MOH/P/PAK/490.22(TR)-e

TECHNOLOGY REVIEW (MINI-HTA)

VERSAJET HYDROSURGERY SYSTEM FOR WOUND DEBRIDEMENT: AN UPDATE

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
011/2021

IPT Mark
INAHTA
Mini-HTA

DISCLAIMER
This technology review (mini-HTA) is prepared to assist health care decision-makers and health care professionals in making well-informed decisions related to the use of health technology in health care system, which draws on restricted review from analysis of best pertinent literature available at the time of development. This technology review has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Other relevant scientific findings may have been reported since the completion of this technology review. MaHTAS is not responsible for any errors, injury, loss or damage arising or relating to the use (or misuse) of any information, statement or content of this document or any of the source materials.

Please contact htamalaysia@moh.gov.my if further information is required.

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590, Putrajaya
Tel: 603 8883 1229

Available online via the official Ministry of Health Malaysia website: http://www.moh.gov.my

e-ISBN:978-967-2887-39-3

SUGGESTED CITATION: Fatin NM and Izzuna MMG. VersaJet Hydrosurgery System for Wound Debridement: an Update. Technology Review. Ministry of Health Malaysia: Malaysian Health Technology Assessment Section (MaHTAS); 2021. 33 p. Report No.: 007/2021. e-ISBN: 978-967-2887-39-3

DISCLOSURE: The author of this report has no competing interest in this subject and the preparation of this report is entirely funded by the Ministry of Health Malaysia.

AUTHOR

Fatin Nabila Mokhtar
Research Officer
Assistant Director
Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

REVIEWER

Dr. Izzuna Mudla Mohamed Ghazali
Public Health Physician
Deputy Director
Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

EXTERNAL REVIEWER

Prof. Dr. Harikrishna K. R. Nair
Head and Consultant Wound Care Unit
Internal Medicine Department
Hospital Kuala Lumpur
Ministry of Health Malaysia

EXECUTIVE SUMMARY

Introduction

The presence of necrotic or infected tissue in a wound (including diabetic wound) creates a significant barrier to healing. According to National Diabetes Registry Report 2013-2019, the proportion of patients with diabetic foot ulcers remained static at 1.2% to 1.3% over the six years. If an unintended consequence of surgical debridement was performed, this might have a significant impact on clinical outcomes because the greater the excision of healthy tissue, the worse the resulting scar or tissue function might be. Removal of healthy tissue more than necessary may also lead to greater blood loss compared with precise removal of necrotic tissue alone.

There are several types of conventional techniques of debridement that can achieve removal of devitalised tissue. The autolytic debridement is a natural process by which endogenous phagocytic cells and proteolytic enzymes break down necrotic tissue. However, this technique is a slow process, similarly as the enzymatic debridement. The enzymatic debridement is a selective technique using an exogeneous proteolytic enzyme, collagenase, to debride *Clostridium* bacteria. Nevertheless, this technique is not recommended for an advanced process. In contrast, the mechanical debridement is a nonselective technique but has possibility to cause infection where water baths are used. As for the biological debridement, this technique uses sterile larvae on the necrotic tissue. The sterile medical grade maggots however are hard to be found. Lastly, the use of sharp instruments in surgical debridement has high potential to cause bleeding and complications due to anesthesia.

Hydrosurgery technique for debridement

In the last decades, hydrosurgery has become available as an alternative technique for tangential excision alongside the golden standard of conventional tangential excision by guarded knives. The hydrosurgery debridement is a technique that removes tissue tangentially from the wound surface. Intrinsically, it may be capable of preserving more viable tissue than conventional surgical debridement and perhaps lead to less operative bleeding.

In term of local practice in Malaysia, the hydrosurgery technique for wound debridement is being practised in public and private health facilities. For instance, the Orthopedics and Traumatology department, Plastic and Reconstructive Surgery department, and Wound Care Unit in Hospital Kuala Lumpur utilise this system as one of the debridement techniques.

