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NICE advice

The Versajet II hydrosurgery system for surgical debridement of acute and chronic wounds and burns

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Summary

Effectiveness	Adverse events and safety
• Six randomised controlled trials and 3 non-randomised comparative studies evaluated the original Versajet hydrosurgery system. • The Versajet hydrosurgery system was faster or took the same time to debride wounds compared with the comparators.	• In 1 randomised controlled trial 25% of patients had adverse events in the Versajet arm compared with 9.5% in the comparator arm. • Pain experience was no different in 1 randomised controlled trial and 1 comparative study. • In 1 randomised control trial there was less blood loss using the Versajet system compared with conventional debridement with scalpels and electrocautery. In another randomised controlled trial a large blood vessel was cut in the Versajet system group.

Cost and resource use	Technical factors
• The costs of the Versajet II system are £5000+VAT for the console and £230+VAT for each single-use hand piece. • Two studies compared the cost of treatment using the Versajet hydrosurgery system against conventional debridement. • One study estimated treatment using the Versajet hydrosurgery system to be less costly and the other found no statistically significant difference between the 2 groups. • In 1 comparative study, the mean number of surgical procedures was lower in the Versajet system arm. It was estimated that the average number of debridement procedures to achieve a healthy wound was 1.2 for the Versajet system and 1.9 for conventional surgical debridement.	• No clinical evidence was found on the Versajet II hydrosurgery system but the available evidence on the predecessor Versajet system is likely to be applicable. • It is advisable to use the Versajet II system in an operating theatre to reduce the risk of transmitting infection through misting or spraying.

Key points

The Versajet II hydrosurgery system (Smith & Nephew) can be used for wound debridement (acute and chronic wounds and burns) and soft tissue debridement in people who need sharp debridement. The Versajet II hydrosurgery system is a modification of an earlier version, Versajet.

No clinical evidence was found for the Versajet II hydrosurgery system. The limited information found on the differences between the Versajet II and Versajet hydrosurgery systems suggests that the clinical evidence for Versajet is likely to apply to Versajet II.

There were 6 randomised controlled trials (3 on burns and 3 on chronic wounds) and

3 non-randomised comparative studies evaluating the original Versajet hydrosurgery system. The outcomes suggested mixed results. Compared with comparators:

- the Versajet hydrosurgery system was either faster or took the same time to debride wounds
- healing time or wound closure was no different or shorter with the Versajet hydrosurgery system
- pain experience was no different
- there was less blood loss using the Versajet hydrosurgery system in one randomised controlled trial, but in another trial, a large blood vessel was cut in the Versajet group.

In one randomised controlled trial 25% of patients had adverse events in the Versajet arm compared with 9.5% in the comparator arm.

Meta-analysis was not possible as numerical results were not given in most of the studies.

Two studies compared the cost of treatment using the Versajet hydrosurgery system against conventional debridement. One study estimated treatment using the Versajet hydrosurgery system to be less costly. The other found no statistically significant difference between the 2 groups in terms of cost of the first operative procedure, cost of surgical procedures during the study, cost of study treatment or cost to achieve stable wound closure.

Introduction

Chronic wounds are a significant burden to patients and the NHS (in the UK in 2008 approximately 200,000 people had chronic wounds). They affect quality of life and can lead to temporary or permanent disability.

Leg ulcers affect 1 in 500 people, and 1 in 50 people over the age of 80. Pressure ulcers affect just under half a million people in the UK; usually people with an underlying health condition. Around 1 in 20 people who are admitted to hospital with an acute illness will develop a pressure ulcer.

Burn wounds cause an estimated hospital admission rate of 0.29 per 1000 cases of burn or smoke inhalation. In the UK, it is estimated that each year about 250,000 people with burn

injuries present to primary care teams. Higher rates of burns are seen in children under the age of 5 and older people over the age of 75.

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 Versajet system was CE marked in 1997. The Versajet II system was CE marked in 2011 and was launched in 2012.

