU: < 1 month: n=43 1-3months: n=4 months: n=0 > 6 months: n=0 Ulcer length (mean cm (SD)): 2.93 (1.96) Ulcer width (mean cm (SD)): 2.24 (1.89) Group 2 Randomised N: 51 Completed N: 49 Dropouts: 2	application of the dressing. The dressing was applied in rolling motion and had to extend at least 1 inch beyond the wound edge. Both groups: Pressure reducing mattress or bed were provided if necessary (70% G1 and 73% G2)	Mean percentage ulcer length reduction Outcome 6: Mean percentage ulcer width reduction Outcome 7: Mean pain at dressing change Outcome 8: Proportion of patients reporting ulcer pain at and of the study Outcome 9: Proportion of patients with adverse events (dressing related)	Group 1: 32 Group 2: 17 P value: 0.034 Group 1: 28 Group 2: 24 P value: >0.05 Group 1: 2.1 (2.1); range: 1-10 Group 2: 4.3 (1.75); range: 2-9 Group 1: 8/47 Group 2: 15/49 P value: <0.05 Group 1: 0/47 Group 2: 4/49 (increase in necrotic tissue, wound size and depth, inflammation of surrounding skin, severe pain upon dressing removal, and bleeding P value: 0.012	ulcers; no report on multiple ulcers Additional outcomes: Number of dressing changes: G1: 197 vs G2: 201 Average wear time in continent and incontinent patients Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: No a priori sample size calculation. Setting: eight different acute care hospitals in the United States, United Kingdom and Canada. Length of study: six dressings or until complete healing. Assessment of PUs: The ulcer was assessed and measured utilizing a centimeter ruler prior to the first application and every subsequent dressing change. Photographs were taken at every dressing change. Classification of PUs: NPUAP classification (1989). Multiple ulcers: not reported.	Age (mean years (SD)): 78 (13) Gender (m/f): 64 (3.7) Diabetes: 11 Activity level: Ambulant: n=4 Some ambulant: n=3 Mainly sitting: n=19 Recumbent: n=23 Incontinence: Urine: n=3 Faecal: n=11 Both: n=15 Ulcer stage: Stage II: n=41 Stage III: n=8 Duration of PU: < 1 month: n=39 1-3months: n=7 months: n=2 > 6 months: n=1 Ulcer length (mean cm (SD)): 2.97 (1.68) Ulcer width (mean cm (SD)): 1.73 (1.19) Inclusion criteria: Stage II or III PU; legally consenting; PU at sacral				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	area Exclusion criteria: signs and symptoms of wound infection; treated with systematic steroid; condition that impairs healing (e.g. AIDS); receiving concomitant topical or local treatment that could not be interrupted; chronic skin conditions or hypersensitivity to the skin adhesives; participation in similar study one month prior to this study; previous use of tested dressings.				

Table 224: Felzani 2011[73]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Felzani (2011) **Title**: Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients. **Journal:** Advances in Therapy, 28 (5); 439-445	Patient group: Hospitalized patients aged 18 years and older with stage I, II or III PUs (according to the NPUAP classification). All patients Randomised N: 59 patients and 63 ulcers	Group 1: Hyaluronic acid, Lys-HA (Lysial®, Fatai-Nyl Srl, Jasper LLC, Lugano, Switzerland). Ulcers were cleansed with saline and the cream was applied as a thin layer across the ulcer surface. The ulcer was covered with a fat gauze and on top of that a sterile gauze. Group 2: Sodium hyaluronate.	Outcome 1: Percentage of ulcer area healed at 15 days in stage I PUs Outcome 2: Percentage of ulcer area healed at 15 days in stage II PUs	Group 1: 90 Group 2: 70 P value: < 0.05 Group 1: 70 Group 2: 40 P value: < 0.02	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no ITT analysis; on report on required

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: blinding of nurses, outcome assessor and statistician. Unclear if patients were blind to the allocation but products were provided in identical containers. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis: Data are expressed as average ±1 standard deviation or as percentage where appropriate. Data were assessed to evaluate normal distribution according to the Kologorov–Smirnov test. The two-tailed Student t test for matched data was used in order to test	Completed N: 50 patients and 54 ulcers Drop-outs: 9 (3 were discharged, 2 worsened and required antibiotics, 2 were suspended from the study treatment) Characteristics of completed N: Age (mean years (SD)): 56 (7) Gender (m/f): 21/29 Diabetes: n=9 Ulcer stage: Stage I: n=20 Stage II: n=20 Stage III: n=14 (two subjects had two ulcers and one subject had three ulcers) Group 1 Randomised N: not reported Completed N: 17 ulcers Dropouts: not reported BMI (mean kg/m² (SD)): 27.4 (2.8) Ulcer stage: Stage I: n=10	Ulcers were cleansed with saline and the cream was applied as a thin layer across the ulcer surface. The ulcer was covered with a fat gauze and on top of that a sterile gauze. Both groups: Necrotic tissue were removed with gauze and macerated skin borders were surgically removed. Dressings were used on top of the standard therapy for cutaneous lesions.	Outcome 3: Percentage of ulcer area healed at 15 days in stage III PUs Outcome 4: Time (days) to 50% reduction in ulcer diameter in stage I PUs Outcome 5: Time to 50% reduction in ulcer diameter in stage II PUs Outcome 6: Time to 50% reduction in ulcer diameter in stage III PUs	Group 1: not reported Group 2: not reported P value: <0.01 Group 1: 9 Group 2: 15 P value: < 0.05 Group 1: 9.5 Group 2: 15 P value: < 0.05 Group 1: 12.9 Group 2: 19.2 P value: < 0.05	sample size, despite calculation; difference between groups not statistically measured; no report on preventive measures of ulcers Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
pretreatment and posttreatment differences in each group. The difference between groups was tested by analysis of covariance (ANCOVA), utilizing basis values as constant covariates. A value of P<0.05 was accepted as level of statistical significance. Baseline differences: Difference was not measured statistically. Study power/sample size: Sample size was calculated according to the hypothesis that there should be a 30% difference between the two preparations (the Lys-HA and the SH groups) at the primary endpoint: time taken to reach a 50% reduction of the skin lesion diameter. Setting: one hospital Length of study: 15 days of treatment. Assessment of PUs: Ulcer size (length, and	Stage II: n=10 Stage III: n=7 Group 2 Randomised N: not reported Completed N: 17 ulcers Dropouts: not reported BMI (mean kg/m² (SD)): 26.9 (3.1) Ulcer stage: Stage I: n=10 Stage II: n=10 Stage III: n=7 Inclusion criteria: Older than 18; hospitalized for a period of 15 days or longer; PU grade I, II or III Exclusion criteria: patients who could not cooperate with the hygienic measures; patients with a history of intolerance to hyaluronic acid.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
width) location, condition, duration and stage were measured. Ulcers were digitally photographed, including a reference ruler was taken before the treatment start, then every 3 days during the study period, and at the end of the study. The picture was taken with an 8-megapixel digital camera with digital zoom. Classification of PUs: NPUAP classification Multiple ulcers: 50 patients and 54 ulcers					

Table 225: Graumlich 2003[85]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Graumlich (2003) **Title**: Healing pressure ulcers with collagen or hydrocolloid: A randomized, controlled trial. **Journal:** Journal of the American Geriatrics	Patient group: Patients aged 18 years and older with a stage II or III PU (according to the NPUAP 1994 classification). All patients Randomised N: 65	Group 1: Type I collagen dressing (Medifil®, Kollagen, BioCore, Topeka, KS) covered with dry gauze. Changed daily. Group 2: Hydrocolloid (DuoDerm®; ConvaTec, ER Squibb & Sons, Inc. Princeton, NJ) and perimeter was rimmed with tape. Changed every four	Outcome 1: proportion of patients completely healed at eight weeks Outcome 2: Mean healing time (weeks) (complete	Group 1: 18/35 Group 2: 15/30 P value: 0.893 Group 1: 5 (95% CI: 4-6) Group 2: 6 (95% CI: 5-7)	Funding: BioCore Medical Technologies, Topeka, Kansas, donated the collagen product used in the trial. A grant from the Retirement

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Society, 51 (2); 147-154 Type of study: randomized controlled trial Sequence generation: computerized random number generator. Assignment was in a 1:1 ratio Allocation concealment: stratified (diabetes) and block (4 and 10) design. Assignment by personnel unassociated with trial. Blinding: blinding of outcome assessor. Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: For categorical variables, comparisons involved chi-square or Fisher exact tests. Comparisons for continuous variables employed t tests or Mann-Whitney tests when appropriate. Two-sided P values less than .05 were considered	Completed N: 54 Drop-outs: 11 (5 died, 3 were hospitalized, 1 withdrew, 2 were lost to follow-up) Ulcer location: Sacrum/coccyx: n=34 Heel: n=12 Ankle: n=8 Group 1 Randomised N: 35 Completed N: 29 Dropouts: 6 (3 died, 1 withdrew, and 2 were hospitalized) Age (mean years (SD)): 82.0 (9.9) Gender (m/f): 13/22 Braden score (mean (SD)): 12 (3) Ulcer stage: Stage II: n=29 Stage III: n=6 Duration of PU (median weeks (25%, 75%)): 3.0 (1.6, 8.0) Surface area (median mm² (25%, 75%)): 121 (63, 338) Ulcer depth (median mm	days Both groups: All ulcers were irrigated with sterile saline before applying the dressing. Ancillary wound treatment were prohibited.	healing) Outcome 3: Mean area healed per day (mm²/day) Outcome 4: Percentage healing rate within eight weeks Outcome 4: Adverse events related to study treatment as assessed by physicians	P value: 0.409 Adj for depth: P value: 0.229 Group 1: 6 (19) Group 2: 6 (16) P value: 0.942 Group 1: 33% Group 2: 9% P value: 0.197 Group 1: 0/35 Group 2: 0/30	Research Foundation, Chicago, Illinois, paid for other study supplies and paid partial salary support for the investigators. Limitations: no blinding of patient and nurses; sample size lower than calculated Additional outcomes: The multivariate logistic regression model entered stage, depth, duration, and area. In the model, only ulcer depth remained a significant predictor of complete healing within 8 week. Exploratory analyses related ulcer stage, ulcer

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
significant. Adjustment for multiple comparisons involved the Bonferroni inequality. Analysis of time to complete healing used survival methods. Pairwise comparisons between groups employed the log-rank test with event rates calculated by the Kaplan-Meier method. Exploratory logistic regression analyses evaluated the relationship between the primary endpoint and covariates identified by literature review. Covariates included the following variables associated with pressure ulcer development: age, weight, blood pressure, Braden score, dementia, diabetes mellitus, nursing home, and sex. Covariates associated with ulcer healing were area, depth, age, and	(25%, 75%)): 1 (0, 2) Group 2 Randomised N: 30 Completed N: 25 Dropouts: 5 (2 died, 2 were lost to follow-up, and 1 was hospitalized) Age (mean years (SD)): 80.6 (12.2) Gender (m/f): 11/19 Braden score (mean (SD)): 13 (3) Ulcer stage: Stage II: n=23 Stage III: n=7 Duration of PU (median weeks (25%, 75%)): 6.5 (2.0, 12.0) Surface area (median mm² (25%, 75%)): 174 (50, 436) Ulcer depth (median mm (25%, 75%)): 0 (0, 3) Inclusion criteria: Older than 18; at least one pressure ulcer stage II or III Exclusion criteria: hypersensitivity to collagen or bovine				duration, ulcer area, and diabetes to healing was performed. After adjustment for these variables (individually), there was no significant difference in healing time between collagen and hydrocolloid. Average cost was [acquisition cost + (labor cost per hour x hours per dressing change x dressing changes per week x 8 weeks) + (ancillary supplies cost per dressing change x dressing changes per week x 8 weeks)]: G1: $627.56 per patient versus G2: $222.36 per patient. Sensitivity analysis did not reveal likely conditions in which the cost analysis

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
stage. Covariates chosen from recommendations of expert consensus were serum albumin and ulcer duration before enrollment. Variables significant at the .10 level were examined further in a multivariate model with forward and backward stepwise procedures (SPSS for Windows, Release 9.0.0, SPSS Inc., Chicago, IL). Baseline differences: No statistical difference between groups. Study power/sample size: The sample size estimate assumed that 24% difference in healing rates was clinically important (alpha 0.05 and 80% power). The estimated sample size was 58 patients per group, and estimated dropout rate was 10%. After adjusting sample size for	Products; concomitant investigational therapy; previous enrollment in the trial; osteomyelitis, cellulitis or malnutrition, ulcers covered by eschar or necrotic material (rescreened after successful debridement); ulcers covered by orthopedic casts or devices; burn ulcers; diabetic foot ulcers distal to tarsals; life expectancy less than 8 week; anticipated transfer to acute care within 8 weeks.				would favor collagen. Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
dropouts, the total sample size was 128 patients. The final sample size was lower than calculated. Setting: 11 skilled nursing facilities in central Illinois Length of study: eight weeks of treatment, with a median follow-up of 35 days. Assessment of PUs: Ulcer are and perimeter were assessed by using photography with a computer-aided system with image capture and morphometric software. During each study visit, the observers used validated, standardized techniques to record ulcer length, width, and appearance. The center ulcer depth (in mm) was measured with a sterile probe. Classification of PUs: NPUAP (1994).					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: only one ulcer per patient was included in the study.					

Table 226: Günes 2007[93]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Günes (2007) **Title**: Effectiveness of a honey dressing for healing pressure ulcers. **Journal:** Journal of Wound, Ostomy and Continence Nursing, 34 (2); 184-190. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: no blinding. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis: Data are analysed using the Statistical Package for	Patient group: Hospitalized patients aged 18 years and older with stage II or III PUs (according to the US Agency for Health Care Research and Quality's PU Guideline Panel classification). All patients Randomised N: 27 patients Completed N: 26 patients and 50 ulcers Drop-outs: 1 (died) Ulcer stage: Stage II: n=2 Stage III: n=48 Group 1 Randomised N: 15 patients and 25 ulcers	Group 1: Honey dressing (3.8% concentration, and sterilized at 25kGy Gamma irradiation). Ulcers were irrigated with NaCl0.9% at each dressing change. A gauze dressing impregnated with honey (20ml) was used as a primary dressing. A semipermeable adhesive dressing was used as secondary dressing to prevent leakage of honey. Dressings were changed once daily or when contaminated with urine or faeces. Group 2: Ethoxydiaminoacridine and nitrofurazone dressing. Ulcers were cleaned with ethoxydiaminoacridine solution (0.1%) and a nitrofurazone cream was spread to the surface of the wound. A gauze dressing soaked with ethoxydiaminoacridine covered	Outcome 1: Mean percentage decrease in PUSH score Outcome 2: Mean percentage reduction in ulcer size Outcome 3: Proportion of ulcers completely healed Outcome 4: Proportion of patients with adverse events attributed to the treatment	Group 1: 12.62 (2.15) Group 2: 6.55 (2.14) P value: < 0.001 Group 1: 56 Group 2: 13 P value: < 0.001 Group 1: 5/25 Group 2: 0/25 P value: < 0.001 Group 1: 0/15 Group 2: 0/11	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priori sample size calculation Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
the Social Sciences (Version 11.0 for Windows). PUSH scores were used to characterize PU healing. Chi-square analysis was conducted to compare wound and patient demographics by groups. Repeated anova were calculated to compare PU healing in both groups. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: one university hospital in Izmir Length of study: maximum five weeks of treatment or until complete healing. Assessment of PUs: Ulcers were made by standard acetate hand tracing. Ulcer characteristics were documented via the PUSH instrument. Measurements were	Completed N: 15 patients and 25 ulcers Dropouts: 0 Age (mean years (SD)): 65.80 (6.30) Gender (m/f): 9/6 BMI (mean kg/m² (SD)): 27.2 (1.38) Mobility level (mean score (SD)); score 1 to 4, with 1 greater impairment: 1.20 (0.40) Group 2 Randomised N: 12 patients Completed N: 11 patients and 25 ulcers Dropouts: 1 (died) Age (mean years (SD)): 66.56 (5.53) Gender (m/f): 8/3 BMI (mean kg/m² (SD)): 26.4 (1.40) Mobility level (mean score (SD)); score 1 to 4, with 1 greater impairment: 1.32 (0.47) Inclusion criteria: Older than 18; life	the ulcer. A semipermeable adhesive dressing was used as secondary dressing. Dressings were changed once daily or when contaminated with urine or faeces. Both groups: all patients received preventive skin regimen (a turning and repositioning program and a pressure relieving mattress)			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
carried out at baseline and on each weekly visit. The total score ranged from 0 to 17, with 0 representing a healed wound. Classification of PUs: Agency Health Care Research and Quality's Pressure Ulcer Guideline Panel classification (1994) Multiple ulcers: 26 patients with 50 ulcers were included.	expectancy > 2 months Exclusion criteria: diabetes mellitus				

Table 227: Hollisaz 2004[99]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Hollisaz (2004) **Title**: A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings for the treatment of pressure ulcers [ISRCTN33429693]. **Journal:** BMC Dermatology, 4 (1); 18-26	Patient group: Patients with a spinal cord injury and a stage I or II PU (according to the NPUAP or Shea classification) All patients Randomised N: 83 patients with 91 ulcers Completed N: 83 patients with 91 ulcers Drop-outs: 0	Group 1: Hydrocolloid adhesive dressing was used after cleaning and washing (3 times with normal saline) of the ulcer. The adhesive dressing was changed twice a week. Group 2: Phenytoin cream was used after cleaning and washing (3 times with normal saline) of the ulcer. A thin layer was applied to the ulcer before the dressing was performed. The dressing was changed	Outcome 1: proportion of ulcers complete healed after eight weeks (all stages; all sites) Outcome 2: proportion of ulcers complete healed after eight weeks (stage I; all sites)	Group 1: 23/31 Group 2: 12/30 Group 3: 8/30 P value G1 vs G2: <0.01 P value G1 vs G3: <0.005 Group 1: 11/13 Group 2: 2/9 Group 3: 5/11 P value G1 vs G2: <0.005	Funding: The study was supported by the Jaonbazan Medical and Engineering Research Center, the medical and research section of the official governmental body responsible for SCI war victims.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: random number table was used. The statistician in the team generated the random allocation sequence. Allocation concealment: stratified randomization (ulcers stage and location) was used. The statistician delivered the treatment category in an opaque sealed envelope bearing only the number of the patient. Blinding: outcome assessor blinding. Addressing incomplete outcome data: no drop-out. Statistical analysis: All the data collected from the patients' preliminary and complementary questionnaires were analyzed by SPSS software using ANOVA	Group 1 Randomised N: 28 patients with 31 ulcers Completed N: 28 patients with 31 ulcers Dropouts: 0 Age (mean years (SD)): 36.81 (6.71) Gender (m/f): 28/0 Duration of PU (mean weeks (SD)): 7.63 (5.59) Ulcer stage: Stage I: n=13 Stage II: n=18 Ulcer location: Gluteal: n=6 Ischial: n=18 Sacral: n=7 Surface area (mean cm² (SD)): 7.26 (15.4) Group 2 Randomised N: 28 patients with 30 ulcers Completed N: 28 patients with 30 ulcers Dropouts: 0 Age (mean years (SD)): 36.5 (4.99)	daily. Group 3: Simple dressing was used after cleaning, washing (3 times with normal saline) and drying of the ulcer with a sterile gauze. The ulcer was covered with wet saline gauze dressing and was changed twice a day. Both groups: all ulcers were debrided before treatment. No concomitant topical or systematic antibiotic, glucocorticoid or immunosuppressive agent were allowed during the treatment.	Outcome 3: proportion of ulcers complete healed after eight weeks (stage II; all sites) Outcome 4: proportion of ulcers complete healed after eight weeks (all stages; gluteal) Outcome 5: proportion of ulcers complete healed after eight weeks (all stages; ischial) Outcome 6: proportion of ulcers complete healed after eight weeks (all stages; sacral) Outcome 7: proportion of ulcers partially	P value G1 vs G3: <0.05 Group 1: 12/18 Group 2: 10/21 Group 3: 3/19 P value G1 vs G2: >0.05 P value G1 vs G3: <0.005 Group 1: 6/6 Group 2: 2/7 Group 3: 1/8 P value G1 vs G2: <0.005 P value G1 vs G3: <0.001 Group 1: 13/18 Group 2: 8/18 Group 3: 3/14 P value G1 vs G2: <0.1 P value G1 vs G3: <0.005 Group 1: 4/7 Group 2: 2/5 Group 3: 4/8 P value G1 vs G2: >0.35 P value G1 vs G3: >0.20	Limitations: no blinding of patients and nurses; sample size lower than calculated sample size Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and Chi square tests, and P-values of <0.05 were assumed significant. The 95% confidence intervals were also calculated and reported. For rare events (more than 20 percent of cross tabulation cells had values less than 5), Fisher's exact test was used. Based on stage and location of ulcers, subgroup analyses were performed using the same statistical tests. Baseline differences: no statistical difference between groups. Study power/sample size: A response rate of 30%, 40% and 80%w was assumed for SD, PC and HD, respectively. Based on a 40% difference, power of 0.85, 95% confidence level and estimated follow-up loss of 10%, 29 patients were required for each study	Duration of PU (mean weeks (SD)): 5.84 (8.04) Ulcer stage: Stage I: n=9 Stage II: n=21 Ulcer location: Gluteal: n=7 Ischial: n=18 Sacral: n=5 Surface area (mean cm² (SD)): 5.12 (3.63) Group 3 Randomised N: 27 patients with 30 ulcers Completed N: 27 patients with 30 ulcers Dropouts: 0 Age (mean years (SD)): 36.6 (6.17) Duration of PU (mean weeks (SD)): 5.25 (5.39) Ulcer stage: Stage I: n=11 Stage II: n=19 Ulcer location: Gluteal: n=8 Ischial: n=14 Sacral: n=8 Surface area (mean cm²		healed after eight weeks Outcome 8: proportion of ulcers worsened after eight weeks Outcome 9: proportion of patients completely healed after eight weeks (one ulcer per patient randomly drawn)	Group 1: 4/31 Group 2: 4/30 Group 3: 5/30 Group 1: 2/31 Group 2: 2/30 Group 3: 9/30 Group 1: 20/28 Group 2: 11/28 Group 3: 8/27 P value G1 vs G2: <0.01 P value G1 vs G3: <0.005	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
group. Final sample size lower than calculated. Setting: home care and long-term care centres Length of study: 8 weeks of treatment Assessment of PUs: The general practitioner filled in a questionnaire on ulcer status. One of the authors assesses complete/partial/without/worsening healing at the end of the study. Ulcer surface area was measured by tracing on an paper overly, which was scanned, redrawn and measured by AutoCAD 2000 Classification of PUs: NPUAP (1989) and Shea (1975) classification. Multiple ulcers: if a patient had more than one ulcer, all ulcers were treated by the same method. Ulcers were the unit of analysis.	(SD)): 10.27 (15.32) Inclusion criteria: Paraplegia caused by spinal cord injury; PU stage I or II according to Shea or NPUAP classification; informed consent; smoothness of ulcer area to establish whether adhesive could be used at the site Exclusion criteria: Addiction; heavy smoking (more than 20 cigarettes a day or more than 10 packs per year; concomitant chronic disease (e.g. diabetes mellitus or frank vascular disease such as Buerger's disease).				