VersaJet™ hydrosurgery system

The VersaJet™ hydrosurgery was developed in 1997 for the purpose of debriding many types of wounds, including burns prior to skin grafting. The original system was superseded by the VersaJet II™ (Smith and Nephew) hydrosurgery system in 2011. This system uses a high-pressure jet of sterile normal saline to debride wounds, drawing tissue debris and fluid into a chamber via the Venturi effect created by the normal saline jet. However, the actual benefit of VersaJet™ is uncertained. Thus, this technology review was requested by the Orthopaedic Department, Hospital Kajang, to

provide an update on the best available evidence related to the VersaJet™ hydrosurgery system for debridement.

Objective/aim
To evaluate the efficacy, safety, cost-effectiveness and organisational issue related to VersaJet™ hydrosurgery system for debridement.

Results and conclusions
A total of 943 titles were retrieved. After removing duplicates, applying inclusion and exclusion criteria, finally eight studies were included in this review. Out of eight studies included, there were three randomised controlled trials, one cohort study, two case series, one case study and one experimental study

There was substantial evidence on VersaJet™ hydrosurgery system for debridement. However, some studies have high risk of bias due to inappropriate randomisation sequence generation and selective measurement of the outcome, hence varying the quality of the included trials. Nevertheless, the evidence showed that VersaJet™ may reduce the healing and operative time to treatment, improve quality of scar or dermal plane efficacy, and optimise the need for grafting.

As per safety, the VersaJet™ hydrosurgery system may reduce the blood loss and transfusion, and decrease the infection rate. Even though there was one serious adverse event and some mild or moderate adverse events were reported, none of them were related to VersaJet™ hydrosurgery system. The latest version of VersaJet™ hydrosurgery system had received 510(k) from United States Food and Drug Administration and was Conformité Européenne (CE) marked in 2011 before launched in 2012. The hydrosurgery system also had been approved by Medical Device Authority Malaysia in 2018.

There was no significant difference between the two 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. Approximately, the price for one set of the latest version of VersaJet™ hydrosurgery system was [redacted] (United States Dollars).

Methods
Electronic databases were searched through the Ovid interface; Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to 13 August 2021, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to August 13, 2021, Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations 1946 to August 13, 2021, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 2017 to August 13, 2021, Ovid MEDLINE(R) 1946 to August Week 1 2021, Ovid MEDLINE(R) 1996 to August Week 1 2021, Ovid MEDLINE(R) Epub Ahead of Print August 13, 2021, Ovid MEDLINE(R) Daily Update August 13, 2021 and Ovid MEDLINE(R) 2017 to August Week 1 2021. Searches were also run in PubMed, INAHTA, Cochrane Library and US Food and Drug Administration. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 20 August 2021.

TABLE OF CONTENTS

ABBREVIATIONS

CASP	**Critical Appraisal Skills Programme**
CE	**Conformité Européenne**
NICE	**National Institute for Health and Care Excellence**
ROB	**Risk of Bias**

1.0 BACKGROUND

The presence of necrotic or infected tissue in a wound (including diabetic wound) creates a significant barrier to healing.[1] According to National Diabetes Registry Report 2013-2019, the proportion of patients with diabetic foot ulcers remained static at 1.2% to 1.3% over the six years.[2] If an unintended consequence of surgical debridement was performed, this might have a significant impact on clinical outcomes because the greater the excision of healthy tissue, the worse the resulting scar or tissue function might be.[3-5] Removal of healthy tissue more than necessary may also lead to greater blood loss compared with precise removal of necrotic tissue alone.[6,] level III

1.1 Technique of debridement

Table 1 shows several types of the debridement that can achieve removal of devitalised tissue.

Table 1: Conventional techniques of debridement.