Intended use

The Versajet II hydrosurgery system is intended for wound debridement (acute and chronic wounds and burns), soft tissue debridement and cleansing of the surgical site if clinicians judge that sharp debridement and pulsed lavage irrigation is needed.

It can be used in adults and children, for indications including pressure, diabetic and foot ulcers, burns and wounds that need plastic surgery, and dehisced and non-healing wounds.

The original Versajet system was similar in construction and had the same indications for use. There are currently no published details about the changes between Versajet and Versajet II, but some information was available from 2 conference posters supplied by the manufacturer: Martin (2012) noted that the console and the hand piece insertion mechanisms have been completely redesigned. Liebert (2011) stated that the Versajet II system was developed to enhance the user experience and to deliver additional functionality.

Setting and intended user

The Versajet II system, with the Plus and Exact 15° hand pieces, should only be used in operating theatres due to the potential of excessive misting or spraying (Smith and Nephew Medical Ltd, 2012). Only the 45°Exact hand piece is suitable to be used outside an operating theatre. Using the system in an operating theatre may lessen the risk of transmission of infective material because of the universal infection control procedures in operating theatres (Smith and Nephew Medical Ltd, 2012). The Versajet II system must only be used by staff fully trained in its use including nurses, podiatrists and doctors.

Description

The Versajet II system consists of a re-usable console with footswitch, a single use disposable hand piece and a regionally configured power cord. The console pressurises saline or water and causes a very fine jet of fluid to shoot across an aperture at the tip of the hand piece. The speed of the jet creates a localised vacuum, which is claimed to lift only non-viable tissue into the path of the jet. This obliterates the tissue and carries the debris away into a collection canister.

Two styles of hand piece are available: the 'Exact' hand piece for gentle debridement of wounds and the 'Plus' hand piece for more aggressive debridement and excision. The hand pieces are available in different deck heights and channel widths and come in 3 different options: 15°/14mm, 45°/14mm and 45°/8mm. These angled hand pieces are intended to enable the user to remove thin layers of tissue.

The power setting on the Versajet II system is set using a footswitch or a switch on the front panel, and varies between setting 1 (tenuous tissue, gentle resurfacing), through settings 5–6 (medium quality tissue, deeper necrosis), up to setting 10 (major tissue necrosis). At setting 10 the pressure can be up to 15,000 lb per square inch. At higher pressures there is a possibility that viable soft tissue can be damaged.

It is unclear whether the Versajet II system has equivalent clinical functionality to the earlier Versajet system model but it is likely to be similar. The technical differences include an enhanced footswitch incorporating the ability to change power settings, and an improved hand piece designed to enhance the user interface. This means that the Versajet II system may be more responsive to user control and may have different debridement characteristics to the Versajet system. Martin (2012) suggested that the Versajet II system tends to remove tissue more deeply than the Versajet system at the

same power settings and angle of cut but within 1 standard deviation. The standard deviations were wide, probably because of the small number of samples taken (12 test areas for each device), and the study was probably underpowered to detect a significant difference.

Alternative NHS options

There are several other ways of debriding wounds (Smith, 2011) including surgical debridement, sharp debridement, autolytic debridement, larval debridement and mechanical debridement. The Versajet II system is intended to be comparable to surgical or sharp debridement.

NICE is not aware of other CE marked devices fulfilling a similar function.

Costs and use of the technology

The costs (list price) of the Versajet II system are £5000+VAT for the console and £230+VAT for each single-use hand piece.

It is unclear whether the Versajet system is still available to purchase. In 2009 the cost of a Versajet console was £6000–£7000, and each hand piece was £220–£240 (Sainsbury, 2009). It has been estimated by the manufacturer that the cost per treatment is £264 for the technology and £429 for staff and operating theatre time (Smith & Nephew: personal communication [2013]).

The device costs per treatment of surgical debridement with scalpels and other consumables associated with surgical debridement are considerably less than for the technology because the acquisition costs of scalpels and blades are minimal. However, the costs for staff and operating theatre time per treatment are likely to be similar.

Likely place in therapy

The Versajet II system would be used in the normal pathway of care for patients who need debridement of acute or chronic wounds or burns. Patients would have debridement at the same point of the pathway.

