Collection of clinical evidence

VERSAJET◊ Hydrosurgery System*

Evidence in focus
Developed by Evidence Communications, Global Clinical & Medical Affairs

Smith+Nephew
August 2021

*This compendium includes evidence for the VERSAJET Hydrosurgery System and VERSAJET II Hydrosurgery System
VERSAJET™ System indication

The VERSAJET System is intended for wound debridement (acute and chronic wounds, and burns), soft tissue debridement and cleansing of the surgical site in applications that, in the physician’s judgment, require sharp debridement.

The VERSAJET System enables a surgeon to hold, cut and remove damaged tissue and contaminants while simultaneously irrigating a wound using a high velocity stream of sterile saline.¹,² Irrigation fluid from the wound is evacuated into a container, minimising saturation of the debridement area and reducing the risk of splashing and aerosolisation.¹,²

Introduction

The VERSAJET® System has a strong evidence base.

As of March 2021, 87 clinical publications regarding the VERSAJET and VERSAJET II Systems have been identified. This evidence collection contains a summary of the most relevant publications, including those that present data on the key outcomes for the product and present the highest level of evidence (levels 1–3). It does not include all publications due to the volume of studies.

Levels of evidence

- **4**
  - High-quality RCTs, systematic review of level I studies

- **10**
  - Lesser quality RCTs, prospective comparative studies, systematic review of level II studies

- **10**
  - Retrospective comparative studies, systematic review of level III studies

- **31**
  - Case series

- **32**
  - Expert opinion, case studies or bench research (including 4 in vitro and 8 preclinical studies)
### Key studies

**Click on** the arrow by the study name to see the study overview

<table>
<thead>
<tr>
<th>Study</th>
<th>Controlled tissue removal</th>
<th>Impact on bacterial load</th>
<th>Wound bed preparation</th>
<th>Impact on bleeding</th>
<th>Impact on pain</th>
<th>Efficient resource use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edmonson SJ, et al. Burns. 2018</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Kakagia DD, et al. J Burn Care Res. 2018</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Granick MS, et al. Ostomy Wound Manage. 2007</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>James CV, et al. Wounds. 2021</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mosti G, Mattaliano V. Wounds. 2006</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Click here** to see additional studies
Overview

• A systematic literature review comparing VERSAJET® System debridement, ultrasound therapy and plasma-mediated bipolar radio-frequency ablation therapy (COBLATION® Technology) for the management of chronic wounds
• 389 references were identified from MEDLINE, PubMed and Embase published up to January 2016
• A total of 14 studies were selected for inclusion:
  – 7 studies with VERSAJET System (255 patients)
  – 6 studies with ultrasound (296 patients)
  – 2 studies with COBLATION Technology (31 patients)

Results

• Majority of wounds required one procedure with the VERSAJET System (Figure) and with COBLATION Technology; for ultrasound the number of procedures was highly variable ranging from 1–10

Conclusions

The majority of patients treated with the VERSAJET System and COBLATION Technology only required one procedure compared with a variable range for ultrasound.
Overview

- A systematic literature review comparing the VERSAJET® System or NexoBrid™ with conventional debridement for the treatment of acute burns
- 7,148 articles were identified from CENTRAL, PubMed, CINAHL, Embase and clinical trial registries published up to July 2017
- A total of 18 studies were selected for inclusion:
  - 9 studies with the VERSAJET System
  - 9 studies with NexoBrid™

Results

- The VERSAJET System enabled precise excision of burnt skin, maximising dermal preservation (two studies)
- The VERSAJET System was useful to access difficult areas, reducing chance of damage to fragile structures (one study)
- Bacterial load was reduced following debridement with the VERSAJET System compared with baseline (two studies)
- Compared with conventional debridement, use of the VERSAJET System:
  - Reduced the loss of viable dermis
  - Decreased the number of debridement procedures
  - Was potentially cost effective

Conclusions

Use of the VERSAJET System offers comparable outcomes to conventional debridement with benefits of increased dermal preservation, decreased number of debridement procedures and the potential to be cost effective.
The efficacy of Versajet™ hydrosurgery system in burn surgery. A systematic review


Overview
- A systematic literature review to evaluate the efficacy, safety and cost-effectiveness of the VERSAJET® System for the treatment of adult and paediatric burns published between 2005 and October 2016
  - Of 78 studies extracted from MEDLINE and Scopus databases, a total of 20 manuscripts were identified for inclusion