Table 228: Hondé 1994[100]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Hondé (1994) **Title**: Local treatment of pressure sores in the elderly: Amino acid copolymer membrane versus hydrocolloid dressing. **Journal:** Journal of the American Geriatrics Society, 42 (11); 1180-1183. Type of study: randomized controlled trial Sequence generation: randomised list prepared by the Biometry group (using procedure Plan of the SAS package). Allocation concealment: not reported. Blinding: not reported. Addressing incomplete outcome data: all patient with at least one assessment after day 0 were included in the analysis with the last	Patient group: Hospitalized patients aged 65 years and older with a grade II, III or IV PU (according to the Shea classification) All patients Randomised N: 168 Completed N: 130 Drop-outs: 38 (10 local complications, and 28 reasons unrelated to the treatment such as discharge, death, transfer) Ulcer location: Foot: n=91 Sacrum: n=61 Trochanter: n=5 Shoulder: n=1 Elbow: n=1 Knee: n=4 Thigh: n=1 Back: n=3 Group 1 Randomised N: 80 Completed N: 66 Dropouts: 14 (4 local	Group 1: Amino acid copolymer membrane (InterpanTM, Synthélabo). Ulcers were cleansed with normal saline and dried at each renewal of dressings. Group 2: Hydrocolloid dressing (ComfeelTM, Coloplast). Ulcers were cleansed with normal saline and dried at each renewal of dressings. Both groups: All patients received standardized local care	Outcome 1: proportion of patients complete healed Outcome 2: Median healing time (days; range) Outcome 4: proportion of patient with infection	Group 1: 31/80 Group 2: 23/88 P value: 0.089 Group 1: 32; 13-59 Group 2: 38; 11-63 P value adj for wound depth: 0.044 Group 1: 6/80 Group 2: 6/88	Funding: Funded by Synthélabo Recherche Limitations: no report on allocation concealment; no report on blinding; no a priori sample size calculation; statistical difference between groups for age Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
observed carried forward technique. Statistical analysis: Statistical methods used included Student's t test, Fisher exact test, chi-square test, Wilcoxon test (survival curves), and 2-way anova. Wilcoxon was chosen to compare survival curves. Means throughout the paper are expressed as mean +/- SD. Baseline differences: Groups were not statistical different, except for age, which was not a significant factor in the survival curve. Study power/sample size: No a priori sample size calculation. Setting: multiple French hospitals Length of study: 8 weeks of treatment or until complete healing, whichever came first Assessment of PUs:	complications, and 10 reasons unrelated to the treatment such as discharge, death, transfer) Age (mean years (SD); range): 80.4 (8.2); 63-98 Gender (m/f): 26/54 Norton score (mean (SD)): 12.5 (3.2) Ulcer grade: Grade II: n=51 Grade III: n=24 Grade IV: n=5 Surface area (mean cm²): 8.99 Group 2 Randomised N: 88 Completed N: 64 Dropouts: 24 (6 local complications, and 18 reasons unrelated to the treatment such as discharge, death, transfer) Age (mean years (SD); range): 83.5 (7.8); 64-101 Gender (m/f): 21/67 Norton score (mean (SD)): 12.0 (3.0) Ulcer grade: Grade II: n=48				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Ulcer depth scores, and the area trace were measured. The area was determined rom this tracing by computer planimtery. A color photograph was taken at the initial visit and at each visit thereafter. Classification of PUs: Shea (1975) classification. Multiple ulcers: only one ulcer per patient was evaluated.	Grade III: n=35 Grade IV: n=5 Surface area (mean cm²): 6.85 Inclusion criteria: Hospitalized; 65 years or older; grade II to IV PU; less than 10 cm in diameter Exclusion criteria: signs and symptoms of clinical infection; necrotic PU; PU on irritated skin; Pu requiring surgery; PU extending to bone with risk of osteitis; patients on air-fluized beds.				

Table 229: Kaya 2005[111]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kaya (2005) **Title**: The effectiveness of a hydrogel dressing compared with standard management of pressure ulcers. **Journal:** Journal of Wound Care, 14 (1); 42-	Patient group: Hospitalized patients with a spinal cord injury and with PUs (according to the NPUAP classification) All patients Randomised N: 27 patients and 49 ulcers	Group 1: Hydrogel dressing (Elasto-GelTM, South-West Technologies, North Kansas City, Missouri, USA). Dressings were changed every four days, or more if membrane became contaminated or non-occlusive. Group 2: Povidone-iodine soaked gauze dressings which	Outcome 1: Mean healing rate (cm²/day; range)	Group 1: 0.12 (0.16); 0.02-0.36 Group 2: 0.09 (0.05); 0.03-0.23 P value: 0.97	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no report on drop-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
44 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: not reported. Statistical analysis: The Mann-Whitney U test was used to compare arithmetic means and differences between groups. All statistical analyses were performed using SPSS Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: Hospital. Length of study: Not reported Assessment of PUs:	Completed N: not reported Drop-outs: not reported Group 1 Randomised N: 15 patients and 25 ulcers Completed N: not reported Dropouts: not reported Age (mean years (SD); range): 35.27 (14.57) Ulcer grade: Grade I: 6 Grade II: 17 Grade III: 2 Ulcer location: Sacral: n=7 Ischia: n=6 Heel: n=6 Greater trochanter: n=3 Knee: n=1 Lateral malleolus: n=2 Ulcer area (mean cm² (SD); range): 4.13 (2.73) Group 2 Randomised N: 12 patients and 24 ulcers Completed N: not	were changed every daily. Both groups: necrotic areas were mechanically debrided			outs; no report on blinding; little information on ulcer assessment and statistical analysis; no information on preventive measures. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Ulcers were measured in cm². The surface area was evaluated every four days until epithelisation was complete. Classification of PUs: NPUAP classification.Multiple ulcers: 27 patients with 49 ulcers.	reported Dropouts: not reported Age (mean years (SD); range): 29.67 (6.41); 17-39 Ulcer grade: Grade I: 6 Grade II: 17 Grade III: 1 Ulcer location: Sacral: n=6 Ischia: n=3 Heel: n=2 Greater trochanter: n=4 Iliac cest: n=4 Knee: n=2 Fibula: n=2 Foot: n=1 Ulcer area (mean cm² (SD); range): 6.45 (6.88); 2-35 Inclusion criteria: SCI patient; PU Exclusion criteria: /				

Table 230: Kerihuel 2010[114]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kerihuel (2010) **Title**: Effect of activated charcoal dressings on healing outcomes of chronic wounds. **Journal:** Journal of Wound Care, 19 (5); 208-215 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: Randomisation was by blocks of four. Identical sealed boxes containing the allocated dressings were randomly allocated to each patient. Blinding: outcome assessor blinding. Addressing incomplete outcome data: intention-to-treat analysis Statistical analysis: Scale variables are presented as mean ±	Patient group: Hospitalized patients with a stage III or IV PU (according to the Yarkoni classification). All patients Randomised N: 60 Completed N: 46 Drop-outs: 15 (5 had wound stagnation, 1 had septicaemia, 3 died, 2 were discharged, 1 had a wound infection, 1 had a hip fracture, 1 had a wound graft, 1 withdrew) One patient was not included in the analysis despite ITT because no information was available on wound tracing (died two days after randomisation) Group 1 Randomised N: 29 Completed N: 22 Dropouts: 7 (3 had wound stagnation, 1 had septicaemia, 1 died, 2	Group 1: Charcoal dressing (Actisorb® without silver). The wounds were cleansed with sterile saline only and dressings were changed two or three times a week or when needed. Group 2: Hydrocolloid (DuoDerm®, ConvaTec). The wounds were cleansed with sterile saline only and dressings were changed two or three times a week or when needed. Both groups: Standardized PU management strategies (regular repositioning and use of pressure-redistributing surfaces) were applied to all patients.	Outcome 1: Median reduction in ulcer area (cm²; range) at 4 weeks Outcome 2: Median percentage reduction (%; range) in ulcer size at 4 weeks Outcome 3: Proportion of patients with maceration Outcome 4: Proportion of patients with ulcer infection Outcome 5: Proportion of patients with ulcer aggravation Outcome 6: Proportion of patients with overgranulation	Group 1: -4.3 (-31.2-13.8) Group 2: -3.1 (-24.1-46.0) Group 1: -26.9 (-82-97.9) Group 2: -18.5 (-100-260.9) Group 1: 0/29 Group 2: 2/30 Group 1: 1/29 Group 2: 2/30 Group 1: 0/29 Group 2: 1/30	Funding: / Limitations: no report on sequence allocation; no blinding of patient and nurses; no a priori sample size calculation; no statistical calculation of difference between groups at baseline; high drop-out (ITT); small sample size Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
standard deviation or as median (range). Absolute and relative changes in ulcer area were compared between groups at weeks 1, 2, 3 and 4 using the non-parametric Mann-Whitney U test. No adaptation of the alpha risk for repeated testing was used. Ordinal and nominal variables were compared using either the chi-square test or Fisher's exact test. SPS software was used. A p value of less than 5% (<0.05) was considered as indicating statistical significance. Baseline differences: Difference not statistically measured. Groups were comparable Study power/sample size: No a priori sample size calculation. Setting: six hospitals Length of study: four	were discharged) Age (mean years (SD)): 83.2 (13.2) Gender (m/f): 5/24 BMI: > 30: n=1 20-29: n=26 < 19: n=2 Duration of PU: > 1 month: n=15 > 3 months: n=3 Ulcer location: Sacrum: n=4 Heel: n=22 Other: n=3 Surface area (mean cm²; median): 25.3 (24.6); 17.5 Group 2 Randomised N: 31 Completed N: 23 Dropouts: 8 (2 had wound stagnation, 2 died, 1 had a wound infection, 1 had a hip fracture, 1 had a wound graft, 1 withdrew) Age (mean years (SD)): 78.5 (16.5) Gender (m/f): 9/21 BMI:		Outcome 7: Proportion of patients with eczema Outcome 8: Proportion of patients with pruritus Outcome 9: Proportion of patients with wound pain Outcome 10: Proportion of patients with skin irritation Outcome 11: Proportion of patients with bleeding at dressing removal Outcome 12: Proportion of patients with pain at dressing change	Group 1: 0/29 Group 2: 1/30 Group 1: 0/29 Group 2: 1/30 Group 1: 1/29 Group 2: 0/30 Group 1: 0/29 Group 2: 0/30 Group 1: 0/29 Group 2: 0/30 Group 1: 0/29 Group 2: 0/30	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weeks of treatment. Assessment of PUs: Ulcer was traced and photographed, and the exudate level and ulcer bed characteristics were assessed. Classification of PUs: Yarkoni classification (1994). Multiple ulcers: only one ulcer was included per patient.	> 30: n=3 20-29: n=19 < 19: n=8 Duration of PU: > 1 month: n=15 > 3 months: n=1 Ulcer location: Sacrum: n=6 Heel: n=20 Other: n=4 Surface area (mean cm²; median): 22.6 (18.4); 16.0 Inclusion criteria: PUs with an area ranging from 5 to 100cm²; PUs of less than three months' duration; PUs graded IIc or IV on the Yarkoni classification; PUs considered by investigators to have abundant necrotic tissue and slough (covering >50% of the wound surface) Exclusion criteria: Inability to give written consent to participate; severe illness; Pus totally covered with necrotic			Group 1: 19/29 Group 2: 19/30	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	tissue or requiring surgical debridement; infected ulcers requiring systemic antibiotics; known allergy to the study dressing; previous use of Actisorb				

Table 231: Kim 1996[116]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kim (1996) **Title**: Efficacy of hydrocolloid occlusive dressing technique in decubitus ulcer treatment: a comparative study. **Journal:** Yonsei Medical Journal, 37 (3); 181-185 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: no	Patient group: Patients with a stage I or II PU (according to the NPUAP classification). All patients Randomised N: 44 Completed N: 44 Drop-outs: 0 Group 1 Randomised N: 26 Completed N: 26 Dropouts: 0 Age (mean years (SD)): 50.5 (18.3) Gender (m/f): 23/3 Incontinence: Urine: n=19 Faecal: n=10	Group 1: Hydrocolloid occlusive dressing (DuoDerm®, Squib, Princeton, NJ). Ulcers were cleaned with saline irrigation and boric solution prior to application of the dressing. Dressings were changed every 4-5 days. Group 2: Wet-to-dry dressing. Ulcers were cleaned with saline irrigation and boric solution prior to application of the povidine soaked wet gauze. Dressings were changed three times a day. Both groups: All ulcers were debrided prior to application of the dressing. All patients received position change to relieve the pressure to the ulcer site.	Outcome 1: Healing rate (%) Outcome 2: Mean healing speed (mm²/day) Outcome 3: Proportion of patients with complete healing Outcome 4: Proportion of patients with hypergranulation	Group 1: 80.8 Group 2: 77.8 P value: > 0.05 Group 1: 9.1 (5.4) Group 2: 7.9 (4.7) P value: > 0.05 Group 1: 21/26 Group 2: 14/18 Group 1: 3/26 Group 2: 0/18	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no report on multiple ulcers Additional outcomes: cost (won): G1: 8204 (2664) versus G2: 14571 (6700) Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
missings reported Statistical analysis: The chi-square and t-test were used for the statistical analysis. Baseline differences: No statistical difference between groups Study power/sample size: No a priori sample size calculation. Setting: department of rehabilitation medicine Length of study: mean treatment duration was 18.9 (8.2) days in G1 and 24.3 (11.2) days in G2 Assessment of PUs: Ulcer size was estimated by measuring the longest diameters and the longest diameter perpendicular to it. Other measured variables were ulcer site, size and degree, presence of necrotic tissue, exudate, serum albumin level, hemoglobin level and urinary and fecal incontinence.	Ulcer stage: Stage I: n=6 Stage II: n=20 Ulcer location: Sacrum: n=7 Pelvic girdle: n=7 Other: n=12 Surface area (mean cm²): unclear Group 2 Randomised N: 18 Completed N: 18 Dropouts: 0 Age (mean years (SD)): 46.9 (16.8) Gender (m/f): 13/5 Incontinence: Urine: n=12 Faecal: n=7 Ulcer stage: Stage I: n=6 Stage II: n=12 Ulcer location: Sacrum: n=4 Pelvic girdle: n=7 Other: n=7 Surface area (mean cm²): unclear				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: NPUAP classification (1989). Multiple ulcers: not reported.	Inclusion criteria: PUs stage I or II Exclusion criteria: PU stage III or IV; systemic infection, endocrinological disorder, difficulty keeping pressure relieving positions; aggravated general condition due to other factors				

Table 232: Kordestani 2008[121]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kordestani (2008) **Title**: A randomised controlled trial on the effectiveness of an advanced wound dressing used in Iran. **Journal:** Journal of Wound Care, 17 (7); 323-327 Type of study: randomized controlled trial Sequence generation: alternating sequence	Patient group: Hospitalized patients with a PU (according to the NPUAP classification). Also patients with diabetic foot ulcers and leg ulcers were included (separate analysis) All patients Randomised N: 85 patients and 98 wounds Completed N: 54 patients and 60 wounds (28 PUs) Drop-outs: 31 patients and 38 wounds (10	Group 1: Bioactive dressing (containing hydrophilic mucopolysaccharide, chitosan). The wound was then covered with a non-adherent pad and fixed with a polyurethane adhesive. Ulcers were irrigated with normal saline prior to application of the dressing. Dressings were changed every other day or every four days (exudate) Group 2: Gauze. Wet-to-dry dressing. Ulcers were irrigated with normal saline and covered with gauze secured with a bandage and adhesive tape.	Outcome 1: Proportion of ulcers completely healed Outcome 2: Proportion of infected ulcers	Group 1: 14/16 Group 2: 4/12 Group 1: 0/16 Group 2: 0/12	Funding: Sponsored by Chito Tech Limitations: little information on sequence allocation; little information on allocation concealment; no report on blinding; no a priori sample size calculation; no measurement of statistical

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
randomization; no further information Allocation concealment: concealed; no further information Blinding: blinding; no further information Addressing incomplete outcome data: no drop-out Statistical analysis: Data were analyzed using analysis of variance (ANIOVA) and chi-square test, using SPSS software. A p value of <0.05 was considered significant. Baseline differences: Difference was not statistically measured. Groups were comparable. Study power/sample size: The power is between 1.5 and 2 for a sample size (wounds) of 65. Setting: five major teaching hospitals in Tehran Length of study: 21 days	patient died, 21 patient withdrew) Age (mean years (SD)): 43.42 (5.08) Gender (m/f): 25/29 Ulcer width (mean cm (SD)): 14.13 (2.3) Ulcer length (mean cm (SD)): 8.24 (1.92) Ulcer duration (mean days (SD)): 21.5 (6.2) Group 1 Randomised N: 33 patients and 45 wounds Completed N: 32 patients and 34 wounds (16 PUs) Dropouts: 1 patient and 11 wounds (died) Age (mean years): 45.8 Group 2 Randomised N: 52 patients and 53 wounds Completed N: 22 patients and 26 wounds (12 PUs) Dropouts: 30 patient and 27 wounds (9 patient died, 21 patient withdrew) Age (mean years): 41.2	Both groups: All ulcers were debrided as required. None of the patients received pressure relief of offloading.			difference between groups at baseline; high drop-out; no-intention-to treat analysis Additional outcomes: / Notes: Patient characteristics are for all patients. The outcome are for PU patients only.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
of treatment and three months follow-up Assessment of PUs: Wound size was estimated by photographs, which were scanned. The exact length and width were calculated using AutoCAD 2000. All wound were swabbed if signs of wound infection Classification of PUs: NPUAP classification. Multiple ulcers: multiple ulcers included. Ulcers unit of analysis	Inclusion criteria: PU, diabetic foot ulcer or leg ulcer Exclusion criteria: PU pregnancy; addiction to alcohol, cigarettes or narcotics; immunocompromising condition				

Table 233: Kraft 1993[123]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Kraft (1993) **Title**: A comparison of Epi-Lock and saline dressings in the treatment of pressure ulcers. **Journal:** Decubitus, 6 (6); 42-48	Patient group: Male veterans with a stage II or III PU (according to the Enterstomal Therapy definition). All patients Randomised N: 34 Completed N: 17	Group 1: foam dressing (Epi-LockTM). Epi-LockTM: a sterile, non-adherent, semi-occlusive polyurethane foam wound dressing with an adhesive cover. Group 2: saline moistened gauze dressing.	Outcome 1: Proportion of patients/ulcers completely healed	Group 1: 10/24 Group 2: 3/14	Funding: funding by Calgon Vestal Labaratories Limitations: no report on sequence allocation; no report on allocation

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: intention-to-treat analysis Statistical analysis: Not reported except for correlation between determined variables and ulcer healing. Data were analyzed using regression analysis. Baseline differences: Difference was not statistically measured. Study power/sample size: Unclear if a priori sample size calculation was performed. Sample size was targeted to allow for drop-outs. The sample size was adequate to permit statistical analysis to	Drop-outs: 17 (2 died, 2 withdrew, staff requested withdrawal for 6 patients, 1 had surgery, 1 had special bed treatment, 5 had a reaction to RX) Age (mean years; range): 56; 28-78 Gender (m/f): 38/0 Spinal cord injury: 33 Ulcer stage: Stage II: n=22 Stage III: n=16 Ulcer duration: range: new to five years ≤ 2 months: n=20 > 2 months: n=14 Group 1 Randomised N: 24 Completed N: 11 Dropouts: 13 (1 withdrew, staff requested withdrawal for 5 patients, 1 had special bed treatment, 4 had a reaction to RX) Group 2 Randomised N: 14	Both groups: Standardized dressing procedures were performed in all patients.			concealment; no report on blinding; a priori sample size calculation unclear; small sample size and high drop-out (ITT); no measurement of statistical difference between groups at baseline; no information on statistical analysis; no information on ulcer assessment; little information on dressing and standardized procedure. Additional outcomes: Cost (nursing time and dressing cost): G1: $20.48 versus G2: $74.97 Correlation (variables: medication, cultures, age, smoking, serum albumin, TIBC, CBC, fasting blood sugar,

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
detect difference in healing between groups, stages and over time. Setting: tertiary care veteran's hospital in the Midwest consisting of a spinal cord injury centre and an extended care centre. Length of study: 24 days of treatment Assessment of PUs: All subjects were assessed by the same rater who noted stage, tissue color, drainage, odor and condition of the skin surrounding the ulcer. Classification of PUs: Enterstomal Therapy definition (1987). Multiple ulcers: Indirect: one ulcer per patient.	Completed N: 6 Dropouts: 8 (2 died, 1 withdrew, staff requested withdrawal for 1 patients, 1 had surgery, 1 had a reaction to RX) Inclusion criteria: / Exclusion criteria: PU stage I or IV; clinically infected ulcer; patient on special bed; unstable insulin-dependent diabetes; serum albumin < 2gm; hemoglobin < 12gm; class IV congestive heart failure; chronic renal insufficiency; documented severe peripheral vascular disease; documented COPD				electrolytes, CO2 levels): serum albumin was inversely related to patients age Notes: /

Table 234: Ljungberg 2009[134]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ljungberg (1998) **Title**: Comparison of dextranomer paste and saline dressings for management of decubital ulcers. **Journal:** Clinical Therapeutics, 20 (4); 737-743. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: intention to treat analysis Statistical analysis: Treatment comparisons were based on the change from study entry to day 15 or the end of the study (end point) and using the chi-square test. The level of	Patient group: Male patients with a spinal cord injury, aged 18 years and older, and with exudative PUs (according to the Eltorai classification). All patients Randomised N: 23 patients with 30 ulcers Completed N: not reported Drop-outs: not reported Age (range years): 23-73 Gender (m/f): 23/0 Group 1 Randomised N: 15 ulcers Completed N: not reported Dropouts: not reported Duration of PU (mean months; median months; range): 4.2; 4; 0.5-12 Ulcer stage: Stage II: n=10 Stage III: n=4 Stage IV: n=1 Ulcer location:	Group 1: Dextranomer paste (Debrisan®, Pharmacia Pharmaceuticals, AB, Uppsala, Sweden). Ulcers were cleaned with mild soap and water and rinsed with saline solution. Paste was applied on the wet ulcer and was covered with a dry sterile dressing. Debrisan®: contained 64% dextranomer, 30.5% polyethylene glycol 600 and 5.5% distilled water Group 2: Saline dressing. Ulcers were cleaned with mild soap and water and rinsed with saline solution. The saline soaked dressing was applied on the wet ulcer and was covered with a dry sterile dressing. Both groups: All ulcers were surgically debrided before application of the dressing.	Outcome 1: Proportion of ulcer improved with 25% Outcome 2: Proportion of ulcers with granulation after 15 days Outcome 3: Proportion of ulcers with epithelialization after 15 days Outcome 4: Proportion of patients with adverse events	Group 1: 11/15 Group 2: 2/15 P value: < 0.01 Group 1: 10/15 Group 2: 8/15 P value: > 0.05 Group 1: 7/15 Group 2: 4/15 P value: > 0.05 Group 1 and 2: 0/23	Funding: Grant from Pharmacia Pharmaceuticals AB, Sweden. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no measurement of statistical difference between groups; little information on ulcer assessment; no information on number of patients per group. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
significance for all tests was p < 0.05. Baseline differences: Difference not statistically measured. Groups were comparable. Study power/sample size: No a priori sample size calculation. Setting: Spinal cord injury service, Long Beach Veterans Administration Hospital, Long Beach, California. Length of study: 15 days of treatment. Assessment of PUs: Qualitative assessment of the ulcers was conducted with the aid of photographs. The extent of granulation was measured on a six-point scale. Ulcers were assessed each time the nurse changed the dressing. Classification of PUs: Eltorai classification. Multiple ulcers: 30 ulcers in 23 patients.	Ischium: n=6 Sacrum: n=3 Hips: n=4 Ankle: n=2 Other: n=0 Infected ulcers: 6 Group 2 Randomised N: 15 ulcers Completed N: not reported Dropouts: not reported Duration of PU (mean months; median months; range): 4.3; 4; 0.5-10 Ulcer stage: Stage II: n=12 Stage III: n=3 Stage IV: n=0 Ulcer location: Ischium: n=5 Sacrum: n=3 Hips: n=3 Ankle: n=1 Other: n=3 Infected ulcers: 9 Inclusion criteria: Aged 18 years and older;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Ulcers was unit of analysis.	exudative PU Exclusion criteria: PU involving the bone				

