NICE advice

Oxyzyme and Iodozyme 2-layer hydrogel wound dressings with iodine for treating chronic wounds

Medtech innovation briefing
Published: 19 November 2014

www.nice.org.uk/guidance/mib11

Summary

Oxyzyme and Iodozyme are chronic wound dressings that release iodine and oxygen onto the wound surface. They are intended for use under the supervision of a healthcare professional in any community care setting or hospital by clinical staff such as nurses, or other staff such as podiatrists.

Effectiveness

- One randomised controlled trial (n=100) reported no significant difference in wound healing outcomes at 12 weeks between Oxyzyme or Iodozyme dressings and standard care.
- Three non-comparative case series using Oxyzyme or Iodozyme dressings for chronic

wounds reported a reduction in the mean wound area over the study period.

- Results for case series should be interpreted with caution because of the large numbers of withdrawals, incomplete reporting of outcomes and lack of comparator.

Adverse events and safety

- There were 8 withdrawals from the RCT, 2 in the control arm and 6 in the patients receiving Oxyzyme or Iodozyme dressings. The study reports 26 adverse events. 18 of these were in patients being treated with the Oxyzyme or Iodozyme dressings, of which 3 were dressing related, and 8 adverse events were reported in in the control group. The authors state that the majority of adverse events were related to pain.
- There were high numbers of withdrawals (55 in total) from the 3 non-comparative case series. The reasons for withdrawal were not recorded as adverse events; 12 were noted as unrelated to the dressing. Reasons for withdrawal included infection, wound deterioration, pain, bleeding and maceration.

Cost and resource use

- The list price for 1 Oxyzyme dressing, excluding VAT, is £6.00 for the 6.5×5 cm size and £10.00 for the 10×10 cm size.
- The list price for 1 Iodozyme dressing, excluding VAT, is £7.50 for the 6.5×5 cm size and £12.50 for the 10×10 cm size.
- A separate, air-permeable covering dressing is needed at an additional cost.
- One RCT (n=100) found the use of Oxyzyme or Iodozyme dressings to be cost saving compared to standard care due to a reduction in the number of dressings used.
- One case series (n=13) considered costs and resource use and found the use of Oxyzyme and Iodozyme dressings to be cost saving compared with standard treatment. The results should be interpreted with caution, because of inappropriate calculations of healing rates.

Technical factors

- Oxyzyme and Iodozyme dressings consist of 2 hydrogel layers that must be placed on the wound in the correct order and covered with an air-permeable dressing.
- Oxyzyme and Iodozyme dressings release iodine when the 2 hydrogel layers are

combined.

- The Oxyzyme dressing is normally used for non-infected wounds.
- The Iodozyme dressing releases a higher concentration of iodine than Oxyzyme and is normally used for infected wounds.
- Choice of wound dressing is one of many factors that affect wound healing.

Introduction

Chronic wounds include pressure, leg and foot ulcers. Some patients may have wounds that do not heal for years. In addition to wound pain, and pain when the dressing is changed, there is a high adverse effect on quality of life. A lack of mobility, sleep deprivation, and exudate and odour from the wound can lead to an inability to participate in normal activities and social isolation (Persoon et al. 2004, Posnett and Franks 2007).

Posnett and Franks (2007) estimated that there are approximately 200,000 people in the UK at any one time with a chronic wound.

Venous leg ulcers are estimated to affect around 1 in 500 people in the UK, becoming more common with age. An estimated 1 in 50 people over the age of 80 years has a venous leg ulcer (NHS Choices).

Approximately half a million people in the UK will develop at least 1 pressure ulcer in any given year. People with an underlying health condition and people aged over 70 years are particularly at risk of developing pressure ulcers (NHS Choices).

In addition to the effect on the patient from chronic wounds, there is a cost and resource issue for the NHS; ongoing treatment of chronic wounds is expensive. The total treatment cost for the NHS for chronic wounds, including nursing time and other treatments, was estimated by Posnett and Franks (2007) using 2005/6 prices, as £2.3 billion to £3.1 billion a year. The cost was calculated from a variety of sources for pressure, leg and foot ulcers.

Appropriate wound dressings are a single component of the wound healing process. Many chronic wounds are preventable, and many will heal within 24 weeks with appropriate diagnosis and treatment (Posnett and Franks 2007).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The Oxyzyme and Iodozyme dressings received CE marks in 2006 and 2007 respectively, and are class III medical devices, incorporating a medicinal substance. The current Declaration of Conformity was made by Archimed in 2011, for 'Oxyzyme sterile wound dressing with iodine' and 'Iodozyme sterile wound dressing with iodine'. The dressings are now manufactured by Crawford Healthcare.

Description

Oxyzyme and Iodozyme dressings are used on external wounds. They comprise a 2-component, hydrogel layer, which releases iodine and oxygen at the wound surface. The 2 sterile components are supplied in individual white pouches with easy peel tabs:

- pack 1 – a larger wound contact hydrogel (first layer)
- pack 2 – a smaller hydrogel (second layer).

The first layer of the Oxyzyme and Iodozyme dressings contains glucose and potassium iodide and is placed directly on the wound. The second layer, containing glucose oxidase, is placed on top of the first. Atmospheric oxygen diffuses into the outer second layer, producing hydrogen peroxide. This diffuses into the first layer, producing molecular iodine (Davis et al. 2009, Wood et al. 2010). The layers must be placed in the correct order on the wound.

The Oxyzyme and Iodozyme dressings must be covered with an additional dressing that is permeable to air to allow production of iodine. A polyurethane film or foam dressing may be used, for example Tegaderm (3M Health Care) or Mepilex (Mölnlycke Health Care). This

is a common requirement for hydrogel dressings.

The Iodozyme dressing releases approximately 5 times higher concentration of iodine than the Oxyzyme dressing and is intended for use with infected wounds (Wood et al. 2010).

Iodine in wound dressings provides an antimicrobial effect. Antimicrobial agents may reduce the colonisation of microbes on a non-infected wound, but there is little clear evidence of the effect of this on wound healing. If the wound is infected, action should be taken to treat the infection. This may include the use of antimicrobial agents (European Advisory Pressure Ulcer Panel 2009, European Wound Management Association 2008).

Hydrogels, such as those in the Oxyzyme and Iodozyme dressings, are designed to provide a moist environment and facilitate autolytic debridement of necrotic tissue. They may be able to absorb small amounts of exudate (British national formulary, 2014).

Intended use

Oxyzyme and Iodozyme dressings may be used on moderately exuding, non-exuding or dry wounds, and under compression therapy. The manufacturer states that the Oxyzyme dressing is intended for the treatment of non-infected or mildly infected wounds and the Iodozyme dressing may be used in the management of infected wounds.

Oxyzyme and Iodozyme dressings should not be used in people with a known or suspected sensitivity or allergy to iodide or iodine, or those with a thyroid disorder.