Specialist commentator comments

The Versajet II system is a hydrosurgery device used for debridement of wounds. Depending on the wound, different debridement methods are considered. For some wounds sharp or surgical debridement is the most efficient and effective, for example dealing with calluses or hard eschar. When the necrotic tissue consists of adherent, stringy slough, lavage techniques or the Versajet II system may be more effective than sharp or surgical debridement.

The Versajet system may be useful in certain burn scenarios. In superficial burns it could be used before biological dressings (particularly Biobrane). These dressings need a very clean wound bed otherwise there is a high risk of infection. The Versajet system could be a useful way of preparing such a wound bed. In deep dermal burns before skin grafting, the Versajet system may allow for thinner slices of tissue to be removed at each pass (compared with conventional excision). This has 2 consequences: firstly that the correct level can be reached more accurately, preserving as much dermis as possible and therefore improving function and appearance; secondly, it is slower, and so tends to be used only for deep dermal burns in children, and hand or face burns in adults. The Versajet system may not be as useful in full thickness burns as it 'bounces' off the tissue and causes irregular grooves.

In traumatic wounds, the Versajet system could be useful in removing contaminated material that is difficult to remove with conventional tools such as forceps, scissors and scalpels. Because the Versajet system grabs, cuts and sucks up this tissue it allows the surgeon to see exactly where they have been and therefore where they still need to go. For general plastic surgery the Versajet system may be useful in smoothing down tissue to a common level, such as when smoothing out granulation tissue.

The Versajet II system has improved usability and improved debridement efficiency compared with the original Versajet. There is no convincing evidence that the Versajet system is superior to standard methods of debridement with regard to the most desirable outcome, which is healing time.

Training is essential to avoid adverse events (for example, transection of blood vessels or destruction of healthy tissue).

Evidence review

Clinical and technical evidence

There was no evidence found through independent searches or provided by the manufacturer about the clinical effectiveness or safety of the Versajet II system. Two pre-clinical studies in the form of conference posters were available. One evaluated the speed of set up of the Versajet II system compared with the original Versajet system (Liebert 2011) and concluded that the Versajet II system was faster by a number of seconds. The other evaluated pig subcutaneous tissue depth removed at 45° and 90° angles and at various power settings for both models (Martin 2012). This found that the Versajet II system removed tissue more deeply than the Versajet system at the same power settings, within 1 standard deviation of the depth.

It is assumed that the clinical evidence for the Versajet system would also apply to the Versajet II system, because the manufacturer's website cites references to studies on the Versajet system rather than any new studies on the Versajet II system. Therefore, the evidence for the Versajet system has been summarised here.

There were 6 randomised controlled trials evaluating the Versajet system found: Anniboletti 2011 (abstract), Caputo 2008, Esposito 2009 (abstract), Gravante 2007, Lantis (2013) (abstract) and Liu 2012 (abstract). Three were on burns (see table 1) and 3 were on chronic wounds (see table 2). There were 4 non-randomised comparative studies found: Granick 2006, Mosti 2006 and Scholten 2011 (abstract). Mosti 2005 was a subset of Mosti 2006 so is not described here. See table 3 for the details and results of the comparative studies. Critical appraisal of the conference abstracts was limited as there was insufficient information on study conduct and the results that were presented. All relevant numerical results are included in the tables. The abstracts were not peer reviewed, so their results may not be as accurate as the fully published studies. However, they have been included because they do present interesting findings on the Versajet system.

Many of the studies did not give numerical results per group, just statistical comparisons (p values), so meta-analysis was not done.