Table 235: Matzen 1999[138]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Matzen (1999) **Title**: A new amorphous hydrocolloid for the treatment of pressure sores: A randomised controlled study. **Journal:** Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery, 33 (1); 13-15. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: intention to treat analysis.	Patient group: Patients older than 18 years with a stage III or IV PU (according to the Lowthian classification). All patients Randomised N: 32 Completed N: 6 Drop-outs: 20 (8 had other illnesses, 3 died, 1 had a missing schedule, 2 withdrew, 6 had insufficient effect of the treatment). Ulcer location: Sacrum: n=21 Trochanter: n=11 Group 1 Randomised N: 17 Completed N: 8 Dropouts: 9 (5 had other	Group 1: Hydrocolloid dressing (Hydrogel®, Coloplast A/S, Denmark). The dressing was covered with a transparent hydrocolloid dressing (Comfeel®, Coloplast A/S, Denmark). The ulcers were cleaned and changed daily. Group 2: Saline gauze compresses. The dressing was covered with a transparent hydrocolloid dressing (Comfeel®, Coloplast A/S, Denmark). The ulcers were cleaned and changed daily. Both groups: All ulcers were debrided before application of the dressing as necessary.	Outcome 1: Mean relative volume reduction (%) Outcome 2: Proportion of patients completely healed Outcome 3: Median pain during treatment Outcome 4: Median smell during treatment Outcome 5: Median comfort during treatment	Group 1: 26 (20) Group 2: 64 (16) P value: < 0.02 Group 1: 5/17 Group 2: 0/15 Group 1: 2 (1-4) Group 2: 2 (1-3) Group 1: 2 (1-4) Group 2: 2 (1-3) Group 1: 4 (3-4) Group 2: 3 (2-4)	Funding: /. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no measurement of statistical difference between groups; setting not reported; little information on ulcer assessment, pain, smell, comfort Additional outcomes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: The data were skewed and therefore assessed by the nonparametric Mann-Whitney test. Differences were accepted as significant if the probability was less than 0.05. Baseline differences: Difference not statistically measured. Study power/sample size: No a priori sample size calculation. Setting: not reported. Length of study: 12 weeks of treatment or until complete healing. Assessment of PUs: Healing of ulcers was estimated by measuring the amount of water needed to fill the cavity. Classification of PUs: Lowthian classification (1994). Multiple ulcers: not reported	illnesses, 2 died, 1 had a missing schedule, 1 withdrew) Age (mean years range): 82; 32-97 Gender (m/f): 2/15 Group 2 Randomised N: 15 Completed N: 4 Dropouts: 11 (3 had other illnesses, 1 died, 1 had a missing schedule, 1 withdrew, 6 had insufficient effect of the treatment) Age (mean years range): 84; 46-89 Gender (m/f): 3/12 Inclusion criteria: Stage III or IV PU; non-infected PU Exclusion criteria: diseases or taking drugs known to impair healing				Notes: /

Table 236: Meaume 2003[142]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Meaume (2003) **Title**: A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers. **Journal:** Ostomy/wound management, 49 (9); 44-51. Type of study: randomized controlled trial Sequence generation: predetermined computer-generated randomized list. Allocation concealment: stratified according to study centre. Numbered, sealed envelopes Blinding: no blinding Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: Descriptive statistics	Patient group: Patients aged 65 years or older with a stage II PU (according to the NPUAP classification). All patients Randomised N: 38 Completed N: 36 Drop-outs: 2 (died) – unclear if other also dropped Group 1 Randomised N: 18 Completed N: 17 Dropouts: 1 (died) – unclear if other also dropped Age (mean years; range): 83.8; 74.9-95.1 Gender (m/f): 2/16 Duration of PU (mean weeks; range): 8.3; 1-24 Ulcer area (mean cm²; range): 4.9; 0.7-25.3 Ulcer location: Heel: 7 Foot: 2	Group 1: Self-adherent soft silicone dressing (Mepilex®, Mölnlycke Health Care AB, Sweden). The dressing was changed at least once a week or more frequently as needed. If necessary, extra fixation (Mefix®/Mefilm®) and hydrating gel (Normlgel®) could be used. Mepilex®: Silicone, polyurethane foam, and polyacrylate fibers. Group 2: Self-adherent hydropolymer dressing (Tielle®, Johnson & Johnson Mecial, England). The dressing was changed at least once a week or more frequently as needed. If necessary, extra fixation (Mefix®/Mefilm®) and hydrating gel (Normlgel®) could be used. Tielle®: hydropolymer dressing that contains polyurethane foams, a non-woven layer, and polyurethane backing. Both groups: Most patient received pressure relieving mattresses (78.9% baseline and	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of patients improved Outcome 3: Proportion of patients worsened Outcome 4: Proportion of patients with maceration Outcome 5: Proportion of patients reporting odour Outcome 6: Proportion of patients with dressing related adverse events	Group 1: 8/18 Group 2: 10/20 Group 1: 15/18 Group 2: 19/20 Group 1: 2/18 Group 2: 1/20 Group 1: 0/18 Group 2: 3/20 Group 1: 0/18 Group 2: 3/20 Group 1: 1/18 Group 2: 3/20 (hypergranulation, new ulcer, and redness and irritation)	Funding: / Limitations: no blinding; no a priori sample size calculation; small sample size; no report on multiple ulcers Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
were used to describe the study population and results. A post-hoc significance test using the Fischer exact test was performed for the damage to tissue variable. Baseline differences: No measurement of statistical difference between groups. Groups were similar in distribution. Study power/sample size: No a priori sample size calculation. Setting: three nursing homes (Paris, Antwerp and Pisa). Length of study: eight weeks of treatment or until complete healing. Assessment of PUs: Ulcers were traced to determine size. Classification of PUs: NPUAP classification. Multiple ulcers: not reported	Leg: 1 Sacrum: 3 Back: 3 Ischiatic: 2 Elbow: 0 Group 2 Randomised N: 20 Completed N: 19 Dropouts: 1 (died) – unclear if other also dropped Age (mean years; range): 82.5; 66.4-91.9 Gender (m/f): 4/16 Duration of PU (mean weeks; range): 13.0; 1-52 Ulcer area (mean cm²; range): 5.4; 0.2-26.0 Ulcer location: Heel: 4 Foot: 2 Leg: 4 Sacrum: 6 Back: 2 Ischiatic: 1 Elbow: 1 Inclusion criteria: Aged 65 years or older;	71.1% at final); few patients received position changes and/or use of heel boots (7.9% baseline and 5.3% at final).			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	stage II PU; Modified Norton score ≥ 11; red/yellow wound according to the Red-Yellow-Black systel. Exclusion criteria: underlying disease, that might interfere with the treatment of PU; food and/or liquid intake score ≤ 2 on modified Norton scale; allergic/hypersensitivity to either dressing; wound larger than 11cm x 11cm; necrotic ulcer; clinical signs of local infection				

Table 237: Meaume 2005[141]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Meaume (2005) **Title**: Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection. **Journal:** Journal of Wound Care, 14 (9); 411-419. Type of study: randomized controlled trial Sequence generation: an a priori randomisation list was prepared by block of six. Allocation concealment: stratified according to wound type Blinding: no blinding Addressing incomplete outcome data: intention to treat analysis, after exclusion of two cases (incorrectly included and died three days after randomisation) and per protocol analysis. Statistical analysis: Data	Patient group: Patients aged 65 years or older with a stage III or IV PU (according to the NPUAP classification). Also patients with leg ulcer were included. All patients Randomised N: 99 (28 with PU) Completed N: 80 (24 with PU) Drop-outs: 19 (2 alginate dressing no longer indicated, 1 withdrawal of consent, 5 intercurrent event, 3 wound grafting, 3 wound infection, 6 wound aggravation) Group 1 Randomised N: 51 (13 with PU) Completed N: 41 (12 with PU) Dropouts: 10 (1 alginate dressing no longer indicated, 1 withdrawal of consent, 4 intercurrent event, 1 wound grafting, 1	Group 1: Silver hydroalginate dressing (Silvercel®, Johnson & Johnson). Ulcers were cleansed with sterile saline. The dressing was applied and covered with a sterile pad and a hypoallergenic adhesive was used to secure these. The dressing was changed every two to three days as needed. Silvercel®: a sterile, non-woven pad composed of a high-G (guluronic acid) alginate, carboxymethylcellulose (CMC) and silver-coated fibres. Its tensile strength increases when in contact with wound exudate, facilitating its removal from exuding wounds. Group 2: Alginate dressing (Algosteril®, Brother Laboratories SA, France). Ulcers were cleansed with sterile saline. The dressing was applied and covered with a sterile pad and a hypoallergenic adhesive was used to secure these. The dressing was changed every two to three days as needed. Algosteril®: a sterile, non-woven pad composed 100%	Outcome 1: Absolute decrease in ulcer area (cm²) Outcome 2: Percentage reduction in ulcer area Outcome 3: Healing rate (cm²/day) Outcome 4: Mean mASEPSIS index at week 4 Outcome 5: Proportion of patients with ulcer infection Outcome 6: Proportion of patients with ulcer aggravation	Group 1: -7.2 (9.0) Group 2: -0.8 (10.0) Group 1: 31.6 (38.1) Group 2: 13.9 (50.3) Group 1: 0.26 (0.32) Group 2: 0.03 (0.36) ITT analysis Group 1: 81.8 (45.1) Group 2: 115.3 (80.2) PP analysis Group 1: 87.3 (42.2) Group 2: 111.3 (74.2) Group 1: 1/13 Group 2: 2/15 Group 1: 2/13 Group 2: 4/15	Funding: funded by a grant from Johnson & Johnson Wound Management. Limitations: inadequate allocation concealment; no blinding; sample size calculation based on non-critical outcome; few patients with PU; setting unclear; no direct information on multiple ulcers; no information on preventive measures Additional outcomes: / Notes: Patient characteristics are for all patients. The outcome are for PU patients only.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
analysis was conducted using SPSS. Comparability of groups was verified using univariate anova for continuous variables and chi-square test for categorical variables. Group comparisons used an univariate general linear model procedure (Type III) with dressing and wound as fixed factors. For variables evaluated at weekly intervals, a GLM procedure for repeated measures was performed. To deal with missing data, the last observed value was carried forward. The main efficacy parameter was the two-week global mASEPSIS score calculated on the ITT population. A second analysis was conducted for the PP population, defined as randomized without major violation of the protocol. Changes in wound	wound infection, 2 wound aggravation) Age (mean years (SD)): 74.9 (9.0) Gender (m/f): 30/21 BMI (mean kg/m² (SD)): 28.6 (8.7) Diabetes: 17 Following characteristics are for PU patient only: Duration of PU (mean months (SD); median months): 4.4 (3.7); 2.0 Ulcer area (mean cm² (SD); median months): 22.5 (21.5); 15.6 Group 2 Randomised N: 48 (15 with PU) Completed N: 39 (12 with PU) Dropouts: 9 (1 alginate dressing no longer indicated, 1 intercurrent event, 1 wound grafting, 2 wound infection, 4 wound aggravation) Age (mean years (SD)): 77.6 (10.9) Gender (m/f): 33/15	calcium alginate. Both groups: All ulcers were debrided (surgically or mechanically) as necessary.	Outcome 7: Proportion of patients with poor local acceptability and/or tolerability	Group 1: 1/13 Group 2: 0/15	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
surface are, percentage reduction in wound surface, and wound closure rate were calculated. Log-transformed data were used for statistical analysis. The proportion of closed/improved wounds at week 4 were compared using the chi-square test. Baseline differences: No statistical difference between groups, except for age > 80 years and diabetes. Study power/sample size: The required number of subjects per groups was determined to be 50 (bilateral test, power 0.8, alpha risk 0.05) to detect a maximal between groups difference of 8 to 10 points on this index. Setting: 13 centers. Length of study: four weeks. Assessment of PUs: The mASEPSIS score was	BMI (mean kg/m² (SD)): 25.9 (7.1) Diabetes: 6 Following characteristics are for PU patient only: Duration of PU (mean months (SD); median months): 3.7 (6.0); 2.0 Ulcer area (mean cm² (SD); median months): 22.4 (25.5); 18.7 Inclusion criteria: Ankle brachial pressure index > 0.7 within previous 6 months; grade III or IV PU; no clear signs of infection (investigators opinion); at least 50% of wound covered with yellow slough, discoloured or friable granulation tissue, pocketing or undermining at the base of the wound or foul odour. Exclusion criteria: receiving systematic antibiotics during previous five days; very poor life expectancy; condition that might interfere with				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assessed (score 0—30). Wound appearance and closure were noted at each visit. The target ulcer was measured (planimetry) and photographed Classification of PUs: NPUAP classification. Multiple ulcers: indirectly: one ulcer per patient	healing such as active carcinoma, vasculitis, use of corticosteroids, immunosuppressive agents, radiotherapy or chemotherapy within 30 days; receiving topical chemical debriding agents within previous seven days.				

Table 238: Motta 1999[149]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Motta (1999) **Title**: Clinical efficacy and cost-effectiveness of a new synthetic polymer sheet wound dressing. **Journal:** Ostomy/wound management, 45 (10); 41-49. Type of study: randomized controlled trial Sequence generation:	Patient group: Home care patients with a stage II or III PU. All patients Randomised N: 10 Completed N: 10 Drop-outs: 0 Age (mean years range): 60; 34-76 Gender (m/f): 5/5 Duration of PU (mean days): 49.8 Ulcer location:	Group 1: Polymer hydrogel dressing (AcryDerm®, AcrylMed, Portland, Ore – now known as Flexigel®, Smith & Nephew, Largo, Fla) A/S, Denmark). The ulcers were cleansed and irrigated with sterile saline. The dressings were changed on an "as needed basis" but not less than once weekly. Group 2: Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Skillman, NJ). The ulcers were cleansed and irrigated with sterile saline. The dressings	Outcome 1: Proportion of patients completely healed Outcome 2: Mean healing rate (cm per day) Outcome 3: Mean percentage ulcer reduction	Group 1: 2/5 Group 2: 2/5 Group 1: 0.22 (0.24) Group 2: 0.35 (0.43) Group 1: 79.2 (33.8) Group 2: 88.6 (11.2)	Funding: Funded by an educational grant from AcryMed, Portland, Ore Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation;

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: no drop-out. Statistical analysis: not reported. Baseline differences: Difference not statistically measured. Study power/sample size: No a priori sample size calculation. Setting: home care. Length of study: 8 weeks of treatment. Assessment of PUs: Ulcers were assessed weekly using the Bates-Jensen Pressure Sore Status tool. Classification of PUs: PU classification not reported but they were described as partial thikness wounds, which provide a range of exudate levels and are generally shallow wounds that are	Foot/ankle: n=2 Coccyx: n=4 Buttocks: n=1 Sacrum: n=1 Elbow: n=2 Ulcer stage: Stage II: n=3 Stage III: n=7 Group 1 Randomised N: 5 Completed N: 5 Dropouts: 0 Ulcer location: Coccyx: n=3 Sacrum: n=1 Elbow: n=1 Ulcer stage: Stage II: n=1 Stage III: n=4 Group 2 Randomised N: 5 Completed N: 5 Dropouts: 0 Ulcer location: Foot/ankle: n=2 Coccyx: n=1 Buttocks: n=1	were changed on an “as needed basis” but not less than once weekly. Both groups: All ulcers were lightly debrided.			very small sample size; no measurement of statistical difference between groups; no information on PU classification; little information on PU assessment; no information on preventive measures Additional outcomes: Cost of treatment G1: $57.76 vs G2: $91.48 Average dressings used: G1: 3.38 vs G2: 8 Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
appropriately treated without the use of additional wound fillers (which equates to NPUAP/EPUAP classification system) Multiple ulcers: one ulcer per patient	Elbow: n=1 Ulcer stage: Stage II: n=3 Stage III: n=2 Inclusion criteria: Stage II or III PU Exclusion criteria: /				

Table 239: Mulder 1993[151]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Mulder (1993) **Title**: Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution -- moistened dressings on the management of pressure ulcers. **Journal:** Wound Repair and Regeneration, 1; 213-218 Type of study: randomized controlled trial Sequence generation:	Patient group: Patients with a stage II or III PU. All patients Randomised N: 67 Completed N: unclear Drop-outs: unclear Group 1 Randomised N: 23 Completed N: unclear Dropouts: unclear Age (mean years (SD); range): 56.7 (20.6), 23-86 (evaluated on 21 patients) Gender (m/f): 18/5 Ulcer stage: unclear	Group 1: Hydrogel dressing (Clearsite®, New Dimensions in Medicine, Dayton, Ohio). Dressings were changed twice a week. Group 2: Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Bristol Myers-Squibb, Princeton, NJ). Dressings were changed twice a week. Group 2: Wet-to-moist gauze dressing. Dressings were changed three times a day. Both groups: /	Outcome 1: Mean percentage reduction in ulcer area Outcome 2: Median percentage reduction in ulcer area Outcome 3: proportion of patients with skin irritation Outcome 4: Proportion of patients with	Group 1: 8.0 (14.8) (n=20) Group 2: 3.3 (32.7) (n=21) Group 3: 5.1 (14.8) (n=20) P-value: > 0.05 Group 1: 5.6 (n=20) Group 2: 7.4 (n=21) Group 3: 7.0 (n=20) P-value: 0.89 Group 1: 0 Group 2: 2 Group 3: 0	Funding: / Limitations: no report on allocation concealment; no blinding; no information on preventive measures; multiple ulcers unclear; drop-out, number of patients/ulcers in analysis unclear; missings unclear Additional outcomes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
1:1:1 ratio by a computer generated scheme Allocation concealment: not reported Blinding: no blinding Addressing incomplete outcome data: drop-outs excluded Statistical analysis: For population comparability, continuous variables were assessed by analysis of variance. Categorical variables were assessed by Fischer's exact test. The nonparametric Brown median test was used to calculate statistical significance. SAS was used as software program. Baseline differences: No statistical difference between groups for age, gender and race. Study power/sample size: no a priori sample size calculation Setting: in- and	Stage II: 8 Stage III: 14 Ulcer location: Heel: 3 Buttock: 3 Hip: 1 Malleolus: 3 Sacrum: 3 Trochanter: 1 Ischium: 1 Other: 8 Group 2 Randomised N: 23 Completed N: unclear Dropouts: unclear Age (mean years (SD); range): 63.1 (15.3); 36-82 (evaluated on 16 patients) Gender (m/f): 17/3 (evaluated on 20 patients) Ulcer stage: unclear-missings Stage II: 9 Stage III: 13 Ulcer location: Heel: 5 Buttock: 3 Hip: 2		inflammation Outcome 5: Proportion of patients with excoriation	Group 1: 1 Group 2: 0 Group 3: 0 Group 1: 1 Group 2: 0 Group 3: 0	Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outpatients. Length of study: eight weeks of treatment or until complete healing Assessment of PUs: Ulcers were photographed and measured. The perimeter was traced onto a plastic sheet with a permanent marker. All tracings were measured with a VIAS program. Classification of PUs: not reported. Multiple ulcers: unclear	Malleolus: 2 Sacrum: 0 Trochanter: 2 Ischium: 1 Other: 6 Group 3 Randomised N: 21 Completed N: unclear Dropouts: unclear Age (mean years (SD); range): 57.2 (13.6); 26-75 (evaluated on 16 patients) Gender (m/f): 19/2 Ulcer stage: unclear-more ulcers? Stage II: 5 Stage III: 23 Ulcer location: Heel: 2 Buttock: 3 Hip: 3 Malleolus: 1 Sacrum: 3 Trochanter: 1 Ischium: 0 Other: 8 Inclusion criteria:				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Stage II or III PU; size between 1.5cm x 0.5cm and 10cm x 10cm; aged 18 years and older; life expectancy of at least 2 months Exclusion criteria: pregnant women; receiving chemotherapy; documented wound infection; extensive undermining (>1.0cm) ulcer; positive test for HIV; receiving > 10mg/day corticosteroids				

Table 240: Mûller 2001[153]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Müller (2001) **Title**: Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. **Journal:** PharmacoEconomics, 19 (12); 1209-1216.	Patient group: Hospitalized female patients with grade IV heel PUs. All patients Randomised N: 24 patients and 26 ulcers Completed N: 23 patients and 26 ulcers Drop-outs: 1 (failed treatment)	Group 1: Collagenase dressing (Novuxol®). Ulcers were cleansed with saline 0.9%. Ulcers were treated with collagenase-containing ointment, paraffin gauze (Jelonet®) and an absorbent bandage. Ulcers were treated once a day. Group 2: Hydrocolloid dressing (DuoDerm®). Ulcers were cleansed with saline 0.9% and covered with the dressing.	Outcome 1: Proportion of patients completely healed Outcome 2: Time to achieve complete healing (mean weeks; range)	Group 1: 11/12 Group 2: 7/11 P value: <0.005 Group 1: 10; 6-12 Group 2: 14; 11-16 P value: <0.005	Funding: Unrestricted grant from Knoll AG, Ludwigshafen, Germany. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding;