Techniques	Description	Disadvantages
Autolytic	This is the most conservative type of debridement. This type of debridement is a natural process by which endogenous phagocytic cells and proteolytic enzymes break down necrotic tissue. It is a highly selective process whereby only necrotic tissue will be affected in the debridement.[7]	May be slow to achieve debridement.[8]
Biological	This is also known as larval therapy, uses sterile larvae of the *Lucilia sericata* species of the green bottle fly. It is an effective mode of debridement, particularly appropriate in large wounds where a painless removal of necrotic tissue is needed. The mechanism of action of mega therapy/debridement consists mainly of the release of proteolytic enzymes containing secretions and excretions that dissolve necrotic tissue from the wound bed.[7]	Low availability of sterile medical grade maggots.[8]
Enzymatic	This is a selective method for debridement of necrotic tissue using an exogenous proteolytic enzyme, collagenase, to debride *Clostridium* bacteria. Collagenase digests the collagen in the necrotic tissue allowing it to detach.[7]	A slow method and not recommended for an advanced process, or in patients with known sensitivity to the product's ingredients.[7]
Surgical/ Sharp	This is a type of debridement where devitalised tissue (slough, necrotic, or eschar) in the presence of underlying infection is removed using sharp instruments such as a scalpel, Metzenbaum, curettes, among others. This can be done bedside, in the office or wound care center, or in the operating room depending on the adequacy of anesthesia and the ability to control perioperative complications like bleeding.[7]	High potential to cause bleeding and possible general complications from the anesthesia.[7]
Mechanical	Mechanical debridement is a nonselective type of debridement, meaning that it will remove both devitalized tissue and debris as well as viable tissue. It is usually carried using mechanical force: wet-to-dry, pulsatile lavage, or wound irrigation.[7]	Possible infection risks where water baths are used.[8]

1.2 Hydrosurgery technique for debridement

In the last decades, hydrosurgery has become available as an alternative technique for tangential excision alongside the golden standard of conventional tangential excision by guarded knives.[9, level II-2] The hydrosurgery debridement is a technique that removes tissue tangentially from the wound surface. Intrinsically, it may be capable of preserving more viable tissue than conventional surgical debridement and perhaps lead to less operative bleeding.[; 10, level III; 11]

Globally, there are three major players in hydrosurgery system markets, which are HydroCision, Erbe Elektromedizin and Smith and Nephew. However, HydroCision has developed three applications of its hydrosurgery technology - the ExoJet Tissue Management System which is for arthroscopic joint surgery and has been licensed to DePuy Mitek, a Johnson & Johnson company; the SpineJet® Hydrosurgery System; and the **VersaJet™ Hydrosurgery system that focuses on wound debridement**, which has been licensed to Smith and Nephew Wound Management.[12]

In terms of local practice in Malaysia, the hydrosurgery technique for wound debridement is being practised in public and private health facilities. For instance, the Orthopedics and Traumatology department, Plastic and Reconstructive Surgery department, and Wound Care Unit in Hospital Kuala Lumpur utilise this system as one of the debridement techniques.[22]

1.3 VersaJet™ hydrosurgery system

The VersaJet™ hydrosurgery was developed in 1997 for the purpose of debriding many types of wounds, including burns prior to skin grafting.[14,15] The original system was superseded by the VersaJet II™ (Smith and Nephew) hydrosurgery system in 2011.[15] This system uses a high-pressure jet of sterile normal saline to debride wounds, drawing tissue debris and fluid into a chamber via the Venturi effect created by the normal saline jet **(see Figure 1)**.[14; 16-18; 21, level III] VersaJet™ has also been linked with a reduced number of surgical debridements to achieve a clean wound bed,[11,19,20] earlier or immediate surgical closure after debridement of contaminated wounds,[20] and potential reductions in hospital stay.[19] When used on concave and convex wound surfaces, VersaJet™ has proved to be a faster technique than conventional surgery.[18]

Figure 1: VersaJet™ debridement of hand.[21]

This technology review was requested by the Orthopaedic Department, Hospital Kajang, to provide an update on the best available evidence related to the VersaJet™ hydrosurgery system for debridement.

2.0 OBJECTIVE/ AIM

To evaluate the efficacy, safety, cost-effectiveness and organisational issue related to VersaJet™ hydrosurgery system for debridement.