Setting and intended user

Oxyzyme and Iodozyme dressings are intended for use under the supervision of a healthcare professional, and may be used in any community or hospital care setting. They are applied by the same clinical staff who would normally change the patient's dressings. This would typically be a nurse, including district nurses and tissue viability nurses, but may also include other staff such as podiatrists. As with other treatments for more challenging wounds, and for -higher cost dressings, local supply arrangements are likely to need approval from a specialist such as a tissue viability nurse, or a wound clinic. The setting and staffing needs are similar to those for other wound dressings.

Current NHS options

Choosing the appropriate wound dressing is only part of providing effective wound care for patients with chronic wounds. It is also important to address the underlying causes of the original wound, ensuring patient well-being and quality of life. Additional strategies may include effective compression bandaging for venous leg ulcers, revascularisation, treating existing infection, pressure redistribution for pressure ulcers and adequate nutrition (European Wound Management Association 2008).

There are other wound dressings available (see costs and use of the technology section), with limited evidence to inform choices. The evidence is summarised in NICE key therapeutic topic wound care products, based on evidence in MeReC Bulletin Volume 21 Number 01.

NICE's guideline on diabetic foot problems recommends using the wound dressing with the lowest acquisition cost that is appropriate for the patient and the wound, because of the lack of robust evidence to differentiate dressings. NICE's guideline on pressure ulcers recommends that using a dressing that promotes a warm, moist wound healing environment is considered to treat grade 2, 3 and 4 pressure ulcers, following patient consultation. It recommends that iodine-based dressings are not used for neonates.

NICE's key therapeutic topic on wound care products also notes the importance of avoiding indiscriminate use of antimicrobial dressings because of concerns over bacterial resistance and toxicity. NICE's guideline on pressure ulcers also recommends against routine use of topical antiseptics or antimicrobials to treat a pressure ulcer. Topical antimicrobials should be considered where clinically indicated. Although there is little evidence of bacterial resistance to iodine developing, it may be possible, and the more frequently any antimicrobial is used the greater the possibility of resistance emerging (European Wound Management Association 2013).

The Scottish Intercollegiate Guidelines Network (SIGN) national clinical guideline (SIGN 120, Management of chronic venous leg ulcers, 2010) reviewed the available evidence on iodine-based dressings for the treatment of leg ulcers. It concluded that there was insufficient consistent evidence to make a recommendation about the use of these kinds of dressings.

NICE is not aware of other CE-marked devices that have a similar mode of action to the Oxyzyme and Iodozyme dressings. Alternative antimicrobial dressings are available using

silver, honey or iodine.

Costs and use of the technology

The Oxyzyme and Iodozyme dressings are included in the NHS Drug Tariff (July 2014). The following list prices, excluding VAT, were provided by the manufacturer for May 2014:

- Oxyzyme 6.5×5 cm dressing £6.00
- Oxyzyme 10×10 cm dressing £10.00
- Iodozyme 6.5×5 cm dressing £7.50
- Iodozyme 10×10 cm dressing £12.50.

An additional covering dressing is needed for the 2-layer Oxyzyme and Iodozyme dressings, which is usual for most hydrogel dressings. The covering dressing must be air-permeable, and is not included in the listed dressing prices.

The Oxyzyme and Iodozyme dressings are single-use. Healthcare workers must be aware of the need to apply the dressing layers correctly. The typical frequency of dressing changes indicated in the instructions for use is 2 to 3 times per week, though this will vary according to patient needs.

Typical prices for alternative dressings, taken from the British national formulary (2014) are as follows.

Typical antimicrobial dressings

- Hydrogel, semi-permeable dressing impregnated with medical grade honey: 10×10 cm £2.55, 15×20 cm £5.31 (Medistran, Aspen Medical)
- Silver-impregnated polyurethane foam film dressing with adhesive border: 12.5×12.5 cm £8.71, 18×18 cm £17.47 (Biatain Ag, Coloplast)
- Soft non-woven pad containing hydrocolloid fibres, (silver-impregnated): 4x10 cm £2.70, 4×20 cm £3.52, 4×30 cm £5.27 (Aquacel Ag, ConvaTec)

Typical hydrogel and hydrocolloid dressings

- Hydrogel dressing: 7.5 cm diameter £2.55, 12 cm diameter £5.26 (Aquaflo, Covidien)
- Semi-permeable hydrocolloid dressing: 5×10 cm £0.72, 7.5×7.5 cm £0.75 (Duoderm Extra Thin, ConvaTec)
- Hydrocolloid wound contact layer bonded to plastic foam layer, with outer semi-permeable polyurethane film: 10×10 cm £2.64, 15×15 cm £5.00 (Granuflex, ConvaTec)

Dressings suitable as a covering layer for Oxyzyme and Iodozyme

- Film dressing: 6×7 cm £0.38, 12×12 cm £1.09, 15×20 cm £2.37 (Tegaderm, 3M Health Care)
- Absorbent soft silicone dressing with polyurethane foam film backing: 5×5 cm £1.21, 10×11 cm £2.66, 11×20 cm £4.39 (Mepilex, Mölnlycke Health Care).

There are many other dressings available at a range of costs.

Likely place in therapy

Oxyzyme and Iodozyme dressings are currently available in the NHS. They are currently used in a wound care pathway when other treatments are not considered appropriate. They are likely to be used when wounds have not healed for an extended length of time. Antimicrobial dressings should not be used on wounds that are not infected or not at risk of infection.

Specialist commentator comments

Oxyzyme and Iodozyme dressings are potentially a more user-friendly, less painful method of applying iodine to wounds than current alternatives.

Using a 2-pack dressing increases the risk of user error, resulting in ineffective wound management if the layers are in the incorrect order. For community use, training would be needed for a large number of nurses to ensure the dressing worked as intended.

Hydrogel dressings may make the wound wet and increase the risk of maceration. This

may particularly be a problem for infected wounds that tend to have increased levels of exudate. The high level of exudate found in many infected wounds may make use of a hydrogel dressing inappropriate.

Hydrogen peroxide generated by the dressing must be kept away from any granulating or healthy tissue, which may not be possible on all wounds.

Iodine has been used as an antimicrobial for some time and there are no reported incidents of toxicity or resistance, and no in vivo studies are available.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women, and
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

Age and disability are protected characteristics under the Equality Act 2010. The risk of developing wounds such as pressure, leg and foot ulcers increases with age and the presence of other health problems (NHS Choices). People with diabetes may be considered as having a disability and have an increased risk of developing foot ulcers, and are 15 times more likely than the general population to have a foot amputated due to gangrene (NHS Live Well). Appropriate treatment of chronic wounds may reduce pain, allow increased participation in society and improve quality of life for those people affected.