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: drop-out excluded. Statistical analysis: - rank for efficiency in terms of the rate of complete healing and the Wilcoxon test for time to achieve complete healing were calculated. Tests were two-sided with p <0.05 Baseline differences: Difference not statistically measured. Study power/sample size: The sample size (n=12) was calculated for the parameter 'time to achieve compete healing' for a power of 80%. Setting: Naaldhorst	Group 1 Randomised N: 12 patients and 13 ulcers Completed N: 12 patients and 13 ulcers Dropouts: 0 Age (mean years; range): 74.6; 68-79 Gender (m/f): 0/12 Group 2 Randomised N: 12 patients and 13 ulcers Completed N: 11 patients and 12 ulcers Dropouts: 1 (failed treatment) Age (mean years; range): 72.4; 65-78 Gender (m/f): 0/12 Inclusion criteria: Grade IV PU Exclusion criteria: life expectancy of less than 6 months	Ulcers were treated twice a week. Both groups: Before randomization autolysis and surgical debridement was performed. Occasionally remaining necrosis was treated with collagenase.			no ITT analysis; sample size calculation unclear; very small sample size; no measurement of statistical difference between groups; no information on PU classification; little information on PU assessment; no information on preventive measures Additional outcomes: Cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
hospital, Naaldwijk in the Netherlands Length of study: not reported. Complete healing was achieved at maximum 16 weeks. Assessment of PUs: Ulcer size and depth was assessed weekly by a physician. Photographs were taken. Classification of PUs: not reported. Multiple ulcers: two patients had two ulcers					

Table 241: Münter 2006[155]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Münter (2006) **Title**: Effect of a sustained silver-releasing dressing on ulcers with delayed healing: the CONTOP study. **Journal:** Journal of Wound Care, 15 (5); 199-206.	Patient group: Patients older than 18 years with a grade II or III PU (according to the EPUAP classification). Also patients with leg ulcers and diabetic foot ulcers were included. All patients Randomised N: 619 patients (43 PUs in ?	Group 1: Silver-releasing foam dressing (Contreet® foam, Coloplast). The dressings were changed weekly or depending on exudate. Concreet® foam silver: a soft hydrophilic polyurethane foam containing silver as an integral part of tits matric. The silver ions are present in a form that is really hydro-activated, with sustained silver release for up	Outcome 1: Mean percentage reduction in ulcer area	Group 1: 58.5 Group 2: 33.3	Funding: /. Limitations:; no report on blinding; little information on ulcer assessment; unclear how many patients had PUs Additional outcomes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: a computer-generated list was used Allocation concealment: sealed envelopes were used Blinding: not reported Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: The statistical analyses were carried out using SAS version 8.12. The obtained data were analyzed using the chi-square test, Wilcoxon signed rank test, Mann-Whitney U test and student' t-test. The level of significance was p<0.05. Subgroup analyses were performed. Baseline differences: Difference not statistically measured. Study power/sample size: Based on an	patients) Completed N: not reported Drop-outs: not reported Group 1 Randomised N: 326 (24 PUs in ? patients) Completed N: not reported Dropouts: not reported Age (mean years (SD)): 69.8 (13.7) Gender (m/f): 38/62 Ulcer size (mean cm² (SD); median; range): 52.9 (90.0; 20.0; 0.1-700 Group 2 Randomised N: 293 (24 PUs in ? patients) Completed N: not reported Dropouts: not reported Age (mean years (SD)): 68.8 (14.1) Gender (m/f): 39/61 Ulcer size (mean cm² (SD); median; range): 36.6 (64.4); 12.0; 0.1-400	to seven days. Both adhesive and non-adhesive versions were used. Group 2: Local best practice, including foams/alginates (53%), hydrocolloids (12%), gauze (3%), silver dressings (17%); other antimicrobial dressings (9%) and other active dressings (6%) Both groups: /			Notes: Patient characteristics are for all patients. The outcome are for PU patients only.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assumption of 80% power, a minimum relevant difference in means of 17.1 in relative ulcer are, a common standard deviation of 71.0 and a significance level of 5%, 272 in each group were measured as appropriate. A drop-out rate of 15% was set, resulting in a arbitrary target of 'over 600' Setting: 80 specialist wound-care clinics in Germany, UK, Denmark, Italy, Switzerland, Belgium, Slovenia, Brazil and Canada. Length of study: four weeks of treatment. Assessment of PUs: At each weekly visit ulcer size, odor, appearance, exudate level and number of dressing changes made since the last visit were assessed. Classification of PUs: EPUAP classification (1999). Multiple ulcers: not	Inclusion criteria: Aged 18 years and older; not pregnant or lactating; chronic wounds with delayed healing and producing moderate to high levels of exudate. Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reported					

Table 242: Nasar 1982[157]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Nasar (1982) **Title**: Cost effectiveness in treating deep pressure sores and ulcers. **Journal:** Practice of Medicine, 226; 307-310. Type of study: randomized controlled trial Sequence generation: treatment was selected on a random basis. Allocation concealment: not reported. Blinding: not reported. Addressing incomplete outcome data: drop-out were excluded Statistical analysis: Not reported. Baseline differences: Not reported.	Patient group: Elderly patients with a deep pressure ulcer. All patients Randomised N: 12 patients and 18 ulcers, however unclear in text it seems 16 ulcers were included Completed N: 11 ulcers Drop-outs: 5 (1 patient discontinued due to pain, 1 died, 3 switched to other treatment) Group 1 Randomised N: 8 ulcers Completed N: 6 ulcers Dropouts: 2 (1 patient discontinued due to pain, 1 died) Characteristics of completed N Age (mean years (SD)):	Group 1: Debrisan - dextranomer. The Debrisan was applied in a stiff paste (four parts of Debrisan mixed with one part glycerol), twice daily for the first three days and daily thereafter. Group 2: Chlorinated lime solutions (Eusol) and paraffin packs. The solution was applied trice daily for the first three days and thereafter twice daily until the wounds healed. Melolin were used throughout and these were held in place with micropore tape. A Salvon sachet was used each time the dressing was changed. Both groups: Anaemia, hypoalbuminea, hypo vitaminosis and high blood urea were corrected if present. Scrupulous control of diabetic patients was ensured. Systematic antibiotics were	Outcome 1: Time (days) to healing (defined as granulating and < 25% of original surface area) Outcome 2: Proportion of patients with pain	Group 1: 39.3 (17.67) Group 2: 61.8 (13.86) Group 1: 1/? Group 2: 3/?	Funding: / Limitations: no report on sequence allocation, on allocation concealment, blinding, statistical analysis, PU classification, setting; no ITT analysis; no a priori sample size calculation; number of patients randomized and included unclear. Additional outcomes: cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: No a priori sample size calculation. Setting: Not reported. Length of study: Until complete healing. Assessment of PUs: Ulcers were measured with celluloid squares and photographed. Ulcers were measured every third day by an independent observer. Pain was recorded as yes or no. Classification of PUs: not reported. Multiple ulcers: 12 patients with 18 ulcers were included. Ulcer was unit of analysis.	83.17 (7.86) Group 2 Randomised N: 8 ulcers Completed N: 5 ulcers Dropouts: 3 (switched to other treatment) Characteristics of completed N Age (mean years (SD)): 79.8 (3.27) Inclusion criteria: Patients with deep PUs. Exclusion criteria: Patients with an urinary tract infection.	only administered for organisms such as staphylococcus aureus and β haemolytic streptococci and no local antibiotic creams or lotions were applied. Patients with urinary incontinent were catheterized during the study period. Hardened sloughs were cut off at an early stage. All patients were nursed on a large cell ripple mattress. Concurrent therapy: ultraviolet light.			

Table 243: Neill 1989[158]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Neill (1989) **Title**: Pressure Sore Response to a New Hydrocolloid Dressing. **Journal:** Wounds: A	Patient group: Patients 18 years and older with grade II or III PUs (according to the Shea classification).	Group 1: Hydrocolloid dressing (TegasorbTM). Ulcers (free of debris) were irrigated with 50cc of a 1:1 solution of 3% hydrogen peroxide and sterile normal saline followed by 50cc	Outcome 1: Proportion of ulcers completely healed Outcome 2:	Group 1: 13/42 Group 2: 10/45	Funding: Funded by the 3M Company, Medical-Surgical Division. Limitations:; no

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
compendium of Clinical Research and Practice, 1 (3); 173-185. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: drop-out excluded. Statistical analysis: Nonparametric test was used to compare distribution of healing between groups. Anova with PU grade, treatment group, and interaction as factor in the model was applied to the data after transformation of the data into ranks. A p value less than 0.05 was considered significant. A logistic regression model was used to look at covariates of healing.	All patients Randomised N: 100 ulcers Completed N: 65 patients and 87 ulcers Drop-outs: 13 ulcers (11 intercurrent medical events and 2 violated protocol) Group 1 Randomised N: not reported Completed N: 42 ulcers Dropouts: not reported Ulcer grade: Stage II: n=25 Stage III: n=17 Ulcer volume (mean cm² (SD); range): 8.3 (9.9); 0.43-43.93 Presence of necrosis: 34 Ulcers on hip, heel, or sacrum: 31 Group 2 Randomised N: not reported Completed N: 45 ulcers Dropouts: not reported Ulcer grade:	saline rinse. Ulcers (with necrotic tissue, debris or faeces) were irrigated with 50cc of a 1:1 solution of 1% povidone-iodine and sterile saline solution between the hydrogen peroxide solution and the saline rinse. The skin was dried and the dressing was applied and changed every 7 days unless escar was present (every three days), or the dressing became non-adherent or leaked. TegasorbTM: contains polysaccharide, gelatine, pectin, and polyisobutylene. It consists of a flexible oval mass with an adherent hydrocolloid inner face, and an outer water and bacteria impermeable, adhesive-coated, polyurethane film. Group 2: Wet to damp saline gauze dressing. Ulcers (free of debris) were irrigated with 50cc of a 1:1 solution of 3% hydrogen peroxide and sterile normal saline followed by 50cc saline rinse. Ulcers (with necrotic tissue, debris or faeces) were irrigated with 50cc of a 1:1 solution of 1%	Proportion of ulcers completely healed (grade II PUs) Outcome 3: Proportion of ulcers enlarged (grade II PUs) Outcome 4: Proportion of ulcers completely healed (grade III PUs) Outcome 5: Proportion of ulcers enlarged (grade III PUs) Outcome 6: Median percentage reduction in size (grade II PUs) Outcome 7: Median percentage reduction in size (grade III PUs) Outcome 8:	Group 1: 11/25 Group 2: 9/34 P value: > 0.05 Group 1: 7/25 Group 2: 11/34 P value: > 0.05 Group 1: 2/17 Group 2: 1/11 P value: > 0.05 Group 1: 7/17 Group 2: 4/11 P value: > 0.05 Group 1: 91 Group 2: 48 P value: > 0.05 Group 1: 0.3	report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no ITT analysis; no information on PU classification Additional outcomes: Nursing time; Organism growth Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: A tertiary care facility and its affiliated nursing home Length of study: eight weeks of treatment. Assessment of PUs: Ulcers edges were traced onto transparencies and photographs beside a metric ruler were taken using a Minolta Maxxum 7000 with a 50mm macro lens and a 80PX ring light with automated exposure. A Zeiss IBAS Image Analyzer was used to calculate the ulcer surface area. Classification of PUs: Shea classification. Multiple ulcers: A maximum of 2 PU per patients were included. The second ulcer	Stage II: n=34 Stage III: n=11 Ulcer volume (mean cm² (SD); range): 7.6 (8.6); 0.23-35.16 Presence of necrosis: 28 Ulcers on hip, heel, or sacrum: 34 Inclusion criteria: 18 years and older; ulcer < 1.5cm in depth, <5.6cm by 10cm in width and length; Grade II or III Exclusion criteria: inability of patient or guardian to give informed consent; presence of diabetes mellitus; history of skin hypersensitivity, skin disease, allergies to tape or adhesives; concurrent radiotherapy to PU area; medical condition that could interfere with study controls; pre-existing skin disease around the PU; clinical infection associated with PU; peripheral vascular ulcers evidenced by a Brachial	povidone-iodine and sterile saline solution between the hydrogen peroxide solution and the saline rinse. After an open wide mesh gauze pad was moistened with sterile gauze and applied to the ulcer. A sterile gauze was applied as second dressing and secured with paper tape. The dressing was changed every eight hours Both groups: All subject received standard treatment for PUs: a pressure-reducing air mattress, and air-fluidized bed or a low air loss bed; an eggcrate wheelchair; turning and repositioning et least every two hours; control of incontinence with an external urine catheter and fecal incontinence collector.	Proportion of patients with adverse events	Group 2: 30 P value: > 0.05 Group 1: 9/50 (skin irritation) Group 2: 1/50 (ulcer worsened P value: < 0.06	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
received the alternate therapy	Ankle Index ≤ 0.6; scars, contusions, abrasions, or open skin in the immediate PU area.				

Table 244: Nisi 2005[160]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Nisi (2005) **Title**: Use of protease-modulating matrix in the treatment of pressure sores. **Journal:** Chirurgia Italiana, 57 (4); 465-468. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: no drop-out. Statistical analysis: no reported. Baseline differences:	Patient group: Hospitalized patients a stage II, III or IV PU (according to the NPUAP classification). All patients Randomised N: 80 Completed N: 80 Drop-outs: 0 Age (mean years; range): 45; 35-85 Gender (m/f): 53/27 Ulcer location: Sacrum: n=28 Back: n=2 Upper limb: n=8 Trochanter area: n=24 Heel: n=18 Group 1 Randomised N: 40	Group 1: Protease-modulating matrix (Promogran®). Dressings were changed twice weekly or thrice weekly according to the wound exudation. Promogran®: 55% freeze-dried collagen and 45% oxidised regenerated cellulose. Group 2: Conventional dressing. Ulcers were disinfected with 50% povidine-iodine solution, saline wash, positioning of viscose-rayon gauze soaked in white vaseline and covering with a hydropolymer patch. Both groups: At start of the study (only one time) all ulcers were debrided surgically, disinfected with 50% povidine-iodine solution, saline wash, and use of hydrogels. Once ulcers were cleaned the study	Outcome 1: Proportion of patients completely healed Outcome 2: Time to complete healing (range days) Outcome 3: Proportion of patients with adverse events	Group 1: 36/40 Group 2: 28/40 P value: 0.59 Group 1: 6-15 Group 2: 14-52 Group 1: 0/40 Group 2: 0/40	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation; no report on statistical analysis; difference between groups not statistically measured; multiple ulcers not reported; insufficient information on treatments Additional

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Difference not statistically measured. Study power/sample size: No a priori sample size calculation. Setting: Plastic surgery unit of the university hospital of Siena Length of study: time of treatment not reported. Six months of follow-up. Assessment of PUs: Ulcer extension and depth were recorded. Classification of PUs: NPUAP classification. Multiple ulcers: not reported	Completed N: 40 Dropouts: 40 Group 2 Randomised N: 40 Completed N: 40 Dropouts: 0 Inclusion criteria: PU Exclusion criteria: decompensating diabetes; hypertension; severe hypoalbuminosis (<3.00g/100ml); clinical evidence of arterial or venous insufficiency; hematocrit values < 41% for male and 36% for female; treatment with steroid or immunosuppressive drugs	dressings were applied.			outcomes: / Notes: /

Table 245: Olekse 1986[168]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Oleske (1986) **Title**: A randomized clinical trial of two	Patient group: Patients older than 21 years with stage I or II PUs (according to the Enis and Sarmiento classification).	Group 1: Polyurethane self-adhesive dressing. Cleansing of the ulcer and application of the dressing was according to a standardized protocol. The	Outcome 1: Proportion of ulcers completely healed	Group 1: 1/9 Group 2: 0/10	Funding: the study was sponsored by the Department of Medical Nursing, Rush-Presbyterian-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
dressing methods for the treatment of low-grade pressure ulcers. **Journal:** Journal of Enterostomal Therapy, 13 (3); 90-98. Type of study: randomized controlled trial Sequence generation: not reported. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: drop-out was excluded. Statistical analysis: One-way analysis of variance was used to compare the two treatments. A paired t test was used to compare the largest axis and surface are changes within treatment group. A standard chi-square test was used to compare the PU grades before and after therapy end to compare the two treatment groups. The	All patients Randomised N: 16 patients Completed N: 15 patients and 19 ulcers Drop-outs: 1 (unanticipated transfer to nursing home). Age (mean years (SD); range): 69 (6); 52-93 Ulcer location: Gluteal and coccyx area Group 1 Randomised N: not reported Completed N: 7 patients and 9 ulcers Dropouts: not reported Ulcer grade: Grade I: n=2 Grade II: n=7 Ulcer area (mean cm² (SD): 3.5 (1.2) Group 2 Randomised N: not reported Completed N: 8 patients	dressing was changed if it dislodged from the ulcer site. Group 2: Saline dressing. Cleansing of the ulcer and application of the dressing was according to a standardized protocol. The dressing was changed every four hours around the clock Both groups: All patients received the standardized nursing skin care: repositioning every 3 hours, daily administration of multivitamin tablets, use of a convoluted foam mattress (without sleeves)	Outcome 2: Proportion of ulcers worsened Outcome 3: Mean percentage surface area reduction	Group 1: 1/9 Group 2: 2/10 Group 1: 42.9 Group 2: 2.5	St.Luke's Medical Centre and the Chicago Community trust. Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; small sample size Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
significance of the calculated statistics was determined by a two-tailed test with the level of alpha = 0.05 Baseline differences: No statistical difference in terms of age, sex and race. Study power/sample size: No a priori sample size calculation. Setting: inpatient medicine unit. Length of study: 10 days of treatment. Assessment of PUs: Wound healing was evaluated: ulcer grade, longest wound axis, total wound surface area. A transparent rule was used to measure the longest wound axis. Tracings of the ulcer surface were made onto sterile plastic sheets. Surface area were than computed by means of compensating polar planimeter. Classification of PUs:	and 10 ulcers Dropouts: not reported Ulcer grade: Grade I: n=5 Grade II: n=5 Ulcer area (mean cm² (SD): 7.7 (8.6) Inclusion criteria: Adults (21 years of age or over) with a PU grade I or II; afebrile (< 100°F orally or < 101°F rectally); confined to bed, wheelchair, or chair and expected to be so for at least two weeks: expected hospitalization of two weeks; ulcer caused by pressure; ulcer of at least 2cm diameter; not contained in an area currently being irradiated; no evidence of infection; hemoglobin level > 10g/dL Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Enis and Sarmiento classification (1973). Multiple ulcers: 15 patients with 19 ulcers					

Table 246: Parish 1979[174]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Parish (1979) **Title**: Decubitus ulcers: a comparative study **Journal:** Cutis; 23 (1): 106-110 Type of study: Double-blinded study Sequence generation: Patients were assigned at random, but no randomization method was reported. Allocation: No details Blinding: Neither the principal investigator, nor the patients knew who was assigned to which treatment	Patient group: Patients with pressure ulcers in a long-term care institution for the chronically ill and physically disabled. All patients Randomised N: Not reported Completed N: 17 Drop-outs: Not reported Group 1 Randomised N: Not reported Completed N: 7 Dropouts: Not reported Age: 29-57 Gender (m/f): Not reported Other relevant patient	Group 1: Dextranomer powder is employed in the treatment of secreting skin lesions. Dextranomer (Debrisan, Pharmacia Laboratories) consists of beads of cross-linked dextran molecules 0.1 to 0.3 mm in diameter in a three-dimensional porous network. The beads are hydrophilic and each gm of dry beads has the capacity to absorb 4 ml of fluid. Experimental studies show dextranomer capable of transporting bacteria, inflammatory mediators and debris away from the wound surface and into the bead layers. Patients paced on the dextranomer program were given saline soaks. Dextranomer was poured into the ulcer in a layer of at least	Outcome 1: Proportion of ulcers improved Outcome 2: Proportion of patients improved Outcome 3: Proportion of ulcers completely healed	Group 1: 12/14 Group 2: 5/11 Group 3: 0/9 P-value: G1 vs G2: <0.02 P-value G1 vs G3: <0.001 P-value G2 vs G3: > 0.05 Group 1: 7/7 Group 2: 2/5 Group 3: 0/5 P-value: G1 vs G2: <0.05 P-value G1 vs G3: <0.001 P-value G2 vs G3: > 0.05 Group 1: 6/14 Group 2: 1/11 Group 3: 0/9 P-value: G1 vs G2: >0.05 P-value G1 vs G3: <0.08 P-value G2 vs G3: > 0.05	Funding: : Limitations: No inclusion or exclusion criteria reported; Small sample size; Blinding failed; Randomization method not reported ;Six patients changed treatment during the study. No information was given if there was a washing-out period Additional outcomes: All seven patients treated with dextranomer

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
regimen. The authors state however that while the attempted to keep the study double-blinded, it became obvious which regimens were being used. Addressing incomplete outcome data: Not reported Statistical analysis: A fisher exact test was used to evaluate the data. Average ulcer dimension= square root of surface area. Baseline differences: Not reported. Study power/sample size: Not reported Setting: The Inglis House is a long-term care institution for the chronically ill and physically disabled. Patients in this institution have such incapacitating disorders as paraplegia, quadriplegia,	characteristics: Number of ulcers (n=14) Average ulcer dimension in cm = 4.5 Group 2 Randomised N: not reported Completed N: 5 Dropouts: 1 (patient not responding to the collagenase treatment was switched to the dextranomer group). Age: 28-59 Gender (m/f): Not reported Other relevant patient characteristics: Number of ulcers (n=11) Average ulcer dimension in cm = 3.2 Group 3 Randomised N: not reported Completed N: 5 Dropouts: 5 (patients not responding to the sugar and egg white treatment were switched to the	3mm deep and the sores were then covered with dry dressings. The dextranomer dressings were changed one to three times daily depending on the amount of wound exudate. The removal of the dextranomer beads was accomplished by saline irrigation. Group 2: Patients receiving collagenase (Collagenase, Santyl, Knoll Pharmaceutical Co) were given a saline wash. Collagenase was then applied daily with a wooden applicator, and the ointment was covered with a dry dressing, as recommended by the package insert. Group 3: Patients receiving sugar and egg white were also given a saline wash. The mixture was applied liberally to the area four times daily and allowed to dry. All groups: if a patient did not respond satisfactorily to any treatment at the end of four weeks, the regimen was changed to one of the two	Outcome 4: Proportion of patients completely healed Outcome 5: Side effects	Group 1: 4/7 Group 2: 1/5 Group 3: 0/5 P-value: G1 vs G2: >0.05 P-value G1 vs G3: < 0.05 P-value G2 vs G3: > 0.05 Group 1: 0/7 Group 2: 0/5 Group 3: 0/5	improved during the course of the study. In the collagenase group, two of five patients improved. None of the patients treated with sugar and egg white showed improvement. In four patients treated with dextranomer, improvement was observed within one week of the start of treatment and in two other patients improvement was seen within one month. In the collagenase group, none of the five patients improved within one week of treatment and two patients improved within one month of treatment. All five patients who failed to

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Parkinson's disease, rheumatoid arthritis, cerebral palsy, and multiple sclerosis. Of approximately three hundred residents, about 10 percent have decubitus ulcers at any one time. Length of study: The initial study was to have lasted four weeks, but many subjects were treated and observed for up to four months or longer. Assessment of PUs: Pressure ulcers were assessed as dry or moist. Classification of PUs: The authors believe that there is no purpose in further categorizing the ulcers other than dry or moist. Multiple ulcers: All pressure ulcers of the included patients were treated and assessed.	dextranomer (n=4) or collagenase group (n=1)). Age: 32-70 Gender (m/f): Not reported Other relevant patient characteristics: Number of ulcers (n=9) Average ulcer dimension in cm = 2.4 Inclusion criteria: not reported Exclusion criteria: not reported	other treatments.			respond to the sugar and egg white treatment were changed to either dextranomer or collagenase treatment. The four patients switched to dextranomer all improved, with three patients attaining complete closure of their ulcers (four ulcers). One patient with four decubitus ulcers was switched to the group receiving collagenase. This patient improved, with one of four ulcers closing. One patient for whom collagenase treatment failed to produce an adequate response and who was crossed over into the dextranomer group also improved with one