3.0 TECHNICAL FEATURES

(a) **(b)**

Figure 2: A complete component of VersaJet™ hydrosurgery system. a) An earlier version of debridement system. b) A modification of an earlier version; VersaJet™ II hydrosurgery system was registered in 2011.[22]

The single-use, 45 degree angled of VersaJet™ hydrosurgery system handpiece is attached to a console which is then operated by a foot pedal.[16,17] Normal saline executes a 180-degree turn in the handpiece and is forced out of a narrow nozzle. This focused jet-stream passes parallel to the wound and is captured by an evacuator port which is located eight or 14 mm from the nozzle. This jet of pressurised normal saline functions like a knife and the handpiece allows debridement and aspirations of debris to occur simultaneously.[24] Pressure can be adjusted between 1,787 psi (12.3 MPa) and 11,535 psi (79.5 MPa) to facilitate the desired path of debridement.[23,24]

According to National Institute for Health and Care Excellence (NICE), the limited information found on the differences between VersaJet™ and VersaJet II™ hydrosurgery system suggests that the application for VersaJet™ is likely to apply to VersaJet II ™. [15] **(see Figure 2).**

4.0 METHODS

4.1 Searching

Electronic databases were searched through the Ovid interface:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to 13 August 2021
- Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to August 13, 2021
- Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations 1946 to August 13, 2021
- Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 2017 to August 13, 2021
- Ovid MEDLINE(R) 1946 to August Week 1 2021
- Ovid MEDLINE(R) 1996 to August Week 1 2021
- Ovid MEDLINE(R) Epub Ahead of Print August 13, 2021
- Ovid MEDLINE(R) Daily Update August 13, 2021
- Ovid MEDLINE(R) 2017 to August Week 1 2021

Searches were also run in PubMed, INAHTA, Cochrane Library and US Food and Drug Administration. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 20 August 2021. Appendix 1 shows the detailed search strategies.

4.2 Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria

Population	Debridement
Interventions	VersaJet™ hydrosurgery system, water jet surgery
Comparators	Conventional techniques
Outcomes	**Efficacy** Primary outcome: Healing time, operative time Secondary outcome: Scar quality assessment/ efficacy in dermal plane, need for grafting **Safety:** Blood loss, blood transfusion, infection rate
Study design	Health Technology Assessment (HTA) reports, Systematic Review (SR) and Meta-Analysis, Randomised Control Trial (RCT), Non-randomised Control Trial (RCT), cohort studies, cross-sectional studies, case studies
Type of publication	English, full text articles

Exclusion criteria

Study design	Studies conducted in animals, narrative reviews
Type of publication	Non-English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence graded according to the US/Canadian Preventive Services Task Force (See **Appendix 2**). Data were extracted from included studies using a pre-designed data extraction form (evidence table as shown in **Appendix 3**) and presented in tabulated format with narrative summaries. No meta-analysis was conducted for this review.

5.0 RESULTS

5.1 Selection of the included studies

A total of 943 titles were retrieved. After removing duplicates, applying inclusion and exclusion criteria, finally eight studies were included in this review. Out of eight studies included, there were three randomised controlled trials, one cohort study, two case series, one case study and one experimental study as shown in **Figure 3**. The studies included were conducted in South Africa, United States, Australia, Netherlands, Japan and France.