Evidence review

Clinical and technical evidence

Regulatory agencies

No reports of adverse events were identified from searches of the Medicines and Healthcare Products Regulatory Agency website, or from the US Food and Drug Administration database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

There is 1 published randomised clinical trial (n=100; Moffatt et al. 2014) and 3 published case series (Davis et al. 2009, Wood et al. 2010, Lafferty et al. 2011) on the Oxyzyme and Iodozyme dressings. A publication on 5 patients taken from a multicentre study of 31 patients was excluded because the full results of the study have not been published (Ivins et al. 2007). A report on 3 patients taken from a larger case-study programme (up to 200 patients in progress at the time of publication) was excluded because of incomplete reporting (Hampton et al. 2008). Queen et al. (2007) reported on 4 patients who healed out of a series of 20 patients (22 wounds). This study was excluded because of incomplete reporting.

Some other case studies contained useful information on technical issues. In 1 case report (Kerr 2007a) it was noted at the 3-week assessment that the dressing had been incorrectly applied, with the primary dressing applied on top of the secondary dressing. In another case report (Kerr 2007b) it was noted that an occlusive secondary dressing had been used instead of an air-permeable dressing as specified in the manufacturer's instructions for use.

Randomised controlled trial

Moffatt et al. 2014: Oxyzyme and Iodozyme

This was a UK-based, single-centre trial comparing the Oxyzyme and Iodozyme dressings to standard care, in the treatment of 100 patients with venous or mixed venous/arterial leg ulcers. Standard care was defined as a continuation of the current treatment regimen

based on formulary recommendations for the South Staffordshire PCT Tissue Viability Service. Objectives and outcomes for Moffatt et al. (2014) are described in tables 1 and 2.

The primary outcome was complete healing of the ulcer within 12 weeks of treatment. Analysis was performed using the Kaplan–Meier method. No statistically significant difference was seen in the proportion of patients whose ulcers healed within 12 weeks or 24 weeks, when the Oxyzyme or Iodozyme dressings were compared with standard care.

The authors report no difference in patient-reported quality of life or pain when the Oxyzyme or Iodozyme dressings were used, compared with standard care.

Cost-effectiveness was a secondary outcome and is reported in a later section.

Case series

Davis et al. 2009: Oxyzyme only

This was an observational study of 100 patients with chronic, hard-to-heal wounds of mixed aetiology recruited from 27 European complex wound clinics (22 in England). Objectives and outcomes for Davis et al. (2009) are described in tables 3 and 4.

Wood 2010: Iodozyme only

This case series reported results from 45 patients (51 wounds) in 30 different centres in England. Objectives and outcomes for Wood et al. (2010) are described in tables 5 and 6.

The primary outcome was a clinical assessment of overall wound condition. At the end of the study, clinicians assessed the overall outcome as healed, improved (which included subjective improvement in wound bed condition), static or deteriorated. Data from patients who were withdrawn from the trial were included in the results, and assessment conducted at the time of withdrawal. It was noted that patients who were withdrawn from the trial with problems relating to the wound dressing might still be reported as having an improved wound bed condition, including patients who were withdrawn due to increased wound size. No clear guidance on how assessments should be made was reported. This outcome was not reported here due to the high likelihood of bias.

Clinicians were also asked to assess the dressings compared with other dressings used for similar wounds. There were 51 responses reported (the total number of clinicians

involved was not reported).

Other outcomes measured at entry and during weekly assessments included wound size and depth, condition of the wound margins, wound bed and peri-wound skin. The mean wound area decreased 19.8% from 13.1 cm^2 (median 6.0, range 0.23 to 98.0) to 10.5 cm^2 (median 4.0, range 0.0 to 98.0). Depth, condition of wound bed, wound margins and peri-wound skin are not reported.

During weekly clinic visits, patients were asked to report wound pain using an non-validated numbered visual analogue scale, and overall satisfaction on a 5-point scale. Average pain scores were reported at the start (3.7) and end of the trial (2.6), but without intermediate results, ranges or standard deviations. Overall satisfaction was not fully reported.

Lafferty et al. 2011: Oxyzyme and Iodozyme

This was a case series of 13 patients with 17 wounds in a single UK centre. Objectives and outcomes for Lafferty et al. (2011) are described in tables 7 and 8.

In vitro evidence

Four papers were identified that reported on in vitro testing of the antimicrobial properties of Oxyzyme or Iodozyme dressings. Two included both Oxyzyme and Iodozyme dressings in the dressings tested, but did not report the results in full (Thorn 2005, Thorn 2006). Two papers (Greenman 2006, Thorn 2009) reported evidence of a reduction in monoculture bacteria with the Iodozyme dressing, compared with control and other dressings. The tests used 2 monocultures, Staphylococcus aureus and Pseudomonas aeruginosa. This does not equate to evidence of antimicrobial efficacy on a wound, or the effect that this might have on healing, and should be interpreted with caution.

Table 1 Summary of the Moffatt et al. (2014) study

–	Oxyzyme/ Iodozyme	Control	Analysis
Randomised	n=47	n=53	–
Efficacy	n=47	n=53	–
Primary outcome: Healed ulcers at 12 weeks	44.7% (21/47)	49.1% (26/53)	ITT

–	Oxyzyme/ Iodozyme	Control	Analysis
Healed ulcers, Kaplan Meier Analysis, 12 weeks	48.4%	50.2%	95% CI unknown, HR 1.05 p=0.87
Healed ulcers, Kaplan Meier Analysis, 24 weeks	unknown	unknown	95% CI 0.7 to 1.84, HR 1.14 p=0.6
Activities (HRQoL at 12 weeks: n, Mean [SD])	n=38, 28.8 (25.8)	n=49, 31.3 (24.9)	0=perfect health, 100=worst possible health
Psychological (HRQoL at 12 weeks: n, Mean [SD])	n=39, 36.9 (26.7)	n=49, 32.4 (27.2)	–
Symptom distress (HRQoL at 12 weeks: n, Mean [SD])	n=39, 36.1 (25.4)	n=49, 32.6 (22.4)	–
Activities (HRQoL at 24 weeks: n, Mean [SD])	n=39, 23.1 (23.3)	n=45, 25.3 (27.9)	–
Psychological (HRQoL at 24 weeks: n, Mean [SD])	n=38, 28.3 (28.1)	n=45, 27.0 (27.4)	–
Symptom distress (HRQoL at 24 weeks: n, Mean [SD])	n=37, 26.1 (27.7)	n=46, 23.5 (26.2)	–
Safety	n=47	n=53	–
Patients reporting adverse events	18 events in 11 patients	8 events in 7 patients	Details of adverse events are not given. Reported as mainly relating to pain.
Reported as relating to dressing	3 events	0 events	–

Notes: Patient reported outcome using VLU-QOL tool, where 0 is perfect health and 100 is

worst possible health. P-values are reported, however it is unclear which values they refer to and therefore they have not been included in this summary. Abbreviations: CI, confidence interval; HRQOL, health related quality of life; ITT, intention to treat; n, number of patients.