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
					of two ulcers closing. The authors did not see any change in the progress of healing whether the patient was turned every two hours, as they had been initially or whether they were allowed to remain in the same position for many hours. Similarly, cleaning the patients and changing their linens frequently led to none but aesthetic improvements. All patients received the same diet as the other residents of the Inglis House. Sepsis did not develop during the course of the study. Bacteriologic cultures, both aerobic and anerobic were

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
					done before, during and after treatment, but no significant trends were noted. Notes: /

Table 247: Payne 2004[177]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Payne (2004) **Title**: An exploratory study of dermal replacement therapy in the treatment of stage III pressure ulcers. **Journal:** The Journal of Applied Research, 4 (1); 12-23. Type of study: randomized controlled trial Sequence generation: computer generated scheme. Allocation concealment: presealed envelops Blinding: single blind, no	Patient group: Patients with a grade III PU. All patients Randomised N: 34 Completed N: 10 Drop-outs: 14 (reason not reported). Ulcer location: (one missing data) Sacrum: n=22/33 Trochanter: n=8/33 Ischium: n=3/33 Incontinence: Urine: n=1 Faecal: n=4 Both: n=26 Group 1	Group 1: Dermal replacement (Dermagraft®, Smith & Nephew, Inc., Heslington, York, UK). Two pieces were applied side by side to the ulcer weekly for the first three weeks. A combination of a non-adherent dressing, saline-moistened gauze and a non-adhesive foam dressing (Allevyn®, Smith & Nephew, Inc., Heslington, York, UK) were added. Dermagraft®: a human dermal replacement consisting of newborn dermal fibroblasts cultured in vitro onto a bioabsorbable mesh to produce living, metabolically active human, dermal tissue. Group 2: A combination of a non-adherent dressing, saline-	Outcome 1: Proportion of patients completely healed by 24 weeks Outcome 2: Median percentage (range) reduction in wound area at 12 weeks for closed ulcers Outcome 3: Median percentage (range) reduction in wound area at 12 weeks for ulcers with incomplete closure	Group 1: 2/18 Group 2: 2/16 Group 1: 49.5 (-81.7-100.0) Group 2: 33.5 (-77.5-100.0) Group 1: 38.8 (-201.7-100.0) Group 2: 17.4 (-434.5-100.0)	Funding: sponsored by Smith and Nephew, Inc. Limitations: insufficient information on blinding; no a priori sample size calculation; small sample size and high drop-out; little information on setting; PU classification not reported; no information on use of preventive measures.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
further information. Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: Values for ulcer area and volume (as measured by the weight of alginate mould) were calculated at Week 12, and compared using the Mann-Whitney U test. Hodges-Lehmann estimates of the difference in the medians of area and volume were calculated using a 95% confidence interval. The primary variable of complete healing by Week 24, and secondary variable of closure by Week 12 were compared between patients using Fischer's exact test. Statistical analysis was conducted using SAS (SAS/STAT Guide for	Randomised N: 18 Completed N: 5 Dropouts: 13 (reason not reported). Age (mean years (SD)): 69.4 (16.5) Gender (m/f): 12/6 Ulcer duration (mean weeks; range): 30.2; 6-95.3 Ulcer area (mean cm²; range): 19.8; 5.2-60.7 Group 2 Randomised N: 16 Completed N: 5 Dropouts: 11 (reason not reported). Age (mean years (SD)): 69.1 (18.5) Gender (m/f): 11/5 Ulcer duration (mean weeks; range): 29.2; 4.0-104.0 Ulcer area (mean cm²; range): 21.1; 3.5-51.2 Inclusion criteria: Age > 18 years; stage III sacral pressure ulcer; ulcer (after debridement)	moistened gauze and a non-adhesive foam dressing (Allevyn®, Smith & Nephew, Inc., Heslington, York, UK) were applied. All groups: Ulcers were debrided	Outcome 4: Mean percentage (range) reduction in ulcer volume area at 12 weeks Outcome 5: Median percentage (range) reduction in ulcer volume area at 12 weeks Outcome 6: Proportion of patients with infected ulcers Outcome 7: Proportion of patients with adverse events related to the treatment	Group 1: 18.7 Group 2: 4.1 Group 1: 41.2 Group 2: 17.4 Group 1: 3/18 Group 2: 3/16 Group 1: 0/18 Group 2: 0/16	Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Personal Computers, Version 8.2, Cary, North Carolina) Baseline differences: Statistical difference only calculated for smoking (not significant). Groups were comparable. Study power/sample size: No a priori sample size calculation. The study was not powered to detect difference between groups Setting: nine centres in the US. Length of study: maximum 24 weeks of treatment and a follow-up of 2 weeks after treatment. Assessment of PUs: Photographs of the ulcer site immediately before and after debridement were taken. Ulcer tracings were performed at the initial and subsequent weekly	is clean and free of both necrotic tissue and infection; ulcer present for at least 2 months, but not more than 24 months, prior to screening; ulcer is > 5 cm2 and < 50 cm2; if more than 1 ulcer, the distance between ulcers is > 10 cm; ulcer is due solely to pressure damage. Exclusion criteria: Stage I, II or IV pressure ulcers; patient has more than 3 full thickness (Stage III or IV) pressure ulcers; evidence of undermining, tunneling or sinus tracts > 1 cm after debridement; ulcers previously treated with a surgical flap procedure; bacterial colonization; ulcer decreased or increased in size by 50% during the screening period; underlying non-pressure ulcer etiology				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
follow-up visits on a Zip-Loc plastic bag and transferred on to an ulcer area grid for planimetry. Pressure ulcer area was determined by direct measurement (length in cm x width in cm). Pressure ulcer volume was determined by alginate mold method. Assessments were performed weekly until either, the patient had a second confirmation of wound closure, or Week 24 (through to Week 26 if the wound closure was first observed at Week 24). Classification of PUs: not reported. Multiple ulcers: the largest ulcer meeting the inclusion and exclusion criteria was selected.					

Table 248: Payne 2009[176]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Payne (2009) **Title**: A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers. **Journal:** Ostomy/wound management 55(2); 50-55. Type of study: randomized controlled trial Sequence generation: randomized schedule. Allocation concealment: not reported. Blinding: not reported. Addressing incomplete outcome data: intention to treat analysis for all analysis except cost-effectiveness. Statistical analysis: An accelerated failure	Patient group: Patients 18 years and older with a stage II PU (according to the NPUAP classification). All patients Randomised N: 36 Completed N: 27 Drop-outs: 9 (5 died, 1 ulcer infection, 1 abscess unrelated to study ulcer, 1 became ineligible, 1 discharged) Group 1 Randomised N: 20 Completed N: 14 Dropouts: 6 (3 died, 1 ulcer infection, 1 abscess unrelated to study ulcer, 1 became ineligible) Age (mean years (SD); median years): 72.5 (14.3); 74.0 Gender (m/f): 13/7 Ulcer duration (mean weeks (SD); median weeks): 56.1 (219.6); 3.5 Ulcer area (mean cm² (SD); median cm²): 5.6	Group 1: Polyurethane self-adhesive foam dressing (Allevyn® Thin, Smith & Nephew Inc, Largo, Fl). Ulcers were cleansed and dried. Ulcers were dressed with the dressing without secondary dressing or fixation. Dressing were changed determined by clinician. Group 2: Saline-soaked gauze dressing. Ulcers were cleansed and dried. Ulcers were dressed with the dressing and with a secondary dry sterile gauze pad held in place with tape. Dressing were changed determined by clinician. All groups: /	Outcome 1: Proportion of patients completely healed Outcome 2: Median (days) time to healing (time at which 50% of the patients achieved complete healing)	Group 1: 10/20 Group 2: 6/16 Group 1: 28 Group 2: 28	Funding: travel grand and funding from Smith & Nephew Limitations: insufficient information on sequence generation;; no report on allocation concealment; no report on blinding; no measurement of statistical difference between groups; no information on use of preventive measures. Additional outcomes: cost-effectiveness Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
time model was used to test for differences between groups for time of healing after adjustment for study center, baseline ulcer area, and duration. Kaplan-Meier methods were used to estimate the median time to healing. Baseline differences: No calculation of the statistical difference between groups. Study power/sample size: To detect a $10 per week difference in cost of dressing and other materials between groups assuming a standard deviation of $9.80. This was based on a two-sided unpaired t-test at the 5% level of significance and 80% power. A sample size of 19 patients per groups are required. Setting: three hospital wards, one outpatient hospital clinic, one long-term residential care,	(11.3); 1.8 Ulcer location: Hips/buttocks: n=7 Sacrum: n=8 Upper leg: n=1 Ankle/foot: n=4 Lower leg: n=0 Group 2 Randomised N: 16 Completed N: 13 Dropouts: 3 (2 died, 1 became ineligible) Age (mean years (SD); median years): 73.3 (12.4); 71.5 Gender (m/f): 9/7 Ulcer duration (mean weeks (SD); median weeks): 7.0 (9.4); 2.0 Ulcer area (mean cm² (SD); median cm²): 6.2 (7.2); 1.4 Ulcer location: Hips/buttocks: n=7 Sacrum: n=7 Upper leg: n=0 Ankle/foot: n=1 Lower leg: n=1				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
one community care clinic. Length of study: four weeks of treatment or until complete healed, whichever came first. Assessment of PUs: Ulcers were measured at baseline and weekly using Visitrak (Smith&Nephew Inc. Largo, FL). Classification of PUs: NPUAP classification. Multiple ulcers: the largest ulcer was included in the study treatment.	Inclusion criteria: 18 years and older; not pregnant or using contraception; stage II PU with light to moderate exudate. Exclusion criteria: Known history of poor compliance; presence of clinical infection in wound; previous participation in the evaluation				

Table 249: Rhodes 1979[181]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Rhodes (1979) **Title**: The treatment of pressure sores in geriatric patients: a trial of sterculia powder. **Journal:** Nursing Times, 75; 365-368.	Patient group: Geriatric patients with a PU. All patients Randomised N: 38 patients with 57 ulcers Completed N: 38 patients with 38 ulcers Drop-outs: 19 ulcers (only	Group 1: Sterculia gum powder (Karaya gum powder, Hills Pharmaceuticals Ltd, Talbot Street, Briercliffe, Burnley). Ulcers got a simple wound toilet and the dressing was insufflated onto the surface. Dressings were changed every 24 hours.	Outcome 1: Proportion of ulcers completely healed Outcome 2: Mean healing index	Group 1: 16/17 Group 2: 9/21 Group 1: 16.8 Group 2: -3.8 P-value: 0.12	Funding: / Limitations: inadequate sequence allocation; no report on allocation concealment; no

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: the charge nurse allocated the subjects alternately to one of the groups whenever a PU occurred. Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: multiple ulcers were included but only the ulcer with the best healing rate was selected for analysis. Intention to treat analysis. Statistical analysis: To determine the differences in healing rate a Mann Whitney U test was applied. In one case this was converted to a z-score because the number of subjects in one groups was greater than 20. The level of significance was set at p<0.05, two tailed.	one ulcer per patient was included in the analysis) Age (mean years; range): 82; 71-92 Gender (m/f): 7/31 Group 1 Randomised N: 29 ulcers Completed N: unclear Dropouts: unclear Group 2 Randomised N: 28 ulcers Completed N: unclear Dropouts: unclear Inclusion criteria: PU Exclusion criteria: /	Group 3: Standard treatment such as zinc sulphate, tinct, benzoin or cod liver oil. All groups: /			report on blinding; no a priori sample size calculation; small sample size; little information on baseline characteristics and no measurement of difference between groups; length of study not reported; drop-outs unclear, reported as patients and ulcers; no inclusion or exclusion criteria; unclear if all stages of PU were included; no classification of PU; no report on preventive measures or debridement Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: No information on baseline characteristics of groups. Study power/sample size: No a priori sample size calculation. Setting: geriatric unit. Length of study: not reported Assessment of PUs: Ulcers were measured weekly. A transparent ruler was used to measure the longest wound axis in millimetres and a second measurement was taken at right angles to the first. A healing index (initial area – final area / time in days) was calculated for each lesion. Classification of PUs: not reported. Multiple ulcers: multiple ulcers were included but only the ulcer with the best healing rate was selected for analysis.					

Table 250: Rhodes 2001[182]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Rhodes (2001) **Title**: Topical phenytoin treatment of stage II decubitus ulcers in the elderly. **Journal:** The Annals of Pharmacotherapy, 35 (6); 675-681. Type of study: randomized controlled trial Sequence generation: Patients were matched for age, gender, size and severity of the ulcers and were placed in one of the three groups based on the treatment preference of the randomly assigned physician prescribing the treatment plan. Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis:	Patient group: Nursing home patients with a stage II PU (according to the AHCPR classification). All patients Randomised N: 47 Completed N: 39 Drop-outs: 8 (1 continually recurrent ulcers, 5 died, 2 were discharged) Group 1 Randomised N: 18 Completed N: 15 Dropouts: 3 (1 continually recurrent ulcers, 2 died) Age (mean years): 75.5 Gender (m/f): 16/2 Group 2 Randomised N: 16 Completed N: 13 Dropouts: 3 (2 died, 1 was discharged) Age (mean years): 78.7 Gender (m/f): 15/1	Group 1: Phenytoin. Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with 100mg phenytoin suspension daily. A sterile gauze was soaked in the suspension and placed on the ulcer, followed by a layer of dry sterile gauze. Phenytoin suspension: a single 100 mg phenytoin cup containing 5ml of sterile NaCl 0.9% to form a suspension. Group 2: Hydrocolloid dressing (DuoDerm®). Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with dressing with the edges extending 1¼ inch beyond the wound. The dressing was changed every seven days or when it became uncomfortable, leaked, or the presence of infection signs. Group 3: Triple antibiotic ointment. Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with a layer of TAO. Followed a sterile gauze was applied as cover. The dressing was changed every day.	Outcome 1: Mean time (days; range) to healing Outcome 2: Proportion of patients with treatment related adverse events Outcome 2: Proportion of patients pain	Group 1: 35.3 (14.3); 15-64 Group 2: 51.8 (19.6); 27-90 Group 3: 53.8 (8.5); 42-67 P-value G1 vs G2: 0.020 P-value G1 vs G3: 0.011 Group 1: 0/15 Group 2: 0/13 Group 3: 0/11 Minimal pain was reported in all groups	Funding: / Limitations:; no report on sequence allocation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation; small sample size; little information on setting; little information on statistical analysis; no report on multiple ulcers Additional outcomes: / Notes: Hydrocolloid dressings was defined as a collagen dressing in this article

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis included the Levine test for homogeneity of variance, anova, and a post hoc Bonferroni adjustment for multiple pairs. Baseline differences: Difference was not statistically different. Study power/sample size: No a priori sample size calculation. Setting: veteran administration nursing home. Length of study: not reported Assessment of PUs: Ulcers were measured with a MediRule, which was centred over the area to be measured. This transparent, disposable ruler consists of concentric circles measured in centimetres around a cross hair ruled in millimetres. Photographs using a Polaroid Spectra AF were taken once weekly.	Group 3 Randomised N: 13 Completed N: 11 Dropouts: 2 (1 died, 1 was discharged) Age (mean years): 76.5 Gender (m/f): 12/1 Inclusion criteria: Age > 60 years; stage II PU Exclusion criteria: signs and symptoms of ulcer infection; anemia; malnutrition; folate deficiency; chronic use of immunosuppressive treatment; immobility; those receiving oral phenytoin; history of adverse events caused by phenytoin.	All groups: All ulcers were surgically debrided as necessary. All patients received preventive measures such as maximum mobilisation, adequate nutrition and hydration, and incontinence care.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Two light beams were placed at eight inches from the object. Classification of PUs: Agency Health Care Research and Quality's Pressure Ulcer Guideline Panel classification (1992). Multiple ulcers: not reported					

Table 251: Sayag 1996[197]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Sayag (1996) **Title**: Healing properties of calcium alginate dressings. **Journal:** Journal of Wound Care, 5 (8); 357-362 Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: sealed envelopes	Patient group: Patients with a grade III or IV PU (according to the Yarkony classification) All patients Randomised N: 92 Completed N: 60 Drop-outs: 32 (11 died, 2 were transferred, 1 deteriorated in health status, 1 had local adverse event, 17 deterioration or stagnation of PU) Group 1	Group 1: Calium alginate dressing (Algosteril®). The dressing covered the entire area. A sterile gauze was applied as secondary dressing. Dressings were changed every day or at least every four days. Group 2: Dextranomer dressing (Debrisan®). The paste was applied uniformly to produce a 3mm layer. A sterile gauze was applied as secondary dressing. Dressings were changed every day or at least every four days.	Outcome 1: Proportion of patients improved (> 75%) Outcome 2: Proportion of patients improved (> 40%) Outcome 3: Mean reduction in ulcer area (cm²/week) Outcome 4: Mean reduction in ulcer	Group 1: 15/47 Group 2: 6/45 Group 1: 35/47 Group 2: 19/45 P-value: 0.002 Group 1: 2.39 (3.54) Group 2: 0.27 (3.21) P-value: 0.0001	Funding: supported by Les Laboratoires Brothier Limitations: no report on sequence generation; no report on blinding; no information on preventive measures. Additional outcomes: number of dressing changes per week

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: not reported Addressing incomplete outcome data: intention to treat analysis. Statistical analysis: Comparisons were made using chi-square and exact Fischer tests for qualitative variables and student's t-test for quantitative variables. The time to the study endpoint was compared by the Logrank test. All calculations were performed on a DEC station by means of SAS/Ultrix software. Baseline differences: No statistical difference between groups. Study power/sample size: Interim analysis (not a priori calculation) based on the first 53 patients, indicated that 90 subjects would be required (two-tailed, alpha risk 0.05, beta risk 0.20). Setting: 17 specialized centres in care of elderly	Randomised N: 47 Completed N: 37 Dropouts: 10 (5 died, 2 were transferred, 1 deteriorated in health status, 2 deterioration or stagnation of PU) Age (mean years (SD); range): 81.9 (8.9); 60-94 Gender (m/f): 12/35 BMI (mean kg/m² (SD); range): 21.9 (3.9); 12.1-28.7 Ulcer grade: Grade III: 33 Grade IV: 14 Ulcer location: Pelvis area: 14 Heel: 30 Other: 3 Ulcer area (mean cm² (SD); range): 20.1 (12.9); 4.2-53.2 Duration of PU (mean months (SD); range): 3.5 (3.8); 1-21 Group 2 Randomised N: 45 Completed N: 23	Both groups: /	area in patients improved > 40% (cm²/week) Outcome 5: Proportion of patients stagnated or deteriorated Outcome 6: Proportion of patients with an infection Outcome 7: Proportion of patients with hypergranulation Outcome 8: Proportion of patients with pain Outcome 9: Proportion of patients with skin irritation Outcome 10: Proportion of patients with bleeding at dressing change	Group 1: 3.55 (2.18) Group 2: 2.15 (3.60) P-value: 0.0004 Group 1: 2/47 Group 2: 15/45 Group 1: 2/47 Group 2: 2/45 Group 1: 1/47 Group 2: 3/45 Group 1: 0/47 Group 2: 5/45 Group 1: 1/47 Group 2: 1/45	Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
people and 3 centres specialized in dermatology. Length of study: maximum eight weeks Assessment of PUs: Ulcers were photographed and planimetry was used. Planimetric drawing were digitalized twice by using a graphic table and areas were calculated using Autocad software. Classification of PUs: Yarkony classification (1990). Multiple ulcers: only one ulcer per patient was selected for the study.	Dropouts: 22 (6 died, 1 local adverse event, 15 deterioration or stagnation of PU) Age (mean years (SD); range): 80.4 (9.1); 60-96 Gender (m/f): 12/33 BMI (mean kg/m² (SD); range): 21.8 (4.0); 14.3-29.9 Ulcer grade: Grade III: 30 Grade IV: 15 Ulcer location: Pelvis area: 23 Heel: 22 Other: 0 Ulcer area (mean cm² (SD); range): 16.1 (12.5); 4.9-62.3 Duration of PU (mean months (SD); range): 3.0 (3.2); 1-15 Inclusion criteria: Aged 60 years and older; hospitalized for at least eight weeks; PU grade III or IV; surface area between 5 and 100 cm²; PU at sacrum, ischium,		Outcome 11: Proportion of patients with pruritus	Group 1: 0/47 Group 2: 3/45 Group 1: 0/47 Group 2: 1/45	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	trochanters or heels Exclusion criteria: more than half the total ulcer area was comprised with granulation tissue; PU covered with necrotic plaque; PU with an active infection; severe renal failure requiring dialysis; heel PU combined with end-stage arteriopathy; treated with radiotherapy or cytotoxic drugs				

Table 252: Scevola 2010[198]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Scevola (2010) **Title**: Allogenic platelet gel in the treatment of pressure sores: A pilot study. **Journal:** International Wound Journal, 7; 184-190. Type of study: randomized controlled trial Sequence generation:	Patient group: Patients with a spinal cord injury and a grade III or IV PU (according to the NPUAP classification). All patients Randomised N: 13 patients and 16 ulcers Completed N at 10 weeks: 13 patients and 16 ulcers Completed N at 14 weeks: 11 ulcers Drop-outs: 5 ulcers	Group 1: Allogenic platelet gel. The gel was applied to the clean wound bed using a sterile syringe. The ulcer was then covered with a polyurethane sponge/semi-permeable film dressing system (Biatain Coloplast®). Platelet gel: the gel was prepared in a Petri dish blending 4-8ml of concentrated platelet preparation, including at least 2x1010 platelets, with 2-4ml of plasma activated with Calcium Chloride. The gel was	Outcome 1: Proportion of ulcers completely healed by 10 weeks. Outcome 2: Proportion of ulcers improved by 10 weeks. Outcome 2: Mean percentage reduction in ulcer volume by 10	Group 1: 0/8 Group 2: 0/8 Group 1: 8/8 Group 2: 7/8 Group 1: 55.0 (22.9) Group 2: 17.2 (98.1)	Funding: / Limitations: no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; small sample size Additional