The outcomes suggested mixed results. Compared with the study comparators (see tables 1, 2 and 3):

- There was no difference in time to debride (3 randomised controlled trials, 1 comparative study) or the Versajet system was faster (2 randomised controlled trials, 1 comparative study).
- Healing time or wound closure was no different (3 randomised controlled trials, 1 comparative study) or shorter with the Versajet system compared with sharp debridement with scalpel plus pulse lavage (1 randomised controlled trial).
- Contractures were no different compared with hand held dermatome escharectomy (1 randomised controlled trial). The mean number of surgical procedures was lower in the Versajet arm (1 comparative study).
- Bacterial load was no different with the Versajet system compared with conventional debridement with scalpels and electrocautery (1 randomised controlled trial) or worse after using the Versajet system compared with sharp debridement (1 randomised controlled trial).
- There was no difference in hypertrophy compared with conservative treatment or guarded knife (1 comparative study).
- Pain experience was no different (1 randomised controlled trial, 1 comparative study).
- There was less blood loss using the Versajet system compared with conventional debridement with scalpels and electrocautery (1 randomised controlled trial) but in another randomised controlled trial a large blood vessel was cut in the Versajet system group.

In one randomised controlled trial, 25% of patients had adverse events in the Versajet arm compared with 9.5% in the comparator arm. In one comparative study there were 2 patients with new necroses along the wound margins after treatment with the Versajet system.

Table 1. Summary of randomised controlled trials on the Versajet system for patients with burns

Study component	Description		
	Anniboletti 2011 (abstract)	Esposito 2009 (abstract)	Gravante 2007

Objective/ hypothesis	Report experience with Versajet	Report experience with Versajet	Compare Versajet to escharectomy
Setting (country)	Unclear (Italy)	Unclear (Italy)	Burn centre in hospital (Italy)
Participants	Total n=35 including 12 children 17 Versajet, 18 escharectomy Age/sex/wound characteristics not given	Total n=36 including 8 children. 14 Versajet, 12 escharectomy, Age/sex/wound characteristics not given	Total n=100 of which 87 received allocated treatment 42 Versajet (17 women, mean age 46 (SD=27), 19 with deep burns), 45 escharectomy (20 women, mean age 50 (SD=28), 21 with deep burns)
Comparator	Hand held dermatome escharectomy	Hand held dermatome escharectomy	Hand held dermatome escharectomy
Variables	Time to debride, correct dermal plane, wound healing, pain, adverse events	Speed of debridement	Operative time, post-operative pain, complete healing, contractures at 6 months
Statistical methods	Unclear	Unclear	Student's T Test

Main numerical results	No difference in time to debridement (p=0.4). Healing time shorter (by 7 days on average) (Pain results not given)	No difference in speed of debridement (p=0.4)	Operative time similar overall (less for limbs or trunk, more for hands, genitals, face). Complete healing in days: Versajet 11 (SD=2), escharectomy 13 (SD=2) (p=NS) Post-operative pain (mean (SD)) Versajet 4.3 (1.6), escharectomy 4.6 (1.2) (p=NS) Contractures at 6 months Versajet n=14, escharectomy n=16 (p=NS)
Safety, adverse events	Not given	Not given	1 patient – larger blood vessel cut in Versajet group.
Narrative results/ conclusions from the article	'Benefits in the treatment of deep burns' 'More easy to reach desirable plane'	'Easier to reach the desirable plane'	'Versajet is a feasible, simple and safe technique'
Quality	Conference abstract so very little information on study conduct	Conference abstract so very little information on study conduct	No information on randomisation, allocation concealment or blinding of outcome assessment
Conclusions	Conference abstract so results should be treated with caution	Conference abstract so results should be treated with caution	Due to the conduct of the study, results may not be reliable
p, probability; SD, standard deviation; N, number; NS, not statistically significant.			