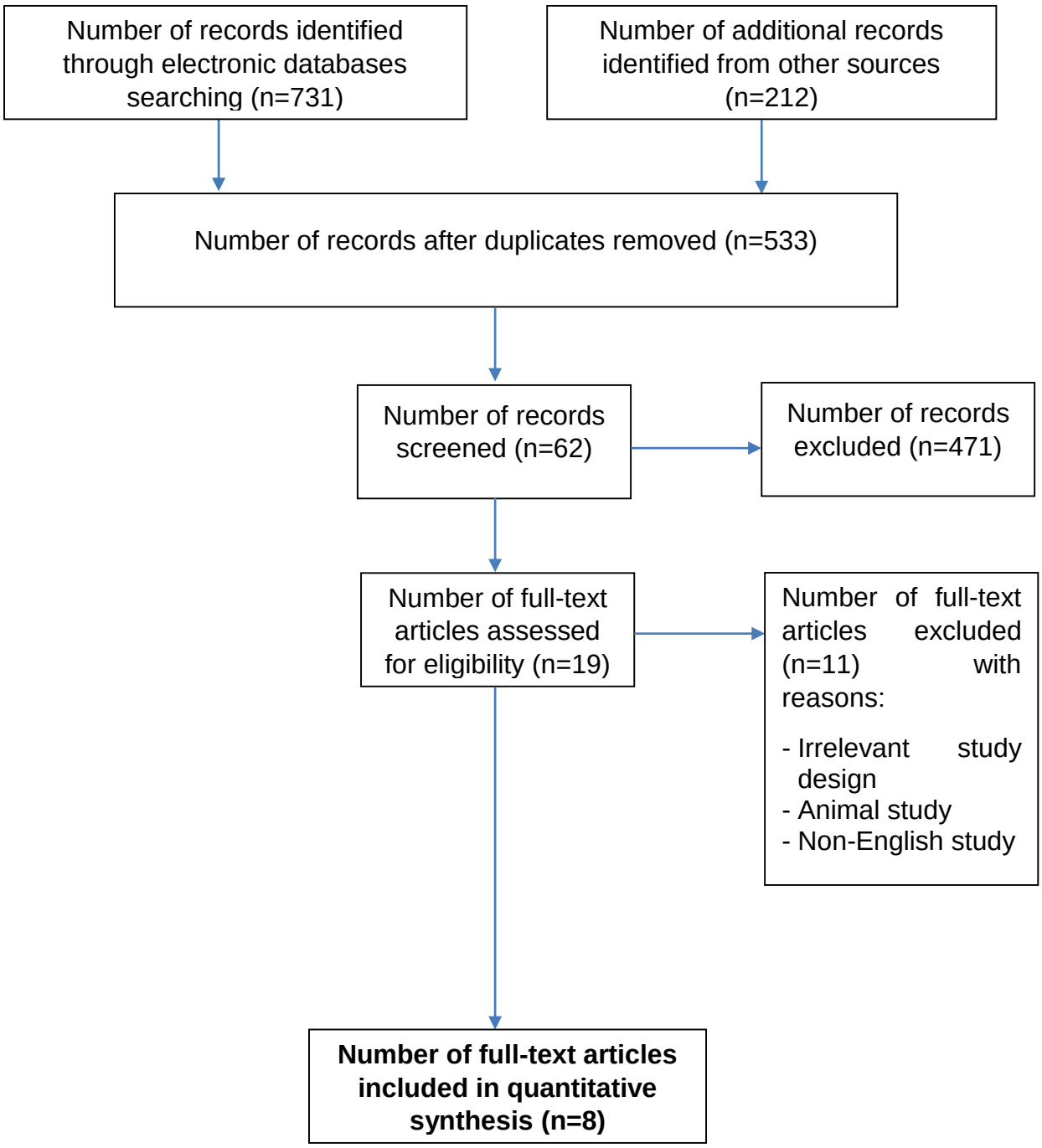

Figure 3: Flow chart of study selection

5.2 Critical appraisal of the included studies

The risk of bias assessment for randomised controlled trial was assessed using Cochrane Risk of Bias Assessment tool (ROB 2.0). Risk of bias assessment of the included study is summarised according to the study design as below. The signalling questions for domain 4 (D4) showed high and some concerns on outcomes measurement. These were due to inappropriate method of measuring the outcome when the measurement or ascertainment of the outcome could have differed between the intervention groups; the outcome assessors were aware of the intervention received by study participants; the assessment of the outcome could have been influenced by knowledge of the intervention received; and it was likely that assessment of the outcome was influenced by knowledge of the intervention received.