Results
- The VERSAJET System was faster in contoured anatomic regions, and more selective and precise than conventional escharotomy
- Similar quantitative superficial bacterial load reduction was observed compared with pulse lavage
- No significant difference in adequacy of debridement, operative time, quality of healing and infection rates compared with conventional escharotomy
- Possible reduction in hospital stay, nursing time, dressing changes and need for reoperations may counterbalance the cost of the VERSAJET System

Conclusions
The VERSAJET System is safe and efficacious for burn debridement, particularly for contoured regions. In addition, reduced resource use may counterbalance the cost of the VERSAJET System.
Efficacy of Versajet hydrosurgery system in chronic wounds: A systematic review

Overview

• Independent, systematic literature review comparing the VERSAJET® System and VERSAJET® II Hydrosurgery System with conventional debridement in adults and children with chronic wounds, skin ulcers and non-acute wounds
  – Of 497 studies extracted, a total of 7 studies (645 patients) published between 1 January 2000 to 10 August 2020 met the criteria for inclusion

Results

• Compared with conventional debridement, use of the VERSAJET System resulted in:
  – Significantly shorter procedure time (two of three studies; mean difference, -8.87min; p<0.00001; Figure)
  – Similar time to wound closure (two studies) and reduction in bacterial load (one study)
  – Less saline use and blood loss (one study each)
  – Potential cost savings (two of three studies)
• In >70% of cases, one session of use with the VERSAJET System achieved adequate debridement to prepare the wound bed for closure or secondary healing (five studies)
• Pain with use of the VERSAJET System was mild to moderate and tolerable to patients (two studies)

Conclusions

Use of the VERSAJET System significantly reduced mean debridement procedure time compared with conventional debridement in a pooled analysis of two prospective RCTs; adequate wound bed preparation was achieved in a single session for most cases.
Overview

- A prospective, randomised, single-centre study to compare the effect of the VERSAJET® System with conventional sharp debridement plus pulse lavage in patients with lower extremity ulcers
  - VERSAJET System debridement (n=22)
  - Conventional sharp debridement (n=19)
- Wounds were monitored for 12 weeks

Results

- 39% significant relative reduction in mean time to debride wounds with the VERSAJET System versus conventional debridement (p=0.008; Figure)
- Compared with conventional debridement, procedures with the VERSAJET System required trays containing fewer instruments (100 vs 13) and no additional Interpulse device
- Significant reduction in saline use with VERSAJET System compared with conventional debridement (431.6 vs 3,000ml; p<0.001)
- No significant difference in median time to wound closure with the VERSAJET System versus conventional debridement (71 vs 74 days; p=ns)

Conclusions

Debridement with the VERSAJET System was quicker than with conventional debridement, requiring trays containing fewer instruments and less saline for the treatment of lower extremity ulcers.
Comparison of wound irrigation and tangential hydrodissection in bacterial clearance of contaminated wounds: results of a randomized, controlled clinical study


Overview

- RCT conducted at two centres in patients with acute, open, surgical and traumatic wounds, to compare debridement with the VERSAJET® System and pulse lavage
  - VERSAJET System, n=12
  - Pulse lavage, n=9
- Tissue samples were taken centrally from the same location in the wound immediately before and after treatment

Results

- Bacterial counts decreased in wounds debrided by the VERSAJET System and pulse lavage (p=ns; Figure)
- In both groups the absolute bacterial counts decreased by an average of one to two orders of magnitude

Conclusions

Use of both pulse lavage and the VERSAJET System reduced bacterial counts in acute, open, surgical and traumatic wounds.

Overview

- Prospective, randomised trial at a single burn centre, comparing the VERSAJET® System with hand-held dermatome escharectomy for thermal burn debridement
  - VERSAJET System, n=42
  - Dermatome escharotomy, n=45
- After debridement, patients underwent immediate skin grafting where possible

Results

- Adequate wound bed debridement achieved with both techniques
- Similar overall operative times with the VERSAJET System and dermatome escharotomy
  - VERSAJET System was significantly faster for body areas that are difficult to debride, such as hands, face and genitals (13 vs 24mins; p=0.02; Figure)
  - Dermatome escharotomy was significantly faster for large surface areas, such as trunk, arms and legs (21 vs 14mins; p=0.01)
- No significant difference in wound closure time and contracture incidence between the two groups
- Where minor wound bed bleeding occurred with the VERSAJET System, it resolved spontaneously or after electrocautery