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded. Statistical analysis: The absolute and percentage differences between volumes at each time between day 0 and week 10 were both considered. The trend of volume changes was tested with descriptive statistics, the t-test, the Mann-Whitney test and the variance analysis. Efficacy evaluation at 10 weeks. Safety evaluation at 14 weeks. Baseline differences: No baseline characteristics were reported. Study power/sample size: No a priori sample size calculation. Setting: Plastic and reconstructive surgery unit of the 'Salvatore Maugeri' foundation	Gender (m/f): 10/3 Ulcer location: Sacrum: n=10 Ischium: n=6 Group 1 Randomised N: 8 ulcers Completed N at 10 weeks: 8 ulcers Completed N at 14 weeks: 4 ulcers Dropouts: 4 ulcers Group 2 Randomised N: 8 ulcers Completed N at 10 weeks: 8 ulcers Completed N at 14 weeks: 7 ulcers Dropouts: 1 ulcers Inclusion criteria: Grade III or IV PU; no signs of necrosis or infection; stable after at least 2 months Exclusion criteria: Metabolic, endocrine, and collagen pathologies; ischemic cardiopathy;	then frozen to -80°C. The preparation was run in an absolute sterile modality. The ulcers were treated twice a week for 8 weeks. Group 2: Standard treatment. Ulcers were cleansed with saline at room temperature. The ulcers were covered a 10% iodoform impregnated gauze or sodium/alginate foams or cadexomer iodine powder and/or vacuum assisted closure therapy. All groups: All patients used pressure-relieving devices and followed their two hourly postural change.	weeks.		outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
hospital of Pavia, Italy. Length of study: eight weeks of treatment and up to 14 weeks of follow-up Assessment of PUs: Ulcers volume was calculated in millilitre by filling the cavity up to the skin surface plane with a liquid transparent gel using a graduated syringe. Granulation tissue and bleeding were assessed. Ulcer dimensions were taken every two weeks and photos were collected. Classification of PUs: NPUAP classification (2007). Multiple ulcers: 12 patients with 16 ulcers were included in the study	corticosteroid or immunosuppressive therapy; obesity; malignancies; organ failure				

Table 253: Seaman 2000[200]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Seaman (2000) **Title**: Simplifying modern wound management for nonprofessional caregivers. **Journal:** Ostomy/wound management, 46; 18-27. Type of study: randomized controlled trial Sequence generation: randomized schedule was generated by the Department of Data Management and Biostatistics at ConvaTec. Allocation concealment: sequentially numbered envelopes Blinding: not reported. Addressing incomplete outcome data: intention to treat analysis for all subjects wearing at least one dressing. Statistical analysis: Dressing wear time and	Patient group: Patients with a stage II, III or IV PU (according to the AHCPR classification). All patients Randomised N: 35 Completed N: 13 Drop-outs: 22 Group 1 Randomised N: 17 Completed: not reported Dropouts: not reported Age (mean years): 78 Gender (m/f): 5/12 Diabetes: 2 Incontinence: Urine: 0 Faecal: 6 Both: 4 Ulcer area (mean cm² (SD)): 4.2 (6.1) Group 2 Randomised N: 18 Completed N: not reported	Group 1: Hydrocolloid dressing (SignaDress®, ConvaTec, Bristol-Myers Squibb Company, Princeton, NJ). Group 2: Hydrocolloid dressing (Comfeel Plus®, Coloplast Corporation, Marietta, Ga). All groups: Wound filler if ulcers were deep enough: moderate to heavily exuding ulcers: Aquacal® HydrofiberTM (ConvaTec, Bristol-Myers Squibb Company, Princeton, NJ); minimal exudate: DuoDerm® Hyrdocative®; Bristol-Myers Squibb Company, Princeton, NJ) 94% of the patients received regular repositioning and 74% received pressure relief	Outcome 1: Proportion of patients completely healed Outcome 2: Percentage reduction in ulcer area Outcome 3: Percentage reduction in ulcer area per week Outcome 4: Proportion of patients dressing related adverse events	Group 1: 6/17 Group 2: 1/18 P-value: 0.04 Group 1: 60 Group 2: 22 P-value: 0.01 Group 1: 33.8 Group 2: 7.0 Group 1: 0/17 Group 2: 0/18	Funding: funding provided by ConvaTec, Bristol-Myers Squibb Company Limitations: allocation concealment by sequentially numbered envelopes; no report on blinding; no a priori sample size calculation; high drop-out; little information on ulcer assessment; little information on interventions; no report on multiple ulcers Additional outcomes: dressing performance (wear time, ease of application) Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
change in ulcer surface area were analyzed using analysis of variance (anova) for the effect of treatment, center, and treatment-by-center interaction. All data were analyzed using the SAS system, with a probability of a type I error selected as 0.05 Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: Home care and long-term care. Length of study: five dressing changes or unless healing occurred first Assessment of PUs: Ulcers tracing and photographs. Classification of PUs: AHCPR classification. Multiple ulcers: not reported	Dropouts: not reported Age (mean years): 66 Gender (m/f): 9/9 Diabetes: 7 Incontinence: Urine: 2 Faecal: 7 Both: 3 Ulcer area (mean cm² (SD)): 4.9 (4.1) Inclusion criteria: Stage II, III or IV PU; legal consenting age; informed consent Exclusion criteria: PU > 2½“ x 2½“ at maximum length and width; radiation treatment to the area; known hypersensitivity to one of the dressings; involved in other concomitant research				

Table 254: Sebern 1986[201]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Sebern (1986) **Title**: Pressure ulcer management in home health care: Efficacy and cost effectiveness of moisture vapor permeable dressing. **Journal:** Archives of Physical Medicine and Rehabilitation, 67; 726-729. Type of study: randomized controlled trial Sequence generation: a sequential list of 100 random numbers (50 G1 and 50 G2) was used. Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs excluded. Statistical analysis: Indirect (reported next to the tables and figures): Student t-test was used to compare	Patient group: Home care patients with grade II or III PUs (according to the Shea classification). All patients Randomised N: 100 ulcers Completed N: 48 patients and 77 ulcers Drop-outs: 23 ulcers (death, hospitalization, non-adherence to study protocol) Group 1 Randomised N: 50 ulcers Completed: 37 ulcers Dropouts: 13 ulcers (death, hospitalization, non-adherence to study protocol) Age (mean years (SD)): 76.3 (17.3) Ulcers grade: Grade II: 22 Grade III: 15 Group 2 Randomised N: 50 ulcers	Group 1: Moisture vapour permeable dressing (TegardermTM, 3M Medical division, St Paul). The dressing was changed daily to three times a week, depending on adherence of the dressing. TegardermTM: polyurethane adhesive dressing, coated with an acrylate adhesive, but permeable to moisture vapour and oxygen. Some were pouch dressings: the dressing is perforated to allow fluid to pass through it into a film pouch. Once in the pouch, fluid may readily evaporate trough the film. Group 2: Wet to dry gauze dressing. Physiologic saline was used on the contact layer of gauze, which was covered with dry gauze and an ABD pad. Two-inch paper tape secured the dressing. The dressing was changed every 24 hours. All ulcers were irrigated at each dressing with half strength hydrogen peroxide and were rinsed with physiologic saline. If the ulcers were contaminated with urine and	Outcome 1: Proportion of ulcers completely healed (grade II) Outcome 2: Proportion of ulcers with no change (grade II) Outcome 3: Proportion of ulcers worsened (grade II) Outcome 4: Decrease in ulcer grade in grade II PUs Outcome 5: Increase in ulcer grade in grade II PUs Outcome 6: Median percentage reduction in ulcer area (grade II)	Group 1: 14/22 Group 2: 0/12 P-value: <0.01 Group 1: 1/22 Group 2: 1/12 P-value: <0.01 Group 1: 3/22 Group 2: 7/12 P-value: <0.01 Group 1: 16/22 Group 2: 0/12 P-value: <0.01 Group 1: 1/22 Group 2: 5/12 P-value: <0.01 Group 1: 100 Group 2: 52 P-value: <0.01	Funding: Partly by a grant award from Sigma Theta Tau, Delta Gamma Chapter, and Marquette University College of Nursing. Financial support was awarded by 3M Medical division, St Paul Limitations: little information on sequence generation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation. Additional outcomes: cost Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
baseline difference between groups. Chi-square test was used to analyze difference between groups for healing status in grade II PUs and the final grade of grade II PUs. The Wilcoxon rank sum test was used to measure the difference between groups for median % decrease in ulcer area and total cost. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: Home care. Length of study: five dressing changes or unless healing occurred first Assessment of PUs: Ulcers length and width were measured with a clear plastic measuring card and the area was calculated by assuming an elliptical shape.	Completed: 40 ulcers Dropouts: 10 ulcers (death, hospitalization, non-adherence to study protocol) Age (mean years (SD)): 72.4 (17.0) Ulcers grade: Grade II: 22 Grade III: 15 Inclusion criteria: Grade II or III PU Exclusion criteria: Eschar; terminal patient; white count below 4000; more than 3 PUs	stool, povidine iodine was applied for two minutes and then rinsed away with physiologic saline. All groups: The protocol included a turning schedule and wheelchair pushups.	Outcome 7: Median percentage reduction in ulcer area (grade III) Outcome 2: Proportion of ulcers with skin maceration	Group 1: 67 Group 2: 44 P-value: > 0.05 Group 1: 17/22 Group 2: 10/12 P-value: >0.05	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: Shea classification (1975). Multiple ulcers: 48 patients and 77 ulcers were analysed					

Table 255: Seeley 1999[202]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Seeley (1999) **Title**: A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers. **Journal:** Ostomy/wound management, 45 (6); 39-47. Type of study: randomized controlled trial Sequence generation: computer generated randomized list. Allocation concealment: stratified according to	Patient group: Patients with stage II or III PU (according to the AHCPR classification). All patients Randomised N: 40 Completed N: 26 Drop-outs: 14 (1 request of patient, 3 lost to follow-up, 8 adverse event, 2 died) Group 1 Randomised N: 20 Completed: 12 Dropouts: 8 (1 request of patient, 3 lost to follow-up, 3 adverse event, 1 died)	Group 1: Adhesive hydrocellular dressing (Allevyn® Adhesive, Smith & Nephew Medical, Hull, England). Ulcers were cleansed with dermal wound cleanser (CarraKlenz) prior to each dressing application. Dressings change was determined by judgement of the clinical investigator. Group 2: Hydrocolloid dressing (DuodermCGF®, ConvaTec, Princeton, NJ). Ulcers were cleansed with dermal wound cleanser (CarraKlenz) prior to each dressing application. Dressings change was determined by judgement of the clinical investigator. All groups: /	Outcome 1: Proportion of patients completely healed Outcome 2: Mean percentage reduction in ulcer area Outcome 3: Mean wound pain (0: none – 3: severe) Outcome 4: Mean wound odour (0: none – 3: severe) Outcome 5: Proportion of patients with	Group 1: 8/20 Group 2: 8/20 Group 1: 50 Group 2: 52 P-value: 0.31 Group 1: 0.15 (0.8) Group 2: 0.47 (0.9) Group 1: 0.16 (0.5) Group 2: 0.47 (0.8)	Funding: / Limitations: inadequate allocation concealment; no report on blinding; no a priori sample size calculation; no report on preventive measures. Additional outcomes: dressing application (ease of application and removal; wear time; number of dressing changes

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
initial ulcer size Blinding: not reported. Addressing incomplete outcome data: intention to treat analysis, one patient was excluded because of death shortly after enrolment. Statistical analysis: The Fischer's exact test was used to test the difference between number of patients whose ulcers improved and did not improve in appearance and developed inflammation and maceration and did not. A mean odour and pain was calculated and difference between groups were tested by the Mann Whitney U test. The Mann Whitney U test was used to measure the difference between groups for the percentage change in ulcer area over the duration of the study. All test were two-sided and the significance level 5% was considered	Age (mean years (SD)): 75.7 (18.6) Gender (m/f): 9/11 Duration of ulcer (mean weeks (SD); median): 11.8 (7.4); 9 Ulcers stage: Stage II: 3 Stage III: 17 Ulcer location: Sacrum or coccyx: 4 Heel: 7 Foot or ankle: 3 Trochanter: 1 Ischium: 1 Thigh: 2 Buttocks: 1 Other: 1 Ulcer area (mean cm² (SD)): 6.84 (8.19) Group 2 Randomised N: 20 (one excluded from baseline characteristics and analysis) Completed: 14 Dropouts: 6 (5 adverse event, 1 died) Age (mean years (SD)):		inflammation or maceration Outcome 6: Proportion of patients with adverse events (unknown if dressing related)	Group 1: 12/20 Group 2: 6/19 Group 1: 3/20 Group 2: 5/20	Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
significant. SAS system was used to analyse the data. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: Home care and several long-term care facilities. Length of study: eight weeks of treatment Assessment of PUs: Ulcers were traced, and photographed. Ulcer area was calculated from tracing using digital image analysis. Classification of PUs: AHCPR classification (1992). Multiple ulcers: only the largest ulcer was selected for the study	76.7 (19.5) Gender (m/f): 9/10 Duration of ulcer (mean weeks (SD); median): 23.1 (38.9); 10 Ulcers stage: Stage II: 2 Stage III: 17 Ulcer location: Sacrum or coccyx: 5 Heel: 3 Foot or ankle: 4 Trochanter: 1 Ischium: 1 Thigh: 1 Buttocks: 2 Other: 2 Ulcer area (mean cm^2 (SD)): 4.61 (5.56) Inclusion criteria: Older than 18 years; stage II or III PU Exclusion criteria: Ulcer smaller than $1cm^2$ or larger than 50 cm^2; clinical infection of ulcer; uncontrolled diabetes; known history of poor compliance with medical				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	treatment				

Table 256: Sipponen 2008[206]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Sipponen (2008) **Title**: Beneficial effect of resin salve in treatment of severe pressure ulcers: A prospective, randomized and controlled multicentre trial. **Journal:** British Journal of Dermatology, 158 (5); 1055-1062. Type of study: randomized controlled trial Sequence generation: permuted block sizes of four according to a random list designed by a specialist in biometrics. Allocation concealment: closed envelopes Blinding: no blinding Addressing incomplete	Patient group: Hospitalized patients with a grade II to IV PU (according to the EPUAP). All patients Randomised N: 37 patients and 45 ulcers Completed N: 22 patients and 29 ulcers Drop-outs: 15 patients and 16 ulcers (7 deaths, 2 operated, 1 allergic skin reaction, 1 misdiagnosed, 4 patients-based refusal) Group 1 Randomised N: 21 patients and 27 ulcers Completed N: 13 patients and 18 ulcers Dropouts: 8 patients and 9 ulcers (3 deaths, 2 operated, 1 allergic skin reaction, 1 misdiagnosed, 1 patients-based refusal)	Group 1: Resin salve (from the Norway spruce (Picea abies). An even layer of resin +/- 1 mm thick was spread between loose sterile cotton gauze. The gauze was placed on both infected and noninfected areas of the pressure ulcer to cover the ulcer area with resin fully. The resin–gauze dressing was changed daily if the ulcer was infected or produced a discharge; if this were not the case, the dressing was changed every third day. Group 2: sodium carboxymethylcellulose hydrocolloid polymer without or with ionic silver (Aquacel® or Aquacel Ag®; ConvaTec Ltd, London, U.K.). The Aquacel–hydrocolloid dressing was changed daily if the ulcer produced excessive discharge, but if there was no secretion the dressing was changed every third day, as for	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of ulcers completely healed Outcome 3: Proportion of ulcers improved Outcome 4: Proportion of ulcers worsened Outcome 5: Mean percentage reduction in ulcer width Outcome 6: Mean percentage reduction in ulcer	Group 1: 12/13 Group 2: 4/9 P-value: 0.003 Group 1: 17/18 Group 2: 4/11 P-value: 0.003 Group 1: 18/18 Group 2: 10/11 Group 1: 0/18 Group 2: 1/11 P-value: 0.003 Group 1: 93.75 Group 2: 57.14 Group 1: 88.46	Funding: grant to A.s. in support of this investigation and the Lappish Resin project Limitations: no blinding; no ITT analysis; final sample size lower than calculated Additional outcomes: bacterial cultures Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: drop-outs were excluded Statistical analysis: Differences between parallel groups were compared with the $\chi 2$ test or Fisher's exact test, as appropriate. Mean and SD were computed for continuous variables and proportions were compared after distribution analysis with the nonparametric Mann–Whitney U-test or Student's t-test, as appropriate. The healing of the ulcers over time was assessed by Kaplan–Meier analysis and the log-rank test was used to estimate the differences in the final outcome and healing time between the parallel groups. $P < 0.05$ was considered statistically significant. SPSS 14.0 was used for the statistical calculations (SPSS, Chicago, IL,	Age (mean years (SD); range): 80 (10); 58-98 Gender (m/f): 6/7 BMI (mean kg/m² (SD); range): 21.8 (7.1); 15.9-35.5 Diabetes: 6 Ulcer width (mean cm (SD)): 3.2 (2.4) Ulcer depth (mean mm (SD)): 5.2 (10.3) Ulcer location: Calcaneus: 8 Trochanter: 3 Sacrum: 1 Ischium: 1 Other: 5 Ulcer grade: Grade II: 7 Grade III: 9 Grade IV: 2 Group 2 Randomised N: 16 patients and 18 ulcers Completed N: 9 patients and 11 ulcers Dropouts: 7 patients and 7 ulcers (4 deaths, 3 patients-based refusal)	the resin–gauze. Both groups: 3 patients received a pressure ulcer mattress.	depth Outcome 7: speed of healing (days) (log-rank-test) Outcome 8: Proportion of patients allergic skin reaction	Group 2: -1.89 P-value: 0.013 (favour G1) Group 1: 1/21 Group 2: 0/16	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
U.S.A.). Baseline differences: No statistical difference between groups. Study power/sample size: A two group $\chi 2$ test with a 0.05 two-sided significance level will have 80% power to detect the difference between a group 1 proportion of 0.900 and a group 2 proportion of 0.500 (odds ratio 0.111) when the sample size in each group is 20. Setting: 11 primary care hospitals in Finland Length of study: six months Assessment of PUs: Ulcer localization, ulcer grade, color, width and depth were measured at the beginning of the study and thereafter monthly for 6 months. All ulcers were photographed and planimetry analysis was performed. Classification of PUs:	Age (mean years (SD); range): 74 (8); 60-88 Gender (m/f): 3/6 BMI (mean kg/m² (SD); range): 21.9 (6.6); 16.9-34.7 Diabetes: 1 Ulcer width (mean cm (SD)): 4.2 (2.8) Ulcer depth (mean mm (SD)): 5.3 (6.5) Ulcer location: Calcaneus: 2 Trochanter: 1 Sacrum: 2 Ischium: 5 Other: 1 Ulcer grade: Grade II: 5 Grade III: 5 Grade IV: 1 Inclusion criteria: One or several severe PU (grade II to IV); with or without an infection Exclusion criteria: Life expectancy < 6 months; advanced malignant disease				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
EPUAP classification. Multiple ulcers: 37 patients and 45 ulcers					

Table 257: Small 2002[207]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Small (2002) **Title**: A comparative analysis of pressure sore treatment modalities in community settings. **Journal:** Curationis, 25; 74-82. Type of study: randomized controlled trial Sequence generation: computer generated randomized list provided by the Department Biostatistics, University of the Free State Allocation concealment: randomization by pressure sore stage Blinding: not reported. Addressing incomplete	Patient group: Patients with stage II, III or IV PU (according to the Stirling classification). All patients Randomised N: 58 Completed N: 41 Drop-outs: 17 (10 died, 4 moved, 2 developed an ulcer infection, and 1 was hospitalized) Group 1 Randomised N: 28 Completed: 23 Dropouts: 5 (3 died, 1 moved, 1 developed an ulcer infection) Age (median years; range): 76.5; 19-89 Gender (m/f): 7/21 BMI (median kg/m²;	Group 1: Hydrogel (IntraSiteTM gel, Smith & Nephew), Foam dressing (AllevynTM hydrocellular or AllevynTMadhesive), or Transparant film dressing (OpSite FlexigridTM). Ulcers were cleansed with a gentle, hypoallergenic soap and water and dried with gauze. Ulcers were than aseptically cleansed with warm sterile, physiological saline. Ulcers were irrigated or ulcer bed was gently patted. Non-viable tissue: a thin layer of IntraSiteTM gel was applied and covered with AllevynTM non adhesive hydrocellular sheet or Allevyn TM adhesive. Granulating tissue: AllevynTM non adhesive hydrocellular sheet or Allevyn TM adhesive as applied. Epithelializing tissue: Transparant OpSite FlexigridTM	Outcome 1: Proportion of patients completely healed Outcome 2: Percentage healed per week (log-rank test) Outcome 3: Proportion of patients dressing related adverse events Outcome 4: Proportion of patients reporting the application of dressing as comfortable Outcome 3:	Group 1: 15/23 Group 2: 9/18 Group 1: / Group 2: / P-value: 0.15 Group 1: 0/28 Group 2: 0/30 Group 1: 14/14 Group 2: 6/7	Funding: / Limitations: inadequate allocation concealment; no report on blinding; no ITT analysis; inadequate a priori sample size determination; no report on preventive measures. Additional outcomes: dressing application (ease of application and removal) Cost Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: drop-outs were excluded. Statistical analysis: Demographic and baseline information was summarized by groups. Numeric variables were summarized by medians and percentiles as distribution were skew. Categorical variables were summarized by frequencies and percentages. Changes between baseline and consecutive treatment information were summarized per group by medians and percentiles or percentages, as appropriate for the difference between the groups, with a 95% confidence intervals. The log-rank-survival test was used to calculate the percentage of patients that healed buy the end of each week. Baseline differences: No	range): 22; 17-27 Ulcer location: Sacrum: 11 Trochanter: 6 Malleolus: 3 Iliac: 2 Ischium: 2 Heel: 2 Wrist: 1 Foot: 1 Elbow: 0 Scapula: 0 Group 2 Randomised N: 30 Completed: 18 Dropouts: 12 (7 died, 3 moved, 1 developed an ulcer infection, 1 was hospitalized) Age (median years; range): 78; 24-97 Gender (m/f): 16/14 BMI (median kg/m²; range): 21; 13-28 Ulcer location: Sacrum: 15 Trochanter: 6 Malleolus: 0 Iliac: 2	dressing Group 2: Standard treatment: Cotton wool, alginates, hydrocolloid, gauze impregnated or gauze. Ulcers were cleansed with a gentle, hypoallergenic soap and water and dried with gauze. The wound was then aseptically cleansed (different cleansers) and covered with a dressing. All groups: /	Proportion of patients reporting discomfort at dressing removal	Group 1: 0/14 Group 2: 1/7	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistical difference between groups. Study power/sample size: In collaboration with a biostatistician was decided that a sample size of at least 40 patients was a statically adequate number. Setting: Primary health care clinics, community health care. Length of study: six weeks of treatment or until complete healing, withdrawal of the patient, or occurrence of adverse events Assessment of PUs: Rate of healing was assessed by standardized digital wound photographs, tracing of wound edges, and measurements of the ulcer and its appearance. Classification of PUs: Stirling classification (1996). Multiple ulcers: one sore	Ischium: 1 Heel: 3 Wrist: 0 Foot: 0 Elbow: 2 Scapula: 1 Inclusion criteria: Aged 18 years and older; clinically uninfected PU; stage II, III or IV PU; informed consent; willing and able to comply with treatment Exclusion criteria: /				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
was chosen at random for inclusion in the study					