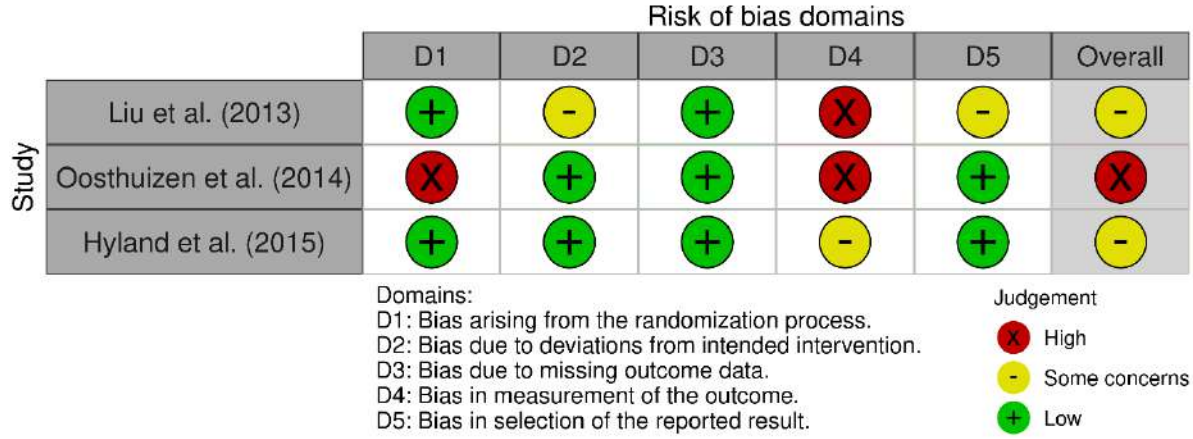

Figure 4a: Assessment of risk of bias of randomised controlled trial (Cochrane ROB 2.0 reference: Traffic Light Plot)

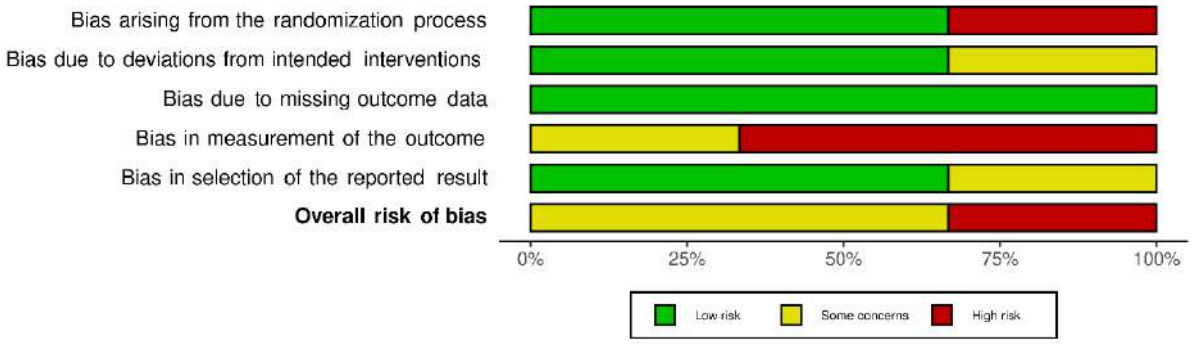

Figure 4b: Assessment of risk of bias of randomised controlled trial (Cochrane ROB 2.0 reference: Summary Plot)

5.3 Efficacy/ Effectiveness

There were eight studies reported on efficacy of VersaJet™ hydrosurgery system for debridement, of which three randomised controlled trials, one cohort study, two case series, one case study and one experimental study. The healing time and operative time were considered as the primary outcomes. Secondary outcomes included scar quality assessment/ efficacy in dermal plane and need for grafting. (Please refer **Table 4** to see the summarised outcomes).

5.3.1 Primary Outcome: Healing Time

Hyland EJ et al. (2015) conducted a **prospective, randomised controlled trial** to compare conventional tangential burn wound debridement with VersaJet™ in children with partial thickness burns. All subjects underwent standard general anaesthesia and received anti-septic povidone–iodine operative site preparation prior to sterile draping. A two-mm punch biopsy was then taken at the site of the unhealed partial thickness burn to be grafted. Thirty-one subjects were then randomised into receiving debridement using the Versajet II™ hydrosurgical system and 30 subjects into the conventional tangential burn wound debridement using a Goulian knife with six to eight thousandths of an inch. All 61 subjects were followed up for six months. The trial however, showed no significant difference between time to healing after-skin grafting (p=0.6) or time to healing after-burn (p=0.2).[25, level I]