Conclusions

The VERSAJET System reduced procedure time for areas that are difficult to debride (eg, hands, face and genitals) versus dermatome escharotomy. The authors noted that the VERSAJET System was simple to use and precise at reaching and maintaining the correct dermal plane.
Prospective, randomised controlled trial comparing Versajet™ hydrosurgery and conventional debridement of partial thickness paediatric burns

Overview

- A single-centre, prospective RCT comparing the VERSAJET® System to conventional debridement for the treatment of partial thickness burns
  - VERSAJET System, n=30 (mean age, 2.2 years)
  - Conventional debridement, n=31 (mean age, 2.9 years)
- All patients were ≤16 years of age

Results

- Median amount of viable dermis lost during debridement was significantly reduced with the VERSAJET System compared with conventional debridement (p=0.02; Figure)
- With the VERSAJET System versus conventional debridement there was no significant difference in:
  - Median duration of surgery (40 vs 35 mins; p=ns)
  - Mean graft take at Day 10 (92 vs 94%; p=ns)
  - Time to healing following grafting (13 vs 13; p=ns)
  - Post-operative wound infection (30 vs 23%; p=ns)
- Scarring at 3 and 6 months (p=ns)

Conclusions

Use of the VERSAJET System is a precise method for burn wound debridement, significantly reducing the loss of viable dermis compared with conventional debridement.

Figure. Median amount of viable dermis lost with conventional and VERSAJET System debridement

Comparing the hydrosurgery system to conventional debridement techniques for the treatment of delayed healing wounds: a prospective, randomised clinical trial to investigate clinical efficacy and cost-effectiveness

Overview
- Single-centre, prospective RCT comparing the efficacy and cost-effectiveness of the VERSAJET® System with conventional surgical debridement
  - VERSAJET System, n=21
  - Conventional debridement, n=19
- Patients had delayed healing traumatic wounds or chronic cutaneous defects of ≥30 days duration or a delayed healing dehisced incision that required excision and closure

Results
- Mean total excision time was more than twice as fast with the VERSAJET System than with conventional debridement (14.2 vs 33.9 mins; p=0.033)
- Maximum blood loss for overall excision procedures was significantly lower with the VERSAJET System compared with conventional debridement (p=0.003; Figure)
  - Less blood loss was also observed with the VERSAJET System during the first excision procedure
- Median log_{10} total bacterial count was reduced from baseline by 20% following treatment with VERSAJET System debridement (4.0 vs 3.2 cfu/g; p=ns) and 17.5% with conventional debridement (4.0 vs 3.3 cfu/g; p=ns)
- No significant difference was identified between the groups in, achievement of, and time and cost to achieve stable wound closure (p=ns)

Conclusions
Use of the VERSAJET System enabled significantly faster debridement and reduced blood loss compared with conventional debridement for the treatment of delayed healing and chronic wounds.

Comparison of standard surgical debridement versus the VERSAJET Plus™ Hydrosurgery system in the treatment of open tibia fractures: a prospective open label randomized controlled trial

Overview

- Prospective RCT comparing the VERSAJET System with standard surgical debridement for open tibia fractures
  - VERSAJET System, n=16
  - Standard surgical debridement, n=24

Results

- Significantly fewer debridement procedures required prior to wound closure with the VERSAJET System compared with standard surgical debridement (p<0.001; Figure)
- Non-significant reduction in median days to closure with the VERSAJET System versus standard surgical debridement (3 vs 5 days; p=ns)
- No significant difference in the number of operating room procedures required for wound closure (p=ns)

Conclusions

With the VERSAJET System, significantly fewer debridement procedures were required prior to wound closure compared with standard surgical debridement for patients with open tibia fractures.
Overview

- Single-centre, prospective cohort study of patients with skin injuries undergoing debridement with the VERSAJET® System before skin or Integra graft (n=27)
- 100 bacteriological swabs were taken, 50 prior to and 50 following debridement with the VERSAJET System
- Correlation between bacterial load and positive or negative result of graft take or integration was investigated

Results

- The most common bacteria in the pre-treatment swabs were: Staphylococcus aureus (21 swabs), Pseudomonas aeruginosa (15 swabs), Proteus mirabilis (8 swabs) and Gram positive polymicrobial flora (GPPF; 6 swabs); 8 swabs did not contain bacteria
- The most common bacteria in the post-treatment swabs were: S. aureus (17 swabs), P. aeruginosa (7 swabs) and P. mirabilis (8 swabs) and GPPF (8 swabs); 12 swabs did not contain bacteria
- 50% of analysed bacterial swabs showed a reduction in bacterial load of the wound, 17% showed an increased bacterial load and 33% showed no change following debridement with the VERSAJET System
- Following treatment with the VERSAJET System, results of skin graft take were as follows:
  - With increased bacterial load: 3 positive, 1 negative
  - With bacterial load unchanged: 5 positive, 3 negative
  - With decreased bacterial load: 5 positive, 7 negative