Table 2. Summary of randomised controlled trials on the Versajet

system for patients with chronic wounds

Study component	Description		
	Caputo 2008	Lantis 2013 (abstract)	Liu 2012 (abstract)
Objective/ hypothesis	Measure debridement time with Versajet vs comparator	Compare bioburden before and after Versajet or sharp debridement	Report clinical and cost effectiveness of Versajet
Setting (country)	Medical centre (USA)	Unclear (USA)	Unclear (USA)
Participants	Lower extremity ulcers Total n=41 19 Versajet (4 women, mean age 68.5, median wound duration 1.2 months) 22 comparator (11 women, mean age 67.6, median wound duration 1.2 months)	Chronic lower leg wounds Total n=14. (numbers in each group not given) Age/sex not given, mean wound duration 13.9 months vs 18.8 months	Chronic wounds Total n=40 21 Versajet, 19 comparator Age/sex/wound characteristics not given
Comparator	Sharp debridement with scalpel plus pulse lavage	Sharp debridement	Conventional debridement with scalpels and electrocautery
Variables	Debridement time, wound closure, adverse events	Bacterial load after debridement	Time to wound closure, bacterial count, first excision time, total excision time, blood loss
Statistical methods	Wilcoxon Rank Sum, Kaplan Maier, Multiple regression,	Unclear	Unclear

Numerical results	Debridement with Versajet significantly quicker (p=0.008). No difference in wound closure time (median 71 days Versajet, 74 days comparator, p=0.73).	Bacterial load – 75% bacteria killed by hydrosurgery compared with 93% killed by sharp debridement (p<0.05)	Versajet – significant improvement for first excision time (p<0.001) and total excision time (p=0.005) No difference in time to wound closure (p=0.77) No difference in bacterial count (p=0.38) Less blood loss (p=0.003) (NB only p values given)
Safety, adverse events	Serious adverse events – 25% patients Versajet, 9.5% comparator (no p value given)	Not given	Not given
Narrative results/ conclusions from the article	'Quicker without compromising wound healing'	'sharp debridement superior for bacterial elimination'	'System did offer advantages'
Quality	Randomisation method not given, treatment allocation revealed 2 days before treatment. Outcome assessment not blinded.	Conference abstract so very little information on study conduct	Conference abstract so very little information on study conduct
Conclusions	Due to the conduct of the study, results may not be reliable	Conference abstract so results should be treated with caution	Conference abstract so results should be treated with caution
p, probability.			

Table 3. Summary of the non-randomised comparative studies on the Versajet system

Study component	Description		
	Granick 2006	Mosti 2006	Scholten 2011 (abstract)
Objective/ hypothesis	Evaluate efficacy, safety and economic impact of Versajet	Report experience with Versajet	Report scar quality with Versajet compared with comparators
Setting (country)	Hospital plastic surgery unit (USA)	Hospital (Italy)	Burn centre in hospital (Netherlands)
Participants	Acute and chronic wounds. n=62 Versajet – 40 (45 wounds) 22 women, mean age 46, 49% chronic wounds comparator – 22 patients (22 wounds) (10 women, mean age 53, 64% chronic wounds)	Chronic leg ulcers, n=469 Versajet – 142, (95 women, mean age 71.3, mean wound duration 55 months) comparator – 327 (222 women, mean age 70.8, mean wound duration 35.9 months)	Burns. Total n=114 (number in each group not given) Age/sex/ wound characteristics not given
Comparator	Sharp debridement	Moist dressings (hydrogel, hydrocolloid)	A, conservative B, guarded knife
Variables	Time to debridement, number of surgical procedures, safety, costs	Pain (VAS), healing rate, and time to obtain clean wound bed, patient satisfaction.	Scar assessment, hypertrophy
Statistical methods	Regression model	None	Unclear

Numerical results	No difference in debridement time (p=0.159) Mean number of surgical procedures less (Versajet 1.18, comparator 1.91 (p=0.002))	Mean time to obtain clean wound bed Versajet 1.3 (SD 0.6), comparator 4.3 (SD 3.9) Healing rate Versajet 82%, comparator 88% Pain (VAS) Versajet 4.3 (SD 1.9), comparator 5.3 (SD 2.1) Patient satisfaction 2.8 (SD 0.1) in both groups	No difference in hypertrophy, (overall results for scar scores not given)
Safety, adverse events	Not given	New necroses after Versajet treatment in 2 patients.	Not given
Narrative results/ Conclusions from the article	'no difference in debridement time'	'reduces the bacterial burden in the wound'	'better result in scar quality' with hydrosurgery
Quality	Historical controls treated by the same surgeon in the previous year. No blinding of outcome assessment.	Unclear as to how patients were chosen for Versajet treatment. No blinding of outcome assessment.	Conference abstract so very little information on study conduct
Conclusion	Due to the conduct of the study, results may not be reliable	Due to the conduct of the study, results may not be reliable	Conference abstract so results should be treated with caution
p, probability; VAS, visual analogue scale; SD, standard deviation; N, number.			