Table 2 Summary of the RCT: Moffat et al. (2014)

Study component	Description
Objectives/ hypotheses	To determine the relative effectiveness of Oxyzyme/ Iodozyme compared with standard care (defined as a continuation of existing care). Effectiveness was defined as complete ulcer closure (100% re-epithelialization) at 12 weeks.
Study design	Randomised controlled trial
Setting	Single-centre trial at an NHS leg ulcer service. Patients were evaluated weekly for 12 weeks, or until their ulcer was healed if sooner, with a further follow up at 24 weeks.
Inclusion/ exclusion criteria	The study included adults with a venous ulcer (ABPI more than 0.8) or a mixed ulcer (ABPI more than 0.6), whose ulcer was present for less than 1 year, and had healthy peri-wound skin. The study excluded patients with ABPI less than 0.6, or if unable to tolerate correct compression levels. Patients with recent acute deep vein thrombosis, surgery for venous insufficiency, or arterial reconstruction or angioplasty were also excluded. Other exclusion criteria included active cellulitis at the start of the trial, treatment for thyroid disorders, or peri-wound maceration.
Primary outcomes	Complete ulcer closure (100% re-epithelialization) at 12 weeks
Statistical methods	Kaplan–Meier analysis was used to examine the rate of healing
Participants	100 patients participated in the study, 53 were randomised to the control and 47 to the intervention. There was no power calculation.

Study component	Description
Results	At 12 weeks, 44.7% (21/47) of ulcers treated with Oxyzyme and Iodozyme had completely healed. 49.1% (26/53) of ulcers treated using standard care had completely healed. Kaplan–Meier analysis resulted in a hazard ratio (active treatment:control) of 1.05 at 12 weeks (p=0.87) and 1.14 at 24 weeks (p=0.60). Neither result was statistically significant
Conclusions	There is no statistically significant difference in clinical outcomes between Oxyzme/Iodozyme and standard care for venous leg ulcers.

Abbreviations: ABPI, ankle to brachial pressure index; CI, confidence interval; ITT, intention to treat; n, number of patients; RR, relative risk.

Table 3 Summary of the objectives of Davis et al. (2009) case series

Study component	Description
Objectives	To assess the performance of the Oxyzyme dressing with a variety of hard-to-heal chronic wounds in clinical settings. To examine the effect of the Oxyzyme dressing on the wound bed. To obtain patient and carer feedback on the Oxyzyme dressing.
Study design	Case series (a report of multiple cases and small series from 27 centres)
Setting	27 European complex wound clinics (22 in England, 2 in Germany, and 1 each in Iceland, Sweden and Turkey). All patients had been receiving treatment in the clinics before recruitment. Each patient received 6 weeks' treatment with the Oxyzyme dressing. Wound area measurements were taken at baseline and at 6 weeks or at withdrawal.

Study component	Description
Inclusion/ exclusion criteria	Inclusion criteria: • Aged over 18 years • Superficial hard-to-heal chronic wound over 12 weeks' duration, static or deteriorating over the previous 4 weeks. Exclusion criteria: • Wound infection based on clinical signs • Known or suspected allergy or sensitivity to iodide or iodine • Thyroid disorder • Pregnancy or breast feeding • Continuing medication with lithium Consecutive patients who met the inclusion criteria were recruited by investigating clinicians. There was an average of 3 patients from each clinic (range 1 to 12). Wound area measurements were taken from digital photographs when these were available and from clinician's area assessments otherwise.
Primary outcome	Not specified, but wound area is the only quantitative outcome reported.
Statistical methods	No statistical analysis was reported. Mean, median and range were reported, but not standard deviation.
Participants	100 patients were included in the study. There were 6 subgroups identified: arterial leg ulcer (14), diabetic foot ulcer (13), mixed aetiology leg ulcer (13) other chronic wounds (8), pressure ulcer (13) and venous leg ulcer (39). At baseline 10 ulcers measured less than 1 cm^2, 49 ulcers measured 1 to 10 cm^2, 39 measured 10 to 100 cm^2 and 2 measured more than 100 cm^2.

Study component	Description
Results	38 patients were withdrawn before the end of the 6-week study period for the following reasons: 13 (13%) infection 7 (7%) wound deterioration (maceration or increase in area) 6 (6%) due to pain or discomfort 5 (5%) other dressing-related reasons (for example bleeding) Mean wound area changed from 15.7 cm^2 (median 5.0, range 0.2 to 250.0) to 10.2 cm^2 (median 2.5, range 0.0 to 96.0) from baseline to study end (6 weeks or at withdrawal).
Conclusions	Without a control group it is impossible to draw any conclusions about how the Oxyzyme dressing compares with other dressings.

Table 4 Summary of the outcomes of Davis et al. (2009) case series

Recruited: 100 patients were recruited into the study, and 62 patients completed the study.

Primary outcome: mean wound area after 6 weeks or at withdrawal

Wound type	Mean baseline wound area (cm2) (median, range)	Mean end point wound area (cm2)	Mean area reduction (%) over 6 weeks
Arterial leg ulcer n=14	42.8 (17.2, 1.0 to 250)	23.0 (15.7, 1.7 to 96)	46.3
Diabetic foot ulcer n=13	10.1 (7.2, 0.2 to 31)	4.7 (2.1, 0.2 to 20)	53.7
Mixed aetiology leg ulcer n=13	13.0 (9.0, 2.0 to 38)	9.9 (8.0, 0 to 36)	23.7
Other chronic wounds n=8	15.1 (6.1, 1.0 to 70)	13.8 (4.4, 0 to 70)	8.4
Pressure ulcer n=13	11.9 (9.1, 0.4 to 35)	10.3 (6.5, 0.1 to 35)	13.1

Wound type	Mean baseline wound area (cm2) (median, range)	Mean end point wound area (cm2)	Mean area reduction (%) over 6 weeks
Venous leg ulcer n=39	10.2 (5.0, 0.3 to 50)	6.8 (2.5, 0 to 34)	33.2
Total	15.7 (5.0, 0.2 to 250)	10.2 (2.5, 0 to 96)	35.0

Selected secondary outcomes

Outcome type	Results	Notes
Pain/comfort scores at final clinic visit n=100	• Very comfortable/ comfortable: 55% (55/100) • Discomfort: 9% (9/100) • Pain: 21% (21/ 100) • Not applicable/not rated: 15% (15/100)	–
Safety	n=100 patients	No adverse events reported, not a clinical trial.
Total patients withdrawn	38% (38/100)	Patients withdrawn from study, not all due to dressing-related issues.
Infection	13% (13/100)	–
Deterioration	7% (7/100)	Maceration or an increase in wound area
Pain/ discomfort	6% (6/100)	–
Other dressing-related reasons	5% (5/100)	Bleeding from a large non-healing surgical wound (n=1), wound static after 3 to 4 weeks (n=3), suspected pyoderma gangrenosum (n=1).