Conclusions

Use of the VERSAJET System helped to reduce bacterial load compared with baseline in half of the wounds assessed. The authors noted that reducing bacterial load is not the only variable involved in successful healing of the skin graft.
Efficacy and cost-effectiveness of a high-powered parallel waterjet for wound debridement


Overview
- Retrospective, single-centre study to compare the efficacy and cost-effectiveness of the VERSAJET® System with conventional surgical debridement for acute and chronic wounds
  - VERSAJET System debridement, \( n=40; 45 \) wounds
  - Conventional surgical debridement \( n=22; 22 \) wounds
- Median wound area was significantly larger in the surgical debridement group compared with the VERSAJET System group \( 213 \) vs \( 88 \text{cm}^2; p=0.016 \)

Results
- Significantly fewer mean debridement procedures with the VERSAJET System compared with surgical debridement \( p=0.0002; \) Figure
  - The result was not affected by patient age or wound area
- Similar debridement times with the VERSAJET System and surgical debridement \( p=\text{ns} \)
  - Pooled mean time for any debridement procedure was 65mins per procedure
- Estimated net cost savings per patient were $1,900 with the VERSAJET System compared with surgical debridement (based on 2002/3 cost-to-charge ratios)

Conclusions
Use of the VERSAJET System resulted in fewer debridement procedures per wound compared with surgical debridement and estimated potential cost savings.
Hydrosurgical debridement use associated with decreased surgical site-related readmissions: A retrospective analysis

Overview

- Independent, retrospective, single-centre review of patients who underwent debridement of lower extremity wounds
- Chart review was undertaken for 289 patients; 190 had undergone one of three mechanical debridement methods in the operating theatre:
  - VERSAJET II System (n=41)
  - Sharp debridement (with scalpel/scissors; n=132)
  - Sharp debridement and pulse irrigation (n=17)

Results

- Of the 190 patients who underwent debridement, 40 (21%) had an unplanned readmission due to a wound-related complication within 30 days of discharge
- Use of the VERSAJET II System had a significant beneficial effect on unplanned readmissions due to SSIs compared with sharp debridement, with or without pulse irrigation (p=0.0033; Figure)
- Use of the VERSAJET II System helped to reduce the odds of unplanned readmission due to SSIs by 69% (OR: 0.31; 95% confidence intervals, 0.142–0.677)

Conclusions

Use of the VERSAJET II System to debride lower extremity wounds helped to significantly reduce the odds of readmission for SSIs compared with sharp debridement. The authors suggest this may be due to superior debridement of wounds with irregular contours and that fewer readmissions may potentially help to reduce wound care costs.
Overview

- Retrospective cohort study of patients admitted to three burns centres, data were collected using the Dutch Burn Repository R3
- Patients (59.5% males; median age, 41 years) with burns of median 5% TBSA received debridement using:
  - VERSAJET® System alone, n=506
  - Standard debridement alone, n=1,008
  - Both, n=599

Results

- Younger age, scalds, larger TBSA burned and head/neck and arm burns were significant independent predictors of VERSAJET System use
  - For burns of one region, the VERSAJET System alone was most commonly used for debridement of the neck, scalp and genitals
- Median TBSA excised was greater in both groups where the VERSAJET System was used versus standard debridement alone (Figure)
- Compared with standard debridement alone, patients treated with the VERSAJET System alone:
  - Received dermal substitutes significantly less frequently (1.5 vs 0.2%; p=0.021)
  - Had a significantly smaller mean volume of blood transfusion (156.0 vs 57.2ml; p=0.036)
  - Underwent significantly fewer surgical procedures (mean 1.4 vs 1.2; p=0.019)
  - Had significantly fewer wound infections (3.8 vs 1.6%; p=0.019)

Conclusions

The VERSAJET System is a useful tool for burn wound debridement prior to skin grafting and is often used in combination with standard debridement. Predictors for VERSAJET System use are young age, scalds, high TBSA burned and burn sites with irregular (convex) contours.
The debridement of hard to heal leg ulcers by means of a new device based on Fluidjet technology