Costs and resource consequences

In a small retrospective cost study with historical controls investigating 45 patients treated

in the USA in 2002–3 it was estimated that the average number of debridement procedures to achieve a healthy wound was 1.2 for the Versajet system and 1.9 for conventional surgical debridement (Granick 2006). In this study the cost of debridement per patient was estimated at $6229 for conventional debridement and $4507 for the Versajet system. These estimates should be treated with considerable caution as there are a number of unexplained issues: the mean cost of the debridement procedure was estimated to be the same for both types of procedure, there were more costs of diagnostic tests and pathology in the conventional procedure arm, and there were no allowances for training in the use of the Versajet system. The increased cost estimates for the operating room and recovery room resource use was more than expected compared with the mean number of debridement procedures in the 2 groups.

A small randomised controlled trial of the Versajet system debridement compared with conventional debridement in the USA in 40 patients (Liu 2012) found no significant difference between the 2 groups in terms of cost of the first operative procedure, cost of surgical procedures during the study, cost of study treatment or cost to achieve stable wound closure.

The Versajet system is being used in the NHS. The manufacturer estimated that 105 centres are currently using the Versajet system on a routine basis (including all of the major burns centres) and a further 20–30 centres are using it less frequently. The majority of use is in burns, and vascular, orthopaedic and podiatry procedures. There is some limited adoption in community settings. No NHS sales information was available.

With regard to future resource consequences of adopting the Versajet II system:

- Other than the need to schedule cases efficiently when and where the device is available for use, there are no anticipated changes to the way current services are organised or delivered.
- There are no additional facilities or technologies needed alongside the Versajet system.
- Staff members need to be trained properly in the use of the Versajet II system because if it is used incorrectly at high settings it can damage viable tissue. It is also possible that bacteria on the wound could be converted into an aerosol that could spread infection.

Strengths and limitations of the evidence

A strength of the evidence is that 6 randomised controlled trials and 3 non-randomised comparative studies were found. Specific features in quality are listed in tables 1–3 (above) and are addressed below. Four of the randomised controlled trials were available in abstract form only, so the quality of these studies cannot be assessed because of lack of information; as a general caution, results from conference abstracts do not always correlate well with the final published results in peer-reviewed articles.

The quality of the 2 fully published randomised controlled trials was poor (randomisation method was not given, treatment allocation was inadequate, outcome assessment was not blinded). Studies like these are unlikely to give unbiased estimates of treatment effects. Also, conclusions drawn from them are unlikely to be useful because they are potentially misleading. There were no sample size calculations given so it was unclear whether the samples were large enough to detect differences in outcomes, even if the quality of the studies had been adequate. Non-randomised comparative studies are even more prone to biases than randomised studies so their results may not be as accurate. However, they had relatively large samples compared with the randomised controlled trials, which is why they were included in the evidence review. Where historical controls were used it was unclear if other aspects of treatment might have changed.

Relevance to NICE guidance programmes

The use of the Versajet II system is not currently planned into any NICE guidance programme.

References

Anniboletti T, Palombo M, Fasciani L et al. (2011) The use of Versajet hydrosurgery: 5 years experience. Burns: 37S:S19

Caputo WJ, Beggs DJ, DeFede JL et al. (2008) A prospective randomized controlled clinical trial comparing hydrosurgery debridement with conventional surgical debridement in lower extremity ulcers. International Wound Journal 5: 288–94

Esposito G, Anniboletti T, Palombo M et al. (2011) Versajet hydrosurgery: our experience in adults and paediatric patients. Burns: 35S:S23

Grannick M, Boykin J, Gamelli R et al. (2006) Towards a common language: surgical wound bed preparation and debridement. Wound Repair and Regeneration: 14: S1–10