Outcome type	Results	Notes
Non-dressing related reasons	7% (7/100)	e.g. hospitalisation

Table 5 Summary of the objectives of Wood et al. (2010) case series

Study component	Description
Objectives/ hypotheses	To assess the performance of the Iodozyme dressing within normal clinical practice
Study design	Case series (a report of multiple cases and small series from 30 centres).
Setting	Recruitment over 12 months, in 30 centres in England, ranging from district nurse bases to complex wound care clinics. Patients continued to be treated in the same care setting. Assessment of the wound was made at entry to the study and at weekly clinic visits during the 6-week duration.
Inclusion/ exclusion criteria	Inclusion criteria: Aged over 18 years Hard-to-heal (static or had deteriorated during the previous 4 weeks) wound that was suitable for treatment with 1 or more 10×10 cm antimicrobial test dressing. Exclusion criteria: Known or suspected sensitivity or allergy to iodide or iodine Thyroid disorder, such as Hashimoto's thyroiditis or non-toxic nodular goitre Pregnancy or breast-feeding Continuing medication with lithium. The method section stated consecutive recruitment, however the abstract reports that clinicians chose patients to be included. Many centres would have recruited very small numbers of patients, so consecutive recruitment is not meaningful. The mean number of patients per centre was 1.5, the range was not reported. Various wound aetiologies were included.

Study component	Description
Primary outcomes	Primary outcome is stated as clinician's overall assessment of the product, but wound area is the only quantitative measurement quantitative outcome fully reported in the paper.
Statistical methods	No statistical analysis was reported. Mean, median and range were reported, but not standard deviation.
Participants	45 patients (21 men, 24 women), with 51 wounds of various aetiologies, all considered difficult to heal, and that had been static or deteriorating for 4 weeks. One patient had 2 arterial leg ulcers, 1 patient had 6 diabetic foot ulcers, the remainder had single wounds. The median wound duration prior to the study was 13 months (range 1 to 312). Median age was 75 years (range 27 to 93). The median wound area at the start of the study was 6 cm^2 (range 0.23 to 98.0). Inclusion of very small wounds may lead to measurement uncertainties, and moderate improvements appearing as large percentage changes.
Results	The mean wound area decreased from 13.1 (median 6, range 0.23 to 98.0) to 10.5 (median 4, range 0 to 98.9) cm^2.
Conclusions	A reduction in mean wound size is seen, however the number of withdrawals, potential for bias and lack of comprehensive reporting make it difficult to draw firm conclusions.

Note: When patients were withdrawn, the outcome is included at point of withdrawal. Two patients withdrew due to increase in wound size, 1 due to reduction.

Table 6 Summary of the outcomes of Wood et al. (2010) case series

- A total of 45 patients (51 wounds) started treatment: 43 patients, with 1 wound each. 1 patient with 2 arterial leg ulcers. 1 patient with 6 diabetic foot ulcers.
- A total of 33 patients completed treatment: 12 patients were withdrawn from the study, not all related to dressing.

Primary outcome: wound area after 6 weeks or at withdrawal

Wound type	Mean baseline area (cm2) (median, range)	Mean endpoint area (cm2) (median, range)	Mean area reduction (%) over 6 weeks
Arterial leg ulcer n=10, wounds=11	14.8 (11.2, 3.3 to 36.6)	11.6 (9.2, 1.0 to 30.0)	21.7%
Diabetic foot ulcer n=6, wounds=11	6.1 (5.0, 0.4 to 28.0)	4.7 (2.3, 0.5 to 20.0)	23.3%
Miscellaneous n=7, wounds=7	8.9 (7.5, 0.2 to 27.3)	5.9 (3.9, 0.0 to 21.1)	33.5%
Pressure ulcer n=4, wounds=4	5.0 (4.5, 3.0 to 8.0)	4.4 (3.5, 2.4 to 8.0)	12.6%
Surgical wound n=8, wounds=8	13.0 (6.0, 2.3 to 50.0)	7.1 (3.5, 0.0 to 29.8)	45.6%
Venous leg ulcer n=10, wounds=10	25.0 (10.4, 2.1 to 98.0)	24.0 (7.6, 0.0 to 98.0)	4.1%
Total n=45, wounds =51	13.1 (6.0, 0.23 to 98.0)	10.5 (4.0, 0 to 98.9)	19.8%

Note: Primary outcome is stated as clinician's overall assessment of the product, however wound area was the only quantitative measurement technique reported.

Selected secondary outcomes

Outcome	Results	Notes
Clinician assessment of product n=51 clinicians	• Much better: 8% (4/51) • Better: 69% (35/51) • Similar: 18% (9/51) • Worse: 6% (3/51) • Much worse: 0% (0/51)	–
Safety	n=45 patients	No adverse events reported, not a clinical trial
Total patients withdrawn	27% (12/45)	Patients withdrawn from study, not all due to dressing-related issues
Bleeding	2.2% (1/45)	Withdrawn after 1 week
Hospitalisation	4.4% (2/45)	Withdrawn after 1 week and 3 weeks, not related to dressing
Slippage	2.2% (1/45)	Patient with sacral pressure ulcer withdrawn after 1 week due to dressing slippage and faecal contamination.
Pain	4.4% (2/45)	Withdrawn after 1 week and 4 weeks
Clinical decision	2.2% (1/45)	Withdrawn after 5 weeks, change to the Oxyzyme dressing following reduction in wound size

Outcome	Results	Notes
Clinical decision	2.2% (1/45)	Withdrawn after 5 weeks when wound became static (despite initial improvement)
Maceration	2.2% (1/45)	Withdrawn after 1 week
Increased wound size	4.4% (2/45)	Both withdrawn after 3 weeks due to increase in wound area
Inflammation	2.2% (1/45)	Withdrawn after 1 week due to inflammation around wound

Notes: Clinician assessment of wound condition is not reported due to the likelihood of bias in assessment. Other secondary outcomes were not reported in sufficient detail to tabulate.

Clinicians were asked for their overall rating of Iodozyme, compared with other treatments used for similar wound types.

When patients were withdrawn, the outcome is included at point of withdrawal. Two patients withdrew due to increase in wound size, 1 due to reduction.

Table 7 Summary of the objectives of Lafferty et al. (2011) case series

Study component	Description
Objectives	To assess whether a modern wound dressing would be able to reduce the burden of chronic wounds and reduce overall costs.
Study design	A single-centre non-comparative case series
Setting	Single UK leg ulcer clinic. All patients who attended the clinic were assessed for suitability.

Study component	Description
Inclusion/ exclusion criteria	Inclusion criteria: Wounds assessed at initial visit as static or deteriorating. Exclusion criteria: Wounds assessed as improving at initial assessment. Wounds not suitable for hydrogel dressing. Wounds exhibiting signs of local infection were treated with the Iodozyme dressing.
Primary outcomes	Not specified, but wound area is the only quantitative outcome reported. Each patient had measurements of wound area using the LUTM telemedicine system weekly for the first 6 weeks and then at weeks 12, 16 and 20.
Statistical methods	A healing rate calculated from the 10 wounds remaining in the study at week 20 was compared with a historical healing rate (2 healed/26 treated) in the clinic over 6 months before the study using a chi-squared statistic. These calculations of healing rate are invalid and not comparable.
Participants	17 wounds in 13 patients were included, of which 3 wounds were treated with the Iodozyme dressing and the remaining 14 with the Oxyzyme dressing. Wound duration at recruitment ranged from 2 to 420 months.
Results	Results are presented for 11 wounds in 9 patients. No data are presented for 6 wounds in 4 patients withdrawn before week 12. One further patient with 1 wound withdrew at week 13. For the 11 wounds reported there was a reduction in wound area from baseline to week 20 from 75.3 cm^2 to 8.8 cm^2 (88.4%).
Conclusions	Without a control group it is impossible to draw any conclusions about how the Oxyzyme dressing compares with other dressings.