Overview

• Single-centre, observational study to compare the effect of the VERSAJET® System with traditional debridement (moist dressings) in patients with hard to heal vascular leg ulcers
  – VERSAJET System debridement, (n=68; 118 ulcers)
  – Moist dressings (n=99; 159 ulcers)
• Almost all procedures were performed on the ward at the patient's bedside

Results

• Adequate wound debridement, suitable for skin graft, was achieved in a single procedure using the VERSAJET System in 46 patients (68%)
• Use of the VERSAJET System substantially reduced the wound bacterial burden from \(10^6\) to \(10^3\) in 43% of patients (n=9/21)
• Reduced mean time to complete ulcer debridement by 4.7 days with the VERSAJET System versus moist dressings (Figure)
  – Consequently, hospital length of stay was also reduced
• Pain during VERSAJET System procedures was acceptable to the majority of patients after adjustment of the power level

Conclusions

Use of the VERSAJET System typically achieved complete ulcer debridement in a single procedure and reduced length of hospital stay compared with moist dressings.
The debridement of chronic leg ulcers by means of a new, fluidjet-based device

Overview

• Single-centre study to compare debridement using the VERSAJET® System with the use of moist dressings for chronic vascular leg ulcers
  – VERSAJET System, n=142 (245 ulcers)
  – Moist dressings, n=327 (532 ulcers)
• Mean ulcer area and duration were 192cm² and 55 months, respectively, for wounds treated with the VERSAJET System compared with 140cm² and 36 months for those treated with moist dressings
• Most procedures were performed on the ward according to the patient and ulcer conditions

Results

• One VERSAJET System procedure was sufficient for debridement of the wound bed in 76.1% of patients
• Mean time to complete ulcer debridement was shorter with the VERSAJET System than with moist dressings (Figure)
  – Hospitalisation time was reduced accordingly
• Bacterial burden was reduced from 10⁶ to 10³ cfu/cm² in 53 VERSAJET System patients who had clinical signs of infection
• Mean VAS pain score was 4.3±1.9 with the VERSAJET System in the 123 patients who did not receive general anaesthesia and 5.3 with moist dressings (no patients received general or local anaesthetic)
• Patient satisfaction score was 2.8 out of 3 in each group

Conclusions

The VERSAJET System provided quicker debridement than treatment with moist dressings in patients with chronic leg ulcers. The VERSAJET System also reduced bacterial burden in patients with clinical signs of infection and length of hospital stay.
Surgical debridement alone does not adequately reduce planktonic bioburden in chronic lower extremity wounds

Overview

- Single-centre, prospective pilot study of patients requiring rapid closure of critically colonised lower extremity ulcers undergoing debridement with the VERSAJET® System or sharp debridement with pulse irrigation
  - VERSAJET System debridement (n=7)
  - Sharp debridement + pulse irrigation (n=4)
  - Both (n=1)
- All debridement was conducted until healthy bleeding granulation tissue was revealed
- Tissue biopsies were taken before and after debridement

Results

- Two surgeons observed that the VERSAJET System removed necrotic, non-viable, fibrinous tissue without harming healthy granulating tissue in close proximity
  - The VERSAJET System was useful for superficial wounds or wounds with a fine fibrinous coating in areas requiring precise debridement to minimise deep tissue damage
  - Sharp debridement outperformed where wounds required more extensive debridement, had eschar or fibrous components, or where deeper structures required evaluation
- The total bacteria reduction was $7.5 \times 10^6$ cfu/g following VERSAJET System debridement compared with $1.3 \times 10^7$ cfu/g after sharp debridement (p=ns)

Conclusions

Two surgeons observed that debridement with the VERSAJET System adequately removed necrotic, non-viable, fibrinous tissue. It was most beneficial for wounds requiring precise debridement with minimisation of deep tissue damage.
### Additional supporting studies (Levels 4 and 5)

<table>
<thead>
<tr>
<th>Study</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cubison TCS, Pape SA, Jeffrey SLA.</strong> Burns. 2006;32(6):714–720.</td>
<td>Dermal preservation using the Versajet hydrosurgery system for debridement of paediatric burns</td>
</tr>
<tr>
<td><strong>McCann MS.</strong> Poster presented at Wounds UK; November 12–14, 2007; Harrogate, UK.</td>
<td>Time to start putting down the knife: A systematic review of burns excision tools of randomised and non-randomised trials</td>
</tr>
</tbody>
</table>