Granick MS, Posnett J, Jacoby M, et al. (2006) Efficacy and cost-effectiveness of a high powered parallel waterjet for wound debridement. Wound Repair and Generation 14: 394–7

Gravante G, Delogu D, Esposito G et al. 2007. Versajet hydrosurgery versus classic escharectomy for burn debridement: a prospective randomized trial. Journal of Burn Care Research 28: 720–4

Lantis J, Schwartz J, Avdagic E et al. (2013) Surgical debridement alone does not adequately reduce planktonic bioburden in chronic lower extremity wounds. EWMA: P311

Liebert C (2011) A volunteer evaluation of the functionality and device performance comparing a next generation hydrosurgery system to current hydrosurgery system. Poster. European Burns Association: P114

Liu J, Ko JH, Chukwu C et al. (2012) Comparing the hydrosurgery system to conventional debridement techniques for the treatment of delayed healing wounds: a prospective randomized clinical trial to investigate clinical efficacy and cost-effectiveness. Wound Repair and Regeneration: 20: A30

Martin R, Williams M, Dodd J et al. (2012) A pre-clinical study to determine the relationship between power settings and angle of attack on the efficacy of debridement using Versajet I and II. Poster ISBI: Edinburgh

Mosti G, Mattaliano V (2006) The debridement of chronic leg ulcers by means of a new fluidjet-based device. Wounds 18:227–37

Mosti G, Iabichella ML, Picerni P et al. (2005) The debridement of hard to heal leg ulcers by means of a new debice based on Fluidjet technology. International Wound Journal 2:307–14

Posnett J and Franks PJ (2008) The burden of chronic wounds in the UK. Nursing Times 104: 44–45

Sainsbury DC (2009) Evaluation of the quality and cost-effectiveness of Versajet hydrosurgery. International Wound Journal 6:24–9

Scholten SM, van den Bosch M, Niewenhuis M et al. (2011) Scar quality after surgical treatment of deep dermal burns with hydro-surgery compared to quarded knife, short and long-term outcome. Poster Burns: 37S:S18

Smith F, Dry burgh N, Donaldson J et al. (2011) Debridement for surgical wounds. Cochrane Database of Systematic Reviews issue 5: CD006214

Smith and Nephew Medical Ltd. (2012) VERSAJET™ II Hydrosurgery System. Smith and Nephew. Hull, England

Search strategy and evidence selection

Search strategy

1. Databases were searched from inception to October 2013 using the following keyword: Versajet. The number of citations found are in brackets after each database.

Medline (via OVID) (35), Embase (80), CAB Abstracts (0), Web of Science Science Citation Index (51), Cochrane Library (Systematic reviews (0), HTA (2), DARE (0), NHSEED (0), Central(6). T

These citations were sifted through to find any relevant material, using the inclusion criteria below.

2. The manufacturer responded to a request for publicly available information about the product.

3. The manufacturer's website was thoroughly investigated (Smith & Nephew).

Evidence selection

The inclusion criteria were as follows:

- patients: any adults or children with acute or chronic wounds or burns
- intervention: the Versajet II or Versajet system

- comparator: any
- outcomes: any relevant clinical outcomes, costs
- study design: for effectiveness – any comparative study; for other aspects of the Versajet or Versajet II system – any including case reports, bench tests etc.

List of non-comparative studies for which the full paper was obtained and subsequently excluded from the evidence