Table 8 Summary of the outcomes of Lafferty et al. (2011) case series

Measure	Oxyzyme and Iodozyme dressings
Recruited	n=13 patients (17 wounds)
Completed	n=8 patients (10 wounds)

Measure	Oxyzyme and Iodozyme dressings
Primary outcome: reduction in wound area over 20 weeks	• Wound 1: 6.1 cm^2 (week 0), 2.3 cm^2 (week 20) • Wound 2: 2.5 cm^2 (week 0), 0 cm^2 (week 20) • Wound 3: 1 cm^2 (week 0), 0.8 cm^2 (week 20) • Wound 4: 30 cm^2 (week 0), 0 cm^2 (week 20) • Wound 5: 2.5 cm^2 (week 0), 1.3 cm^2 (week 20) • Wound 6: 2.8 cm^2 (week 0), 1.3 cm^2 (week 20) • Wound 7: 5 cm^2 (week 0), 0 cm^2 (week 20) • Wound 8: 16.1 cm^2 (week 0), 0 cm^2 (week 20) • Wound 9: 5.3 cm^2 (week 0), 3.1 cm^2 (week 20) • Wound 10: 1.5 cm^2 (week 0), 0 cm^2 (week 20) • Wound 11: 2.5 cm^2 (week 0), 0 cm^2 (week 20) Total area: 75.3 cm^2 (100%) at week 0, 8.8 cm^2 (11.6%) at week 20 Area reduction total: 88.4%
Safety	n=13 patients (17 wounds)
Patients reporting serious adverse events	5/13 (38.5%) patients withdrawn
Death	1 (1/13, 7.7%) patient with 2 wounds died.
Hospitalisation	2/13 (15.4%) patients (3 wounds) were hospitalised for non-wound related reasons.
Non-adherence	2/13 (15.4%) patients were withdrawn for patient non-adherence issues.

Note: Results are only reported for 9 patients (11 wounds) out of 13 patients (17 wounds) recruited. Patient with wound 3 was withdrawn at week 13. Wound measurement is carried forward from week 12.

Recent and ongoing studies

No ongoing or in-development trials on the Oxyzyme dressing for non-infected chronic wounds were identified in clinical trial databases.

Costs and resource consequences

The use of the Oxyzyme or Iodozyme dressings would not need a change in existing treatment facilities or care pathways. No additional equipment would be needed for its use, other than an air-permeable covering dressing, which is already commonly used with hydrogel wound dressings.

It is anticipated that the prescription of the Oxyzyme or Iodozyme dressings would need approval from a specialist such as a tissue viability nurse, or a wound clinic. This is usually needed for more challenging wounds and higher cost dressings and does not mean a change in NHS practice.

The Oxyzyme and Iodozyme dressings have a higher acquisition cost than many other dressings used for hard-to-heal wounds. Any anticipated cost or resource saving would be based on a reduced duration of wound treatment, or reduced frequency of dressing changes.

Published cost studies

A randomised controlled trial (Moffatt et al. 2014) reported cost savings through the use of the Oxyzyme and Iodozyme dressings compared to standard care. The trial also compared clinical outcomes and was described in the clinical evidence section and tables 1 and 2.

The cost of wound treatment was estimated from the number and type of dressings and nurse time during the 12 weeks of the study. The number of dressings used during the weekly assessments, and any additional nurse visits, was recorded. Nurse time was estimated from previous studies combined with information gathered during the trial, but the detail for this calculation is not reported, and there appears to be an assumption that the time is equal for both arms of the study. Cost of nurse time was based on Personal Social Services Research Unit costs for 2011 (Curtis et al. 2011) for a district nurse.

The mean cost per patient treated with Oxyzyme or Iodozyme dressings was £436.33, compared with £525.54 per patient for standard care. The mean cost per ulcer healed at

12 weeks or earlier was £976.54 using Oxyzyme or Iodozyme dressings, compared with £1071.29 per patient for standard care. The cost saving is based on a reduction in the mean number of nurse visits needed per patient, which was 14.8 visits for people who had standard care compared with 10.04 visits for those who had Oxyzyme or Iodozyme dressings.

Moffatt et al. (2014) also included a Markov analysis to model the costs over the 12 week period of patients being treated. The health states used in the model were: treatment according to study protocol, withdrawn from treatment for 2 weeks, treated off-study, or healed. Very little additional information is given about the model inputs and assumptions. The Markov model found a greater number of total ulcer free weeks in the control group (187 weeks), compared with the Oxyzyme or Iodozyme dressing group (175 weeks). The model still showed the total cost of the Oxyzyme or Iodozyme dressing group (£23,801) to be lower than that of the comparator (£28,831). The model results in a cost saving per healed week of £419.25 for people treated with Oxyzyme or Iodozyme dressings.

The resources, costs and results from this study are shown in table 9.

A case series (Lafferty et al. 2011) reported cost savings through the use of the Oxyzyme and Iodozyme dressings. The series also looked at clinical outcomes and was described in the clinical evidence section and tables 5 and 6. The cost of treating wounds using standard care was estimated from the number and type of dressings and clinician time during the 4 months before enrolment in the study. The cost of treating wounds with the Oxyzyme and Iodozyme dressings was estimated from the number and type of dressings and the clinician time over the first 6 weeks of the study. Cost of clinician time was based on Personal Social Services Research Unit costs for 2006 (Curtis et al. 2007). The average weekly cost of treatment with the dressings was £85.40 per patient, compared with £76.80 per patient for standard care. Faster healing with the Oxyzyme and Iodozyme dressings was assumed based on the 6 wounds that healed out of the 10 wounds receiving 20 weeks' treatment. This was compared with a historical healing rate of 2 patients healed out of the entire clinic cohort of 26 patients in the 6 months before the study. It is unclear whether some patients in the historical cohort were also patients included in the study. The authors projected a potential saving of £23,036 over 52 weeks from the use of the Oxyzyme and Iodozyme dressings compared with standard treatment.

The cost estimation (Lafferty et al. 2011) is summarised in table 10.