Table 258: Sopata 2002[210]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Sopata (2002) **Title**: Effect of bacteriological status on pressure ulcer healing in patients with advanced cancer. **Journal:** Journal of Wound Care, 11 (3); 107-110 Type of study: randomized controlled trial Sequence generation: computer numbering system Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: drop out not excluded. Statistical analysis: The Mann-Whitney U	Patient group: Palliative care patients with a grade II or III PU (according to the Torrance classification) All patients Randomised N: 34 patients and 38 ulcers Completed N: 29 patients Drop-outs: 5 patients (died) Group 1 Randomised N: 17 patients and 18 ulcers Completed N: 15 patients and 16 ulcers Dropouts: 2 patients (died) Age (mean years (SD)): 58.5 (16.92) Gender (m/f): 7/10 Ulcer grade:	Group 1: Polyurethane foam dressing (Lyofoam®, Seton, UK). Dressings were changed according to clinical need. Group 2: Hydrogel dressing (Aquacel®, Wytw. Opatrunkow, Poland). Dressings were changed according to clinical need. Both groups: /	Outcome 1: Proportion of ulcers completely healed Outcome 2: Proportion of ulcers completely healed (grade II) Outcome 3: Proportion of ulcers completely healed (grade III) Outcome 4: Proportion of ulcers improved Outcome 5: Proportion of ulcers improved (grade III) Outcome 6: Mean	Group 1: 15/18 Group 2: 15/20 Group 1: 6/6 Group 2: 6/6 Group 1: 9/12 Group 2: 9/14 Group 1: 18/18 Group 2: 19/20 Group 1: 12/12 Group 2: 13/14	Funding: / Limitations: no report on allocation concealment; no report on blinding; little information on ulcer assessment and statistical analysis; little information on interventions; no information on preventive measures. Additional outcomes: bacterial assessment Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
test, chi-square test and Fischer's exact test were used. All means were compared at the significance level (p=0.05. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: Palliative care department at the University of Medical Sciences, Poznan, Poland. Length of study: eight weeks of treatment or until complete healing Assessment of PUs: Ulcers were traced with a pen on acetate and photographed from a fixed distance. Rate of healing was calculated using computer planimetry. Classification of PUs: Torrance classification (1983). Multiple ulcers: 34	Grade II: 6 Grade III: 12 Ulcer location: Buttocks: 6 Coccyx: 8 Sacrum: 2 Other: 2 Ulcer area (mean cm² (SD)): 11.04 (11.65) Duration of PU (mean weeks (SD)): 2.46 (0.24) Group 2 Randomised N: 17 patients and 20 ulcers Completed N: 14 patients and 16 ulcers Dropouts: 3 patients (died) Age (mean years (SD)): 58.7 (14.11) Gender (m/f): 9/8 Ulcer grade: Grade II: 6 Grade III: 14 Ulcer location: Buttocks: 6 Coccyx: 3 Sacrum: 4 Other: 7		healing rate for healed ulcers grade II (cm²/day) Outcome 7: Mean healing rate for healed ulcers grade III (cm²/day) Outcome 8: Mean healing rate for improved ulcers grade III (cm²/day) Outcome 9: Mean healing rate of ulcer not improved grade III (cm²/day)	Group 1: 1.23 (1.33) Group 2: 0.67 (0.37) Group 1: 0.44 (0.27) Group 2: 0.31 (0.21) Group 1: 0.70 (0.63) Group 2: 0.27 (0.11) Group 2: -0.68	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
patients with 38 ulcers	Ulcer area (mean cm² (SD)): 8.28 (13.90) Duration of PU (mean weeks (SD)): 2.45 (1.60) Inclusion criteria: Advanced cancer; life expectancy > 8 weeks Exclusion criteria: poor general condition; very low level of haemoglobin (<7mmol/l) and albumin (<2.5g/dl); use of drugs such as corticosteroids that could affect wound healing				

Table 259: Thomas 1997[226]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Thomas (1997) **Title**: A comparison of two dressings in the management of chronic wounds. **Journal:** Journal of Wound Care, 6 (8); 383-386.	Patient group: Patients with grade II or III PU (according to the Stirling classification). Also patients with leg ulcers were included (separate analysis) All patients Randomised N: 99 Completed N: 96	Group 1: Hydropolymer dressing (Tielle®). Ulcers were cleansed using a sterile solution of sodium chloride 0.9%. After the dressing was applied. Dressing were changed only at leakage or when exudate was seen to be approaching the edge of the dressing. Tielle®: consists of a polyurethane adhesive and an	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of patients improved Outcome 3: Proportion of	Group 1: 10/48 Group 2: 16/48 Group 1: 39/48 Group 2: 39/48	Funding: / Limitations: no report on sequence generation; no report on blinding; no ITT analysis; no a priori sample size calculation; no report on multiple ulcers.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: sealed envelopes Blinding: not reported. Addressing incomplete outcome data: missing data excluded. Statistical analysis: For continuous measurements the two sample t-test was employed, unless validity was in doubt, in which case than Mann-Whitney sum of ranks test was used. Categorical data were analysed using a conventional chi-squared test or, where appropriate, the Fischer Exact test. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation.	Drop-outs: 3 (missing data) Group 1 Randomised N: 50 Completed: 48 Dropouts: 2 (missing data) Age (mean years; (SD)): 80.1 (10.2) Gender (m/f): 45/35 Duration of PU: (1 missing data) < 1 month: 8 month: 21 > 3 months: 20 Ulcer grade: Grade II: 27 Grade III: 23 Ulcer location: Heel: 23 Buttock: 6 Sacrum: 10 Hip: 2 Other: 9 Group 2 Randomised N: 49 Completed: 48	absorbent island of a hydrophilic polyurethane foam. A non-woven fabric layer located between these two components facilitates the lateral dispersion of exudate and thus maximises the utilisation of the central island. Group 2: Hyrdocolloid dressing (Granuflex®). Ulcers were cleansed using a sterile solution of sodium chloride 0.9%. After the dressing was applied. Dressing were changed only at leakage or when exudate was seen to be approaching the edge of the dressing. Granuflex®: consists of a thin polyurethane foams sheet bearing an adhesive polymer matrix containing the gel forming agents gelatine, pectin, and sodium carboxymethylcellulose. All groups: Pressure relieving devices were used.	patients not changed Outcome 4: Proportion of patients worsened Outcome 5: Mean percentage reduction in ulcer size Outcome 6: Proportion of patients with maceration Outcome 7: Proportion of patients with bleeding Outcome 8: Proportion of patients with excess granulation tissue	Group 1: 4/48 Group 2: 2/48 Group 1: 5/48 Group 2: 7/48 Group 1: not reported; figure unclear Group 2: not reported; figure unclear Group 1: 0/50 Group 2: 4/49 Group 1: 0/50 Group 2: 2/49 Group 1: 0/50 Group 2: 0/49	Additional outcomes: dressing application (ease of application and removal; dressing changes) Notes: Patient characteristics are for PU patients only as all information was reported separately for PU and leg ulcer patients.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: Two centers in the community. Length of study: six weeks of treatment. Assessment of PUs: Ulcers were photographed and planimetry was used to determine the ulcer area from tracing. Classification of PUs: Stirling classification. Multiple ulcers: not reported	Dropouts: 1 (missing data) Age (mean years; (SD)): 78.6 (14.3) Gender (m/f): 16/33 Duration of PU: (1 missing data) < 1 month: 9 month: 18 > 3 months: 21 Ulcer grade: Grade II: 30 Grade III: 19 Ulcer location: Heel: 25 Buttock: 2 Sacrum: 6 Hip: 4 Other: 12 Inclusion criteria: Grade II or III PU; ulcer less than 10cm deep and maximum 8cm diameter (allow use of a single dressing) Exclusion criteria: under 16 years; history of poor compliance to medical treatment; insulin dependent diabetes;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	unlikely to survive the study period; previously demonstrated; clinically infected ulcer.				

Table 260: Thomas 1998[225]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Thomas (1998) **Title**: Acemannan hydrogel dressing versus saline dressing for pressure ulcers. A randomized, controlled trial. **Journal:** Advances in Wound Care, 11 (6); 273-276. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs were excluded.	Patient group: Patients older than 18 years with stage II, III or IV PU. All patients Randomised N: 41 Completed N: 30 Drop-outs: 11 (6 died, 2 worsened, 2 hospitalized, 1 violated protocol) Age (mean years (SD); range): 77 (12); 35-97 Gender (m/f): 19/22 Ulcer stage: Stage II: 15 Stage III: 20 Stage IV: 6 Group 1 Randomised N: 22 Completed: 16 Dropouts: 6 (4 died, 1	Group 1: Amorphous hydrogel dressing (Carrasyn® gel, Carrington Laboratories, Inc., Irving, TX). Ulcers were cleansed with saline and gently mechanical wiped with gauze. Ulcers were treated with a 1/8 inch layer of hydrogel and covered with a dry sterile nonwoven gauze, held in place with a thick gauze dressing. Dressings were changed daily. Carrasyn®: the active ingredient is thought to be acemannan, a complex carbohydrate derived from the aloe vera plant. Group 2: Moist saline gauze dressing. Ulcers were cleansed with saline and gently mechanical wiped with gauze. Ulcers were covered with a sterile nonwoven saline soaked gauze and a dry sterile	Outcome 1: Proportion of patients completely healed Outcome 2: Percentage healing rate Outcome 3: Mean time to healing (weeks) Outcome 4: Proportion of patients worsened	Group 1: 10/16 Group 2: 9/14 Odds ratio: 0.93 (95% CI: 0.16-5.2) P-value: 0.92 Group 1: 63 Group 2: 64 Group 1: 5.3 (2.3) Group 2: 5.2 (2.4) P-value: 0.87 Group 1: 1/22 Group 2: 1/19	Funding: grant from Carrington Labaratories, Inc. Irving, Tx. Limitations: no report on sequence generation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation; no report on classification of PU Additional outcomes: healing rate and subject characteristics (odds ratio's)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Comparison of dichotomous variables was performed by chi-square test. Fischer's exact test was used when a cell value was less than 5. Distributions of continuous variables were compared by the Kruskal-Wallis test for groups. Data were analysed using EPI6.. Baseline differences: No statistical difference between groups for the characteristics of the patients after exclusion of drop-outs Study power/sample size: The study had a power of 80% to detect 25% difference at alpha significance 0.05. Unclear if a priori calculation. Setting: skilled nursing facilities and home health care agencies. Length of study: 10 weeks of treatment or until complete healing, whichever came first.	worsened, 1 hospitalized) Characteristics are form completed N Age (mean years (SD)): 79 (9) Gender (m/f): 7/9 Ulcer stage: Stage II: 8 Stage III: 6 Stage IV: 2 Ulcer area (mean cm² (SD)): 8.9 (9.3) Incontinence: Urine: 9 Faecal: 12 Group 2 Randomised N: 19 Completed N: 14 Drop-outs: 5 (2 died, 1 worsened, 1 hospitalized, 1 violated protocol) Characteristics are form completed N Age (mean years (SD)): 72 (13) Gender (m/f): 9/5 Ulcer stage: Stage II: 6	nonwoven gauze, held in place with a thick gauze dressing. Dressings were changed daily. All groups: Pressure relieving devices were used in 26.7% of the patients			Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: Ulcers were photographed and tracing were made. Classification of PUs: not reported. Multiple ulcers: only one ulcer par subject was evaluated	Stage III: 7 Stage IV: 1 Ulcer area (mean cm² (SD)): 5.9 (6.0) Incontinence: Urine: 7 Faecal: 12 Inclusion criteria: Age 18 years and older; stage II, III or IV PU; ulcer area ≥ 1.0cm² Exclusion criteria: venous or arterial insufficiency or other non-pressure etiology; ulcers with sinus tracts and/or undermining greater than 1 cm; clinically infected ulcers; concomitant use of other topical medication or systemic steroid therapy; severe medical condition; estimated survival of less than 6 months ; HIV, currently abusing alcohol or drugs; pregnant, breast feeding or not on acceptable means of anti-contraception; diagnose of cancer; receiving chemotherapy				

Table 261: Thomas 2005[224]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Thomas (2005) **Title**: A controlled, randomized, comparative study of a radiant heat bandage on the healing of stage 3-4 pressure ulcers: A pilot study. **Journal:** Journal of the American Medical Directors Association, 6; 46-49. Type of study: randomized controlled trial Sequence generation: standard computer-generated Allocation concealment: block stratification using opaque envelopes Blinding: not reported. Addressing incomplete outcome data: reported as intention to treat analysis. However drop-outs (and exclusion) are suspected.	Patient group: Patients older than 18 years with stage III or IV PU. All patients Randomised N: 41 Completed N: 41 Drop-outs: 0 Age (mean years (SD)): 75.5 (12.6) Gender (m/f): 21/20 Ulcer stage: Stage III: 22 Stage IV: 19 Ulcer location: Sacrum: 17 Ischium: 9 Coccyx: 6 Other: 9 Group 1 Randomised N: 21 Completed: 21 Dropouts: 0 Age (mean years (SD)): 74.1 (13.8) Gender (m/f): 12/16 Ulcer stage:	Group 1: Radiant heat dressing (Warm-UpTM, Augustine Medical Inc., Eden Prairie, MN). The warming card was used for a 1-hour treatment every 8 hours for the duration of the study. The dressing was changed every 7 days or when the occlusive seal was broken. Warm-UpTM: consists of two layers of plastic film (semi-occlusive and water vapor permeable) supported by and attached to an open-cell pad that adheres to the skin surrounding the wound area. The window portion of the bandage, centered over the wound, is a two layered pocket into which the warming card (heating element) is inserted. The warming card delivers heat at 38°C, warming the wound and periwound area, without coming into direct contact with the wound tissue. Group 2: Hydrocolloid dressing (DuodermTM, ConvaTec, Inc., Princeton, NJ with or without a calcium alginate filler (SorbasanTM, Smith &	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of patients completely healed (stage III PU) Outcome 3: Proportion of patients completely healed (stage IV PU)	Group 1: 8 (unclear if 8 of 14 patients = 56% as reported or 8 of 21 because ITT analysis) Group 2: 7 (unclear if 7 of 16 patients = 44% as reported or 7 of 20 because ITT analysis) Group 1: unclear Group 2: unclear Group 1: unclear Group 2: unclear	Funding: / Limitations: no report on blinding; unclear if ITT analysis was used; no a priori sample size calculation; no report on classification of PU Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: A contingency table was constructed using chi-square techniques to compare healing rates. Kaplan-Meier survival analysis was performed to compare the probability of healing between groups. Statistical analysis was performed using Statistica. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: outpatient clinics, long-term care nursing homes, and a rehabilitation center. Length of study: 12 weeks of treatment. Assessment of PUs: Ulcer area (length, width, and depth) of the wound was measured and a plastic acetate tracing of the wound perimeter was made	Stage III: 11 Stage IV: 10 Ulcer area (mean cm² (SD)): 11.0 (9.5) Braden score (mean (SD): 12.8 (2.1) BMI (mean kg/m² (SD)): 23.9 (4.6) Group 2 Randomised N: 20 Completed: 20 Dropouts: 0 Age (mean years (SD)): 77.0 (11.5) Gender (m/f): 9/4 Ulcer stage: Stage III: 13 Stage IV: 9 Ulcer area (mean cm² (SD)): 12.1 (18.2) Braden score (mean (SD): 13.7 (2.9) BMI (mean kg/m² (SD)): 23.8 (7.7) Inclusion criteria: 18 years or old; non-infected stage II or IV PU; ulcer area ≥ 1.0cm²;	Nephew, Inc. Largo, Fl.) depending in exudate. The dressing was changed every 7 days All groups: Both groups received standard offloading and pressure reducing devices.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
using a felt pin pen. The wound was assessed using the Pressure Ulcer Status for Healing (PUSH) tool Classification of PUs: not reported. Multiple ulcers: only one ulcer was evaluated per subject	truncal PU Exclusion criteria: history of sensitivity to adhesive products; ulcer with a sinus tract and/or extensive undermining (> 1 cm); non-pressure ulcer (venous stasis or arterial insufficiency or vasculitis or diabetic ulcer) based on the investigator's diagnosis; infected ulcer; concomitant use of other topical medication to study ulcer; human immune deficiency virus positive; pregnant, breast-feeding or not on acceptable means of contraception in premenopausal women; current diagnosis of cancer; chemotherapy; severe generalized medical condition with estimated survival of less than 6 months; concomitant systemic steroid therapy at a dose equivalent to > 10 mg prednisone daily; current alcohol or				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	drug abuse.				

Table 262: Trial 2010[229]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Trial (2010) **Title**: Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT. **Journal:** Journal of Wound Care, 19 (1); 20-26. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: sealed envelopes Blinding: not reported. Addressing incomplete outcome data: no drop outs Statistical analysis: Descriptive analysis (mean and SD; median)	Patient group: Patients older than 18 years with a PU. Also patients with diabetic foot ulcers, leg ulcers and acute wounds were included (separate analysis) All patients Randomised N: 24 Completed N: 24 Drop-outs: 0 Age males (mean years (SD)): 65.5 (17.7) Age females (mean years (SD)): 80.9 (9.0) Gender (m/f): 13/11 Ulcer location: Sacrum: 15 Other: 9 Ulcer stage: Superficial tissue damage plus exuding blister: 11 Tissue damage that did not extend to the bone: 8	Group 1: Silver alginate matrix dressing (Askina® Calgitrol® Ag, Braun Medical SAS, Boulogne-Billancourt, France). Askina® Calgitrol® Ag: consists of a proprietary ionic silver alginate matrix and an absorbent polyurethane foam layer. Delivery of ions is controlled and sustained over 72 hours due to the bonding characteristics of the silver alginate molecule. Group 2: Silver free alginate dressing (Algosteril®, Laboratories Brothier, France). All groups: /	Outcome 1: Percentage decrease in infection score	Group 1: 52.2% Group 2: 50.0%	Funding: sponsored by Braun Medical SAS, Boulogne-Billancourt, France Limitations: no report on sequence generation; no report on blinding; sample size lower than calculated; no report on classification of PU and unclear if all stages were included; no report on preventive measures; little information on dressings; no report on multiple ulcers Additional outcomes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and comparisons based on the t-test were performed with Excel. Chi-square test, Wilcoxon singed rank test, Mann-Whitney U test were performed with Statview. Baseline differences: No statistical difference between groups. Study power/sample size: Based on an observed standard deviation of 5 for the score of infection, 40 patients (20 per groups) were needed to reach a difference of 4.7 at day 15 with an alpha risk of 5% and a beta risk of 20%. Setting: wound clinical and Montpellier University Hospital. Length of study: 15 days of treatment. Assessment of PUs: Local infection was assessed by the study investigator using an 18 point scale (0: no infection – 18:	Norton score: ≥ 10: 19 ≥ 15: 9 Group 1 Randomised N: 11 Completed: 11 Dropouts: 0 Group 2 Randomised N: 13 Completed: 13 Dropouts: 0 Inclusion criteria: PU; one or more signs of local infection Exclusion criteria: known allergy to the dressings; burns; ulcer whose etiology is associated with infectious disease such as tuberculosis; use of coagulants; aged under 18 and over 80				Notes: Only data for PU patients are reported.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
infection). Classification of PUs: PU classification not reported. Multiple ulcers: not reported					

Table 263: Wild 2012[243]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Wild (2012) **Title**: Eradication of methicillin-resistant Staphylococcus aureus in pressure ulcers comparing a polyhexanide-containing cellulose dressing with polyhexanide swabs in a prospective randomized study. **Journal:** Advances in Skin & Wound Care, 25 (1); 17-22. Type of study: randomized controlled trial	Patient group: Patients a grade II, III, IV PU and MRSA (according to the NPUAP classification) All patients Randomised N: 30 Completed N: 30 Drop-outs: 0 Group 1 Randomised N: 15 Completed: 15 Dropouts: 0 Age (mean years (SD); range): 70.9 (5.22); 59-77 Gender (m/f): 7/8 Ulcer location: Sacrum: 11	Group 1: Polyhexanide containing cellulose dressing (Suprasorb® [Lohmann & Rauscher, Topeka, Kansas]+ Prontosan® [B. Barun, Bethlehem, Pennsylvania]). Ulcers were cleansed using saline and the assigned treatment was applied. A foam dressing (Suprasorb) was used as secondary dressing. Dressing were changed on average at 2-day interval. Group 2: Polyhexanide swab (Prontosan® [B. Barun, Bethlehem, Pennsylvania]). Ulcers were cleansed using saline and the assigned treatment was applied. A foam dressing (Suprasorb) was used as secondary dressing.	Outcome 1: Percentage reduction in pain score Outcome 1: Proportion of patients MRSA eradicated	Group 1: 82.4 Group 2: 52.6 Group 1: 15/15 Group 2: 10/15	Funding: sponsored by Lohman & Rauscher GmbH. Limitations: no blinding of patient and nurses; no a priori sample size calculation; no measurement of statical difference between groups; no report on multiple ulcers, no report on use of preventive measures Additional outcomes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: computer generated code Allocation concealment: sealed envelopes Blinding: blinding of assessor. Addressing incomplete outcome data: intention to treat analysis Statistical analysis: Statistical evaluation was performed using SPSS and where appropriate, tests were performed at the 5% significance level, with repeated-measures analysis of variance. The confidence interval was 95%. In appropriate cases, a Student t test was used to determine significance. Baseline differences: Difference not measured statically. Study power/sample size: No a priori sample size calculation. Setting: in– and out-	Ischium: 1 Heel: 3 Ulcer grade: Grade II: 2 Grade III: 6 Grade IV: 7 Ulcer area (mean cm² (SD); range): 47.67 (22.75); 12.0-81.0 Group 2 Randomised N: 13 Completed: 13 Dropouts: 0 Age (mean years (SD); range): 66.5 (9.59); 42-79 Gender (m/f): 8/7 Ulcer location: Sacrum: 10 Ischium: 3 Heel: 2 Ulcer grade: Grade II: 2 Grade III: 6 Grade IV: 7 Ulcer area (mean cm² (SD); range): 35.80 (13.47); 15.0-62.0	Dressing were changed on average at 2-day interval. All groups: All patients had PUs with long-term intractable MRSA colonization in which disinfection had not been achieved despite several lege artis attempts at disinfection, such as the use of iodine, silver, and so on, during a 2-week washout period.			Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
patients. Length of study: 14 days of treatment. Assessment of PUs: Ulcers were photographed on a weekly basis using a high-resolution digital camera. Photographs were analyzed using a digital tool, which was applied for both assessing wound size and evolution of the wound bed. Computer-supported digital software W.H.A.T. was used for the analysis of the digital photographs. For pain analysis upon dressing changes, a 10-point visual analog scale (VAS) was used. Classification of PUs: NPUAP classification. Multiple ulcers: not reported	Inclusion criteria: MRSA containing PU; grade II, III, IV PU Exclusion criteria: /				

Table 264: Winter 1990[244]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Winter (1990) **Title**: Testing a hydrocolloid. **Journal:** Nursing Times, 86 (50); 59-62. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: drop-outs excluded Statistical analysis: not reported. Baseline differences: No statistical difference measured between groups. Study power/sample size: no a priori sample size calculation. Setting: general practice, community, hospital.	Patient group: Patients with a PU. Also patients with leg ulcers were included (separate analysis) All patients Randomised N: 114 patients and 141 ulcers (38 patients with PUs, number of ulcers not reported) Completed N: 46 patients (11 patients with PUs) Drop-outs: 68 (2 rash, inflammation, allergy, 9 infection, 21 changed dressing, 7 died, 4 wound deterioration, 6 patient request, 19 other reasons) Age (median years; range): 74; 25-93 Gender (m/f): 38/76 Group 1 Randomised N: 58 patients (20 patients with PUs) Completed: 25 patients (6 patients with PUs)	Group 1: Hydrocolloid dressing (Comfeel®, Coloplast). Ulcers were cleansed with normal saline only. Comfeel paste and powder was used in conjunction with the Comfeel sheet if necessary. Group 2: Paraffin gauze dressing (Jelonet®, Johnson and Johnson) All groups: all patient received comparable pressure relieving aids.	Outcome 1: Proportion of patients completely healed Outcome 2: Proportion of patients improved Outcome 3: Proportion of patients not improved	Group 1: 5/6 Group 2: 3/5 Group 1: 6/6 Group 2: 5/5 Group 1: 0/6 Group 2: 0/5	Funding: Funded by Coloplast Ltd. Limitations: no report on sequence generation; no report on blinding; no ITT analysis; high drop-out; no statistical measurement of difference between groups; no a priori sample size calculation; low number of patients with PUs; little information on ulcer assessment; no information on PU stage and classification; multiple ulcers were included but unclear; little information on dressings; no information on patients who switched to comfeel; reported results are

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 12 weeks of treatment. Assessment of PUs: Photographs and size tracings were made Classification of PUs: not reported. Multiple ulcers: patients with multiple ulcers included	Dropouts: 33 (1 rash, inflammation, allergy, 5 infection, 8 changed dressing, 3 died, 3 wound deterioration, 3 patient request, 10 other reasons) Group 2 Randomised N: 56 patients (18 patients with PUs) Completed: 21 patients (5 patients with PUs) Dropouts: 35 (1 rash, inflammation, allergy, 4 infection, 13 changed dressing, 4 died, 1 wound deterioration, 3 patient request, 9 other reasons) 16 patients switched to Comfeel during trial! Inclusion criteria: PU Exclusion criteria: Terminal illness; ulcer area < 1cm²				questionable! Additional outcomes: / Notes: Patient characteristics are for all patients. The outcome are for PU patients only.