Study	Study design
Anon. VersaJet hydrosurgery system (Smith & Nephew Inc) for treatment of burns. (2011) Healthcare Technology Brief Publication. Hayes Inc, Lansdale Pennsylvania	Evidence review (and cost $4000)
Boeckx, WD, Franck D, Zirak C et al. (2009) Meningococcal sepsis skin lesions treated like burn injuries after early arteriolysis to preserve limb viability. Burns 35S: S1–S47	Case series
Budkevich I, Astramirova S, Soshkina V. (2011) Application of hydrosurgical system "Versajet" in the children burn center. Burns 37S: S1–S25	Case series
Cubison, TC, Pape SA, Jeffery SL. (2006) Dermal preservation using the Versajet (R) hydrosurgery system for debridement of paediatric burns. Burns 32: 714–20	Case series
Dillon CK, Lloyd MS, Dzeiwulski P. (2010) Accurate debridement of toxic epidermal necrolysis using Versajet (R). Burns 36: 581–84	Case series
Gravante G, Esposito G, Montone A. (2008). Versajet hydrosurgery in burn wound debridement – Revised. Burns 34: 299	Response to a letter about a previous article
Gravante, G, Esposito G, di Fede MC, D et al. (2007) Versajet hydrosurgery in burn wound debridement: a preliminary experience. Burns 33: 401–2	Editorial with photos
Gurunluoglu R. (2007. Experiences with waterjet hydrosurgery system in wound debridement. World journal of emergency surgery 2: 10	Case series

Jeffery SL. (2007). Versajet hydrosurgery in burn wound debridement: A preliminary experience by Gravante G, Esposito G, Delogu D, Montone A. Burns 33: 207: 401–2. Burns 33: 800.	Letter
Jeffrey S. (2007) "Versajet: Our first 100 cases." Burns 33S: S10.	Case series
Kimble, RM, Mott J, Joethy J. (2008) Versajet ((R)) hydrosurgery system for the debridement of paediatric burns. Burns 34: 297–98	Case series
Klein, MB, Hunter S, Heimbach DM et al. (2005) The Versajet (TM) water dissector: A new tool for tangential excision. Journal of Burn Care & Rehabilitation 26: 483–87.	Case series
Martin R, Allan N, Olson M et al. (2011) The impact of hydrosurgical debridement on wounds containing bacterial biofilms. Burns 37S: S18	Technical evaluation on pigs
McCardle, JE (2006) Versajet hydroscalpel: treatment of diabetic foot ulceration. British journal of nursing 15: S12–7	Case studies
Pascone M, Papa G, Ranieri A (2008). Use of a novel hydrosurgery device in surgical debridement of difficult-to-heal wounds. Wounds-a Compendium of Clinical Research and Practice 20: 139–46	Case series
Pataia, E, Arleo S, Somma F et al. (2010) Use of Biotechnologies in Cutaneous Injuries Limb Repair. European Surgical Research 4	Case series with multiple controls but no comparative results
Rappl, T, Regauer S, Schintler M et al. (2007) The use of versajet in plastic and reconstructive surgery. Burns 33S: S1–S172	Clinical opinion abstract
Rees-Lee, JE, Burge TS, Estela CM (2008) The indications for Versajet hydrosurgical debridement in burns. European Surgical Research 31: 165–70.	Case series
Rennekampff HO, Schaller HE, Wisser D et al.(2006) Debridement of burn wounds with a water jet surgical tool. Burns 32: 64–6	Case series
Tenenhaus M, Bhavsar D, Rennekampff HO. (2007) Treatment of deep partial thickness and indeterminate depth facial burn wounds with water-jet debridement and a biosynthetic dressing. Injury – International Journal of the Care of the Injured 38: S39–S45	Case series

Vanwijck R, Kaba L, Boland S et al (2010) Immediate skin grafting of sub-acute and chronic wounds debrided by hydrosurgery. Journal of Plastic Reconstructive and Aesthetic Surgery 63): 544–49	Case series
Zgonis T, Stapleton JJ (2008). Innovative techniques in preventing and salvaging neurovascular pedicle flaps in reconstructive foot and ankle surgery. Foot & ankle specialist 1: 97–104	Case studies

The best available evidence on the clinical effectiveness of the medical technology is included in a medtech innovation briefing.

During the checks for factual accuracy, it was highlighted that several non-comparative studies on Versajet had not been included in the briefing. These studies were identified in the literature searches but excluded on the grounds that better quality and more relevant evidence was available. The excluded studies are those for which the full articles were retrieved to check whether the study was comparative or not, because the study design was unclear from the title or abstract.

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 Birmingham and Brunel Collaboration External Assessment Centre (EAC). 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.

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