Table 9 Summary of the cost estimate from Moffatt et al. (2014)

–	Oxyzyme and Iodozyme dressings	Standard care
Resources	• Oxyzyme and Iodozyme dressings • Secondary dressings • Dressing packs • Bandages • Nurse time	• Dressings – based on types used prior to study • Secondary dressings • Dressing packs • Bandages • Nurse time
Quantity of resource	Dressings, packs and bandages are based on the recorded number and type of dressings used during 12-week trial. The number of visits was recorded during the 12-week trial. Nurse time estimated as 27 min contact per dressing change. This is based on previous studies and information collected during this study, but no details are given. The assumption is that times are equal for both trial arms.	Dressings, packs and bandages are based on the recorded number and type of dressings used during 12-week trial. The number of visits was recorded during the 12-week trial. Nurse time estimated as 27 min contact per dressing change. This is based on previous studies and information collected during this study, but no details are given. The assumption is that times are equal for both trial arms.
Value of resource	Published drug tariff prices for dressings and bandages (British National Formulary) Mean number of visits was 10.04, over 12 weeks Nurse time: £60 per hour for District Nurse home visit time (Curtis et al. 2011)	Published drug tariff prices for dressings and bandages (British National Formulary) Mean number of visits was 14.8, over 12 weeks Nurse time: £60 per hour for District Nurse home visit time (Curtis et al. 2011)

–	Oxyzyme and Iodozyme dressings	Standard care
Cost of dressings, bandages, packs	£7,763.37	£6,739.49
Staff cost	£12,744.00	£21,114.00
Mean cost per patient treated	£436.33	£525.54
Mean cost per healed ulcer	£976.54	£1,071.29
Total ulcer-free weeks (Markov)	175	187
Total cost of care for 12 weeks (Markov)	£23,801	£28,831

Table 10 Summary of the cost estimate from Lafferty et al. (2011)

–	Oxyzyme and Iodozyme dressings	Standard care
Resources	• Oxyzyme and Iodozyme dressings • Bandages • Clinician time	• Dressings – based on types used prior to study • Bandages • Clinician time

–	Oxyzyme and Iodozyme dressings	Standard care
Quantity of resource	Estimated weekly resource use per wound over the first 6 weeks of treatment. Faster healing rate (60%) assumed based on 6 wounds healing of the 10 that completed the 20 week study. Using 6/26 wounds originally assessed would give a healing rate of 23.1%.	Based on recorded number and type of dressings and clinician time spent over the 4-month period before the study commenced. Assumed 8% healing rate based on 2 wounds healed out of 26 treated in the previous 6 months. A statement that 8 of the 26 wounds originally assessed (30.7%) were improving and continued on the same care regimen suggests considerable uncertainty in the standard care healing rate.
Value of resource	Published drug tariff prices for dressings and bandages Clinician time: £36 per hour (Curtis et al. 2007)	Published drug tariff prices for dressings and bandages Clinician time: £36 per hour (Curtis et al. 2007)
Projected 52-week cost per wound	£16,055	£39,091

Strengths and limitations of the evidence

One randomised controlled trial and 3 case studies were found for the Oxyzyme or Iodozyme dressings, with only the RCT providing evidence comparing these dressings with standard treatment for chronic wounds. Many of the limitations of the evidence are common in wound care research, as discussed in NICE's key therapeutic topic on wound care products.

The Moffatt et al. (2014) study was a randomised controlled trial comparing Iodozyme and Oxyzyme with standard care in an NHS setting for 100 patients. There was no formal power calculation so the results should be interpreted with caution as in underpowered studies, statistical non-significance could be caused by an insufficient sample size. The methods of this study are well reported and the outcomes are relevant to this briefing. The trial was funded by Archimed, now a subsidiary of the manufacturer Crawford Healthcare, and 1 of the authors was formerly an Archimed employee. No trial protocol was publically

available before the trial commenced. There were no eligibility restrictions based on criteria for ulcer size or duration. Not all results were fully and clearly reported.

The statistical analysis of quality of life results is unclear, and data on patient reported pain is not presented.

For the cost comparison, the nurse time was estimated from previous studies and information gathered during the trial. No more detail is given for this estimation, and there appears to be an assumption that the time is equal for both arms of the study. Nurse time is the largest component of the treatment cost and more detailed information would have been useful in assessing the appropriateness of the assumptions made. For example, if the time taken to change dressings in the standard care group was shorter, this would impact on the results of the study.

Very little additional information was given about the Markov model inputs and assumptions. The model shows an additional cost per healed week for the group of patients treated with standard care, compared to the people treated with the Oxyzyme or Iodozyme dressings. This additional cost is likely to be based on the greater number of dressing changes in the control group, combined with an assumption of equal nurse time. Additional information would allow a better assessment of the model.

The proportion of patients withdrawn from the 3 case studies was very high, resulting in a strong likelihood of bias.

Two case series had very similar protocols. Davis et al. (2009) is a case series using the Oxyzyme dressing for the treatment of chronic wounds (n=100 patients) of various aetiologies conducted in 27 European centres, with a mean of 3 patients per centre (range 1 to 12). Wood et al. (2010) is a case series using the Iodozyme dressing for the treatment of chronic wounds of various aetiologies with 45 patients in 30 centres in England.

Each centre only treated a small number of patients. There was no meaningful consecutive recruitment and therefore a likelihood of recruitment bias.

The large number of centres included means that the variety in practice in wound care was realistically reflected. However, with small numbers in each centre and a variety of wound types, the probable differences in treatment and outcome measurement may have masked a common effect.

Wound area was based on non-blinded clinician assessment if digital photographs were not available. This meant there was a high likelihood of bias for such wounds (number not reported). Patients whose wounds increased in size were withdrawn, so the study could only show a reduction in mean wound area.

A key reported outcome was the overall condition of the wound at the end of the study. This was determined by non-blinded clinical opinion as healed, improved, static or deteriorating. 'Improved' included a reduction in size or an improvement in the wound bed, so that wounds could be classified as improved even when the wound size had increased, or the patient had to be withdrawn due to problems with the dressing. Assessment of wound bed condition was very subjective unless carefully defined and reported, which was not apparent in this paper. These factors make the probability of bias sufficiently high that the outcome was not reported here.

All authors were current or past employees of Archimed Wound Care Division, the manufacturer of the Oxyzyme and Iodozyme dressings when the study was published.

In addition, Davies et al. (2009) included a large number of very small wounds (10 ulcers less than 1 cm^2 and 49 ulcers 1 to 10 cm^2). For very small wounds a small change in wound measurement resulted in a large percentage change.

Lafferty et al. (2011) was a study of the Oxyzyme and Iodozyme dressings in patients with chronic wounds (n=13 patients, 17 wounds) referred to a single UK leg ulcer clinic. The author did not report the results of all the patients recruited into the study (13 patients with 17 wounds recruited, 9 patients with 11 wounds reported). Statistical analysis was applied to the 11 wounds in 9 patients reported, resulting in a strong likelihood of bias. The historical comparator group differed from the patients in the study because:

- it included all patients attending the clinic in a 6-month period, with no inclusion or exclusion criteria
- individual patients were not followed for a specified time period; some may have attended the clinic for considerably less than the 20-week study period of the intervention group
- there were no withdrawals.

For these reasons the historical comparator group was not comparable to the reported patients in the study.