Table 265: Xakellis 1992[246]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Xakellis (1992) **Title**: Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: A cost-effectiveness analysis. **Journal:** Archives of Physical Medicine and Rehabilitation, 73; 463-469. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: intention to treat analysis Statistical analysis: Two-tailed chi-square or Fisher exact tests were performed for all categorical variables. Continuous and ordinal	Patient group: Patients with a stage II or III PU (according to the Shea classification). All patients Randomised N: 39 Completed N: 34 Drop-outs: 5 (1 hospitalized, 1 withdrawal of consent, 3 died) Group 1 Randomised N: 18 Completed: 16 Dropouts: 2 (1 hospitalized, and 1 withdrawal of consent) Age (mean years (SD)): 77.3 (16.9) Gender (m/f): 2/16 Ulcer location: Sacrum: 6 Pelvic area: 8 Other: 4 Ulcer grade: Grade II: 18 Grade III: 0 Ulcer area (mean cm²;	Group 1: Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Princeton, NJ). Ulcers were cleansed with normal saline only. The dressing was applied and rimmed with tape. The dressing was changed twice weekly or if non-occlusive. Group 2: Saline wet-to-moist gauze dressing. The gauze consists of a non-sterile eight ply gauze dressing moistened with saline and placed on the ulcer. This was covered with an additional gauze dressing and rimmed with tape. The dressing was remoistened with 3cc saline after four hours and changed after eight hours. All groups: All patients with necrotic tissue were sharp debrided as necessary All patient received routine care: repositioning every two hours, cleaning of incontinence with warm water, placing on an air-mattress and air-filled wheelchair cushion, and record of diet.	Outcome 1: Proportion of patients completely healed Outcome 2: Median time to healing (days)	Group 1: 16/18 Group 2: 18/21 Group 1: 9 Group 2: 11 P-value: 0.12	Funding: supported by ConvaTec Princeton, NJ and Family Health Foundation of America. Limitations: no report on sequence generation; no report on blinding; no a priori sample size calculation; small sample size; little information on ulcer assessment Additional outcomes: Cost; multivariate analysis Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
data were analysed with the Wilcoxon rank-sum test using the t-approximation for the significance level. The Cox proportional-hazards regression model for survival data was used to determine the factors related to healing time. Logrank statistics were calculated to test the univariate associations between baseline characteristics and healing time. Multivariate analysis was performed using Cox proportional-hazard regression analysis to determine the factors associated independently and significantly (p≤0.05) with healing time. Baseline differences: No statistical difference between groups. Study power/sample size: No a priori sample size calculation. Setting: long-term care	range): 0.66; 0.12-13.4 Incontinence: Occasionally: 1 Usually: 5 Urine and faeces: 12 BMI (mean kg/m² (SD)): 20.2 (5) Norton score (mean score (SD)): 11.4 (2.8) Group 2 Randomised N: 21 Completed: 18 Dropouts: 3 (died) Age (mean years (SD)): 83.5 (10.6) Gender (m/f): 1/20 Ulcer location: Sacrum: 8 Pelvic area: 6 Other: 7 Ulcer grade: Grade II: 19 Grade III: 2 Ulcer area (mean cm²; range): 0.38; 0.04-24.6 Incontinence: Occasionally: 0				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
facility. Length of study: six months of treatment. Assessment of PUs: Ulcer circumference was traced on clear plastic film two times weekly. Classification of PUs: Shea classification (1975). Multiple ulcers: only one ulcer determined by coin toss was included in the study	Usually: 3 Urine and faeces: 13 BMI (mean kg/m² (SD)): 21.1 (5) Norton score (mean score (SD)): 12.8 (3.0) Inclusion criteria: Grade II or III Exclusion criteria: rapidly fatal disease; anticipated discharge within one week: ulcers from other causes than pressure such as venous stasis				

Table 266: Yastrub 2004[248]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Yastrub (2004) **Title**: Relationship between type of treatment and degree of wound healing among institutionalized geriatric patients with stage II pressure ulcers. **Journal:** Care Management Journal, 5	Patient group: Patients with a stage II PU (according to the AHCPR classification). All patients Randomised N: 50 Completed N: 44 Drop-outs: 6 (reason not reported) - unclear	Group 1: Polymeric membrane dressing (Polymen®). Dressing were changed as per protocol. Group 2: Dry clean dressing and antibiotic ointment. All groups: All patient received: nutritional supplements, vitamin C and zinc sulphate, pressure relief mattress, foam cushion and	Outcome 1: Proportion of patients improved Outcome 2: Mean PUSH score	Group 1: 18/21 Group 2: 15/23 Group 1: 3.24 Group 2: 1.61 P-value: > 0.05	Funding: Partial funding by NPUAP award. Limitations: no report on sequence generation; no report on allocation concealment; no report on blinding; ITT analysis

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(4); 213-218. Type of study: randomized controlled trial Sequence generation: not reported Allocation concealment: not reported Blinding: not reported. Addressing incomplete outcome data: not reported Statistical analysis: The t-test was used to determine the difference between PUSH scores of the different groups. Descriptive statistics were computed using SPSS. Baseline differences: Baseline characteristics not reported. Study power/sample size: No a priori sample size calculation. Setting: long-term care facility in Queens, New York. Length of study: four	Group 1 Randomised N: 21 Completed: 19 Dropouts: 2 missings Group 2 Randomised N: 23 Completed: 23 Dropouts: 0 Inclusion criteria: > 65 years; limitation in ADL; PU stage II Exclusion criteria: /	repositioning every 2 hours			unclear; drop-outs unclear; no baseline characteristics reported, comparison between groups unclear; no a priori sample size calculation; little information on ulcer assessment; multiple ulcers not reported; little information on dressings. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weeks Assessment of PUs: Ulcer were weekly assessed using the Pressure Ulcer Scale for Healing (PUSH). Classification of PUs: AHCPR classification (1994). Multiple ulcers: not reported					

Table 267: Piatkowski 2012[178]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Piatkowski (2012) **Title**: Randomised, controlled pilot to compare collagen and foam in stagnating pressure ulcers: a pilot study to compare the clinical efficacy of a collagen dressing **Journal:** Journal of wound care, 21 (10), 505-511 Type of study: randomised controlled	Patient group: stagnating pressure ulcers, of at least 4 weeks' duration All patients Randomised N: 10 Completed N: 10 Drop-outs: 0 Group 1 Randomised N: 5 Completed: 5 Dropouts: 0 Age (years): 67.0 (SD 0.62) range 59-71	Group 1: collagen dressing with the same foam dressing as group one as a secondary dressing Group 2: polyurethane foam dressing All groups: repositioned every 3 hours and placed on a foam mattress Before recruitment both groups had been treated using various moist wound-healing dressings, such as foams, alginates and hydrofiber	Outcome 1: proportion completely healed at 21 days Outcome 2: proportion completely healed at 14 days	Group 1: 4/5 (80%) Group 2: 5/5 (100%) Group 1: 0/5 (0%) Group 2: 2/5 (40%)	Funding: grant from Lohmann & Rauscher GmbH, states that the sponsors had no role in the design or conduct of the study, in the collection, analysis and interpretation of the data or in the preparation , review or approval of the manuscript. Limitations: very

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
pilot trial Sequence generation: allocated using a computer-generated code. Allocation concealment: not reported Blinding: not reported Addressing incomplete outcome data: ITT Statistical analysis: repeated measures ANOVA Baseline differences: Study power/sample size: very small, pilot study Setting: department of plastic surgery and hand surgery, Aachen Length of study: 21 days Assessment of PUs: wound status and size were documented using standardised digital photographs (light, back-ground, distance and agnle), a digital assessment tool, as well as wound tracings and the measurement of ulcer diameter.	M/F: 3/2 Comorbidities: Arrhythmia: 2 (40%) Cardiac failure 3 (60%) Renal disease: 1 (20%) Diabetes mellitus type 1: 3 (60%) Ulcer categorisation (n): Category III: 5 (100%) Ulcer diameter (cm): 11.4 (5.2-19.6) Ulcer location (n): sacrum: 5 (100%) Group 2 Randomised N: 5 Completed: 5 Dropouts: 0 Age (years): 63.0 (SD 0.72) range 52-68 M/F: 4/1 Comorbidities: Arrhythmia: 0 (0%) Cardiac failure 2 (40%) Renal disease: 0 (0%) Diabetes mellitus type 1: 3 (60%) Ulcer categorisation (n): Category III: 5 (100%) Ulcer diameter (cm): 9.3	dressings			small sample size; no details of allocation concealment or blinding. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Computer-supported digital software, Wound Healing Analysing Tool (WHAT) , was used for the analysis of digital photographs. Classification of PUs: EPUAP classification Multiple ulcers: largest ulcer was assessed	(4.3-21.0) Ulcer location (n): sacrum: 5 (100%) Inclusion criteria: stagnating pressure ulcers, of at least 4 weeks' duration; wound bed had to be granulating and free of necrotic tissue and slough; ulcer healing had not progressed or progressed only slightly, over the previous 4 weeks, indicating stagnation of the healing process; no clinical signs of infection and/or critical colonisation. Exclusion criteria: see above				

I.2.9 Management of heel pressure ulcers

Table 268: Landi 2003[127]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Landi (2003) **Title**: Topical Treatment of Pressure Ulcers with Nerve Growth Factor: A Randomized Clinical Trial. **Journal:** Annals of Internal Medicine, 139 (8); 635-642. Type of study: randomized controlled trial Sequence generation: a computer-generated list was used. Allocation concealment: randomly stratified according to age group, sex, and ulcer surface area Blinding: double blind, nurses and outcome assessor Addressing incomplete outcome data: unclear Statistical analysis: Quantitative variables	Patient group: Nursing home patients a stage II or V PU to the foot (according to the Yarkony-Kirk classification). All patients Randomised N: 38 Completed N: 36 Drop-outs: 2 (1 died, and 1 lost to follow up) Group 1 Randomised N: 19 Completed N: 18 Drop-outs: 1 (died) Age (mean years (SD); range): 80.2 (3.0); 75-85 Gender (m/f): 5/13 BMI (mean kg/m²): 24.0 (1.4) Duration of PU (mean days (SD)): 13 (4) Ulcer stage: Stage II: n=3 Stage III: n=9 Stage IV: n=5	Group 1: topical nerve growth factor (2.5 S murine nerve growth factor). One mg of nerve growth factor was dissolved in 20 ml of balanced salt solution, with a final concentration of 50 µg/ml. The nerve growth factor solution was dropped daily on the lesion and allowed to dry for 2 to 3 minutes. Group 2: Balanced salt solution. The solution was dropped daily on the lesion and allowed to dry for 2 to 3 minutes. Both groups: All ulcers received daily local care: irrigation with normal saline, use of debriding enzymes, and application of opaque hydrocolloid occlusive barriers. Al patient received the same preventive skin regimen (turning, repositioning and use of pressure relieving mattress)	Outcome 1: Reduction in ulcer area (mm²)	Group 1: 623 (SD 451) Group 2: 485 (SD 384)	Funding: Grant from the Progetto Finalizzato Invecchiamento of the Italian National Research Council. Support was also provided by interRAI, an international group of clinicians and researchers who collaborate to promote research on resident assessment instruments and quality outcomes for elderly persons. Dr. Aloe (co-author) was supported by a grant from the Italian National Institute of Health (ICG 120/4RA00-90) and by a grant from the Italian National Research

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
are presented as mean values (±SD). Differences in baseline characteristics between patients in the control and treatment groups were analysed in several ways. Quantitative outcomes were tested by using the Student t-test after a pre-test for homogeneity of variance. The Mann–Whitney test was used for cases in which the normality assumption was not reasonable. Categorical variables were analysed by using the Fisher exact test. Analysis of covariance was used to compare reduction in pressure ulcer area from baseline to 6-week follow-up after adjustment for baseline ulcer area, location, and duration. Because the distribution of reduction in pressure ulcer area was not normal, this analysis was	Stage V: n=1 Ulcer location: Heel: n=14 Lateral malleolus: n=4 Surface area (mean mm² (SD)): 1012 (633) Group 2 Randomised N: 19 Completed N: 18 Drop-outs: 1 (lost to follow-up) Age (mean years (SD); range): 80.2 (4.7); 73-93 Gender (m/f): 5/13 BMI (mean kg/m²): 23.8 (1.4) Duration of PU (mean days (SD)): 12 (5) Ulcer stage: Stage II: n=3 Stage III: n=13 Stage IV: n=1 Stage V: n=1 Ulcer location: Heel: n=15 Lateral malleolus: n=3 Surface area (mean mm² (SD)): 1012 (655)				Council, FISR/ Neurobiotechnology (192/03). Limitations:; inadequate allocation concealment; no patient blinding; no a priory sample size calculation; no ITT. Additional outcomes: / Notes: /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
performed after natural log transformation of this variable. Statistical analyses were performed by using SPSS, version 10.0 (SPSS Inc., Chicago, Illinois). Baseline differences: No statistical differences between group according to a p <0.2. Study power/sample size: No a priory sample size calculation. Setting: teaching nursing home of Catholic University of the Sacred Heart, Fontecchio, Italy. Length of study: 6 weeks of treatment or until completely healed Assessment of PUs: The ulcer perimeter was traced onto sterile, transparent block paper and the blocks were counted. Digital photographs were taken at baseline and every week during	Inclusion criteria: PU of the foot that ranged from 1 cm2 to 30 cm2 in total area Exclusion criteria: developed the lesion more than 1 month before admission; terminal illnesses; diabetes; peripheral vascular diseases				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
the follow-up period. Classification of Pus: Yarkony-Kirk classification (1990). Multiple ulcers: indirect: one ulcer per patient					

Table 269: Meaume 2009[140]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Meaume 2009[140] **Title**: Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomised controlled trial Type of study: multi-centre double-blinded RCT Sequence generation: randomised in blocks of four, randomisation codes generated by using computer. A randomisation no. attributed to chronological order of entry of patients into	Patient group: hospitalised or outpatient elderly patients All patients Randomised N=165 ITT N: 160 Drop-outs: 72 Group 1 Randomised N: 89 ITT N:85 (see analysis details) Completed N: 45 Drop-outs:44 Age (mean):80.8+/-8.8 years (ITT) Sex (m/f): 34.1/65.9 BMI: 27.1+6.5	Group 1: one 10g sachet of ornithine alpha-ketoglutarate Group 2: one sachet of placebo Both sachets given during or after lunch, preferably in 200ml of water or mixed with food. Other ulcer management included mechanical debridement, cleaning, heel elevation, dressings, heel offloading with a suspension boot, management of pain with analgesics and topical corticosteroids and topical antibacterials for excessive granulation tissue.	Outcome 1: wound area changes at week 6	Group 1: -2.3+/-4.2cm2 Group 2: -1.7+/-1.cm2 p=0.006	Funding: grant from CHIESI France and Italy. Limitations: well-reported trial with clear details of methodology. Study powered for 70 in each arm which was met for studies randomised but there was a very high drop-out rate in both arms. Due to difficulties in patient recruitment the study was opened to many more centres than
			Outcome 2:% regression in wound area	Group 1:-59.5+/-71.4% Group 2:-54.0+/-69% Relative risk: p=0.477	
			Outcome 3: >90% regression by week 6	Group 1:23.4% Group 2:13.0% OR: 0.49 95% CI: 0.16/1.46	
			Outcome 4: adverse events in patients	Group 1: 13/85 Group 2: 7/75	
			Outcome 5: severe adverse events in patients (all were considered unrelated to study	Group 1: 13/85 Group 2: 15/75	

the double-blind period within each investigational site. Allocation concealment: adequate Blinding: placebo had similar aspect and taste. Investigators and assessors were blinded. Addressing incomplete outcome data: adequate. ITT on efficacy analyses – who take at least one dose of study medication and who had at least one post-treatment evaluation. LOCF applied to deal with missing efficacy time-points. Statistical analysis: ANCOVA (age, history of lesion and patients weight as covariates). Baseline differences: more males in OKG than placebo group; significant difference in ulcer area. Study power/sample size: power calculations 70 patients per group based on previous studies of OKG in	Ulcer area (cm2): mean 8.7+/-6.7 Median: 6.6 Min-Max: 0.71-39.05 Log-transformed ulcer area: 0.816+/-0.349 >8 area </=12cm2: 18.8% Group 2 Randomised N: 76 ITT N:70 (see analysis details) Completed N:43 Drop-outs:33 Age (mean):80.5+/-9.6 Sex (m/f): 52.6/47.4, p=0.017 BMI: 26.7+5.9 Ulcer area (cm2): mean 8.2+/-8.9 Median: 3.9, p=0.044 Min-Max: 0.23-48.14 Log-transformed ulcer area: p=0.027 >8 area </=12cm2, p=0.001 Inclusion criteria: males or females over age of 60 years; heel pressure ulcer (NPUAP stage II or III) occurring after accidental immobilisation; ulcer in	Compliance tested with by collecting treatment kits.	treatment by investigators)		initially planned and 2 or 3 of the centres recruited no more than 2 patients while randomisation was balanced by blocks of four. Randomisation did not balance baseline pressure ulcer characteristics and ulcer area distribution deviated from normal distribution as healing is strongly related to baseline ulcer are the abnormal distribution was a major bias so was subgrouped. Additional outcomes: particular adverse events.
			Outcome 6: Mortality (unrelated to drug):	Group 1: 5/89 (5.6%) Group 2: 3/76 (3.9%) Relative risk: 1.42 95% CI: 0.35 to 5.76	
			Outcome 7: Rate of complete healing at week 6 (cm2/day)	Group 1: -0.07 +/-0.11cm2/day Group 2: - 0.04 +/- 0.08 cm2/day P=0.007	

pressure ulcer treatment. Setting: 67 investigational centres in six European countries. Study length: 6 weeks Assessment of PUs: assessed once a week for 6 weeks. Classification of PUs: NPUAP Multiple ulcers: not reported	process of recovery with early signs of granulation tissue (at least 10% of red tissue on colour scale). Exclusion criteria: patients confined to bed 24 hours a day before the episode triggering development of the pressure ulcer; pressure ulcer entirely covered by necrosis or fibrin, infected ulcer; poorly controlled type I or II diabetes, dialysed patient, active neoplastic disease; parenteral nutrition; serum albumin <22g/l; advanced peripheral arterial occlusive disease [[ABPI (ankle brachial pressure index)ranging between 0.80 and 1.3 with presence of distal pulses]				

Table 270: Russell2000[189]

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Russell 2000 **Title**: Randomised controlled trial of two pressure-relieving systems. **Journal:** Journal of Wound Care 2000; 9(2):52-5. Type of study: RCT Sequence generation: "on admission to the study, subjects were randomly allocated to trial equipment". Method of randomisation not described (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: "images [of the pressure ulcers] were stored on compact discs, using codes that ensured image analysis could be carried out 'blind' to treatment group" Addressing incomplete outcome data: no missing outcome data	Patient group: patients from elderly units with pressure ulcer of grade 2 or above All patients Randomised N: 141 Completed N: 112 Drop-outs: 29 Age: average 83.9 and 84.6 years Group 1 Randomised N: 70 Completed N: 57 Drop-outs: 13 Age (mean): 83.9 years Group 2 Randomised N: 71 Completed N: 55 Drop-outs: 16 Age (mean): 84.6 years Inclusion criteria: patients from care of the elderly units; pressure ulcer of > grade 2; Exclusion criteria: patients	2 types of alternating cell mattress systems with pressure-relieving cushions: Group 1: Huntleigh Numbus 3 with Aura cushion and 4-hourly turning Group 2: Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning.	Outcome 1: proportion of patients completely healed	Group 1: 24/55 (43.6%) Group 2: 17/58 (29.3%)	Funding: not reported Limitations: no details of randomisation method; unclear allocation concealment. Additional outcomes: Ulcer healing: all types, and divided into heel and sacral ulcers at 12 and 18 months

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Selective reporting: all of the study's pre-specified outcomes were reported. Analysis: not specified in study report (high risk) Statistical analysis: Wilcoxon-Mann-Whitney rank sum test Baseline differences: baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: a priori sample size calculation of 80% power was 100 patients per group, the study was underpowered. Setting: care of elderly unit, hospital Length of study: Length of intervention period unclear. 18 month follow-up Assessment of PUs: insufficient information on outcome measurements. Ulcer healing was recorded by weekly camera and nurse gradings – called	excluded if randomised equipment unavailable (not stated how often this occurred)				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
'improvement factor'. Classification of PUs: Torrance classification system Multiple ulcers: if patient had two ulcers areas this counted as two separate ulcers. Timing of outcome assessment similarity: ulcers photographed weekly and patients surveyed at 7 days after trial entry. Not stated when comfort was assessed (low risk)					

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