Of the initial cohort of 17 wounds in 13 patients, 3 wounds were treated with the Iodozyme dressing and 14 with the Oxyzyme dressing. However, after withdrawals it was unclear how many were being treated with the Iodozyme dressing. The study did not compare the Oxyzyme and Iodozyme dressings with any other treatment so it was not possible to form any conclusions about their effectiveness. Two authors were current or past employees of Archimed, the manufacturer of the dressings at the time of study publication.

The cost analysis undertaken in Lafferty et al. (2011) was flawed. The healing rate for the Oxyzyme and Iodozyme dressings was calculated as a proportion of wounds completing the 20-week study (60% [6/10] healed) rather than the total number of wounds in patients recruited (35% [6/17] healed), or the total number of wounds in patients assessed for the study (23% [6/26] healed) if it is assumed that no excluded patients healed. The comparator group included all patients attending the clinic in the previous 6 months, so the patient populations were not comparable. The cost savings claimed were based on the assumed differences in healing rates. The costs of treating patients for whom the study dressings were not suitable were ignored, as were the costs of treating the patients withdrawn.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Type 2 diabetes: Prevention and management of foot problems (2004) NICE guideline CG10
- Surgical site infection: Prevention and treatment of surgical site infection (2008) NICE guideline CG74
- Diabetic foot problems: Inpatient management (2011) NICE guideline CG119
- Pressure ulcers: Prevention and management of pressure ulcers (2014) NICE guideline CG179

The guidance documents do not specify types of wound dressing to be used.

NICE has also issued the following evidence summary:

- Wound care products (2013) NICE key therapeutic topic 14

References

British national formulary (2014) [online; accessed 1 May 2014]

Curtis L, Netten A (2007) Unit Costs of Health and Social Care 2007. Personal Social Services Research Unit

Curtis L (2011) Unit Costs of Health and Social Care 2011. Personal Social Services Research Unit

European Advisory Pressure Ulcer Panel (2009) Pressure Ulcer Treatment Quick Reference Guide

European Wound Management Association (2008) Hard to Heal Wounds: A holistic approach. EWMA Position Documents

Greenman J, Thorn R M S, Saad S et al. (2006) In vitro diffusion bed, 3-day repeat challenge 'capacity' test for antimicrobial wound dressings. International Wound Journal 3: (4) 322–29

Kerr A (2007a) The importance of correctly applying Oxyzyme. Wounds UK 3 (1): 8

Kerr A (2007b) The importance of selecting the correct secondary dressing. Wounds UK 3 (1): 9

Lafferty B, Wood L, Davies P (2011) Improved care and reduced costs with advanced wound dressings. Wounds UK 7 (1): 16–23

Moffatt C, Stanton J, Murray S et al. (2014) A randomised trial to compare the performance of Oxyzyme and Iodozyme with standard care in the treatment of patients with venous and mixed venous / arterial ulceration. Wound Medicine (6) 1-10

NHS Choices. Venous leg ulcer. [online; accessed 29 April 2014]

NHS Choices. Pressure Ulcer. [online; accessed 29 April 2014]

NHS Choices, Peripheral Neuropathy [online;accessed 17 July 2014]

NHS National Prescribing Centre (2010) Evidence-based prescribing of advanced wound dressings for chronic wounds in primary care. MeReC Bulletin, 21 [online; accessed 29 April 2014]

Persoon A, Heinen M M, Van Der Vleuten C J M et al. (2004) Leg ulcers: a review of their impact on daily life. Journal of Clinical Nursing 13: 341–54

Posnett J, Franks P (2008) The Burden of Chronic Wounds in the UK. Nursing Times 104: 44–45

Thorn RM, Greenman J, Austin AJ (2005) In vitro method to assess the antimicrobial activity and potential efficacy of novel types of wound dressings. Journal of Applied Microbiology, 99: 895–901

Thorn RM, Greenman J, Austin AJ (2006) An in vitro study of antimicrobial activity and efficacy of iodine-generating hydrogel dressings. Journal of Wound Care, 15: 305–10

Thorn RM, Austin AJ, Greenman J et al. (2009) In vitro comparison of antimicrobial activity of iodine and silver dressings against biofilms. Journal of Wound Care, 18: 343–46.

Wood L, Wood Z, Davis P et al. (2010) Clinical experience with an antimicrobial hydrogel dressing on recalcitrant wounds. Journal of Wound Care, 19: 287–88

Search strategy and evidence selection

Search strategy

Medline (1946 to present) was searched on 14 March 2014 using the following strategy:

1 oxyzyme.mp.

2 iodozyme.mp.

3 exp Glucose Oxidase/

4 exp Iodine Compounds/ or exp Iodine/ or iodine.mp.

5 exp Oxygen/ or oxygen.mp.

6 oxygenating.mp.

7 5 or 6

8 4 and 7

9 wound.mp. or exp "Wounds and Injuries"/

10 wound healing.mp. or exp Wound Healing/

11 exp Foot Ulcer/ or exp Skin Ulcer/ or exp Pressure Ulcer/ or exp Leg Ulcer/ or exp Varicose Ulcer/

12 9 or 10 or 11

13 1 or 2

14 3 or 8

15 14 and 12

16 13 or 15

This resulted in 74 papers. A similar strategy was adapted for Medline in Process, Embase, CINAHL, Pubmed and DARE (includes Cochrane Library, NHS EED, HTA, CRD) resulting in a total of 234 papers. In addition SCOPUS was used to search for citations of the key papers by Davies and Wood, resulting in 2 additional papers. Several articles were known to be published in Wounds UK, which is not included in the databases. Google Scholar was used to search for Oxyzyme or Iodozyme in Wounds UK, resulting in 4 additional papers, giving a total of 240 papers.

Evidence selection

Evidence was selected by 2 independent researchers using the following criteria:

- Population: Adults with chronic wounds

- Intervention: Iodozyme or Oxyzyme
- Comparator: Standard Care
- Outcomes: Include all fully reported

12 papers were obtained from the initial literature search and read in full by 2 reviewers, and 2 case series were selected for the Oxyzyme dressing, 1 case series for the Iodozyme dressing. The randomised controlled trial (Moffatt et al. 2014) was identified after the initial literature search was carried out.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are not formal NICE guidance.

Development of this briefing

This briefing was developed for NICE by Cedar. The Interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

Project team

Cedar External Assessment Centre

Medical Technologies Evaluation Programme, NICE

Peer reviewers and contributors

- Grace Carolan-Rees, Cedar Director, Cedar
- Megan Dale, Researcher, Cedar

Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Bill Cox-Martin, Clinical Nurse Specialist, Pressure Ulcer Outreach Service, Salisbury NHS Foundation Trust
- Nicky Ivins, Clinical Trials Co-ordinator, Wound Healing Research Unit, Cardiff University
- Nicci Kimpton, Tissue Viability Lead Community, Peninsula Community Health, Community Interest Company (Cornwall and Isles of Scilly)

ISBN: 978-1-4731-0829-5