Another **prospective, randomised controlled trial** by Liu J et al. (2013) was conducted to assess clinical efficacy and cost-effectiveness when treating subjects with chronic wounds. Forty evaluable subjects were recruited for the primary investigation on the time to closure of delayed healing dehisced incisions and traumatic or chronic cutaneous defects. The first subject was recruited on November 2007 and the last subject completed the study on September 2011. The study protocol received approval from the Institutional Review Boards at Northwestern University. Nineteen subjects were randomised to undergo the conventional treatment, other 21 subjects underwent debridement using VersaJet™ hydrosurgery system. The study reported that, nine (42.9%) subjects in the VersaJet™ hydrosurgery group achieved stable wound closure during the study period compared with seven (26.8%) in the conventional group. However, there was no difference in time to achieve stable wound closure between the treatment groups (p=0·77).[26, level I]

Matsumura H et al. (2012) conducted **a case series** to determine the proportion of wounds that had been appropriately debrided. The study was conducted in six surgical centres between June 2008 and June 2009. Forty-seven patients with history of healing failure, older than 16 years, with a burn, dehisced wound, skin or pressure ulcer, contused wound, or traumatic skin loss requiring debridement were included. Each patient underwent debridement using the VersaJet™ hydrosurgery system with a 45 degree/ 8 mm and/or a 45 degree/ 14 mm handpiece. Power settings on the one to 10 scale were at the discretion of the investigator. Wound assessment and photography were carried out before and immediately after the debridement procedure. Wound dimensions were measured using computerised planimetry of wound tracings to assess area and a graduated probe to assess depth. All patients were then followed up for 15 days. The study reported that 12 patients' wounds were

allowed to heal by secondary intention. Of these wounds, 6 (46.2%) were closed at day 15.[6, level III]

Other **case series** was conducted by Tortella BJ et al. (2014) to study the efficacy of VersaJet™ hydrosurgery system in treating wounds. Twenty-five patients included in the study ranged in age from 18 years to 79 years and presented with a myriad of wounds. Specifically, the VersaJet™ hydrosurgery system was used to treat traumatic wounds and burns, to resect necrotic muscle, and to debride decubitus pressure ulcers. The study showed that, the length of the VersaJet™ handpiece permitted the surgeon to access the entire compartment without the need to enlarge the initial wound, sparing the patient increased morbidity and prolonged wound healing.[27, level III]

5.3.2 Primary Outcome: Operative Time

Oosthuizen B et al. (2014) conducted **a prospective, open label, randomised controlled trial** to assess the efficacy of an alternative debridement technology in the treatment of Gustilo & Anderson grade III A and III B open tibia fractures. A total of 40 patients were recruited and randomised into VersaJet™ hydrosurgery (16 patients) and standard surgical debridement (24 patients). Sharp incision with a scalpel was used to extend the wound where necessary and to create linear edges in both groups. The final definition of the Gustilo & Anderson classification was made in the operating room after the debridement (IIIA adequate soft tissue; IIIB soft tissue defect). VersaJet™ hydrosurgery was used on the soft tissues in both proximal and distal soft tissue injuries and to clear the bone ends as thoroughly as possible, after the medullary canal was debrided with a Volkman spoon in order to get any debris out that entered the wound at the moment of injury. Following assessment, debridement and closure or debridement and application of further gauze dressings was performed using either VersaJet™ or standard surgical techniques as appropriate for each group.[28, level I]

The study showed that, there was significant evidence ($p<0.001$) that VersaJet™ patients required fewer debridement procedures than standard surgical debridement prior to wound closure.[28, level I] Due to the simultaneous performance of three parts of standard debridement (initial gross debridement, lavage and final sharp debridement), the operative time of VersaJet™ hydrosurgery system was decreased. This was a critical advantage for the unstable patient during the intervention.[27, level III] However, Hyland EJ et al. (2015) in the **randomised controlled trial** reported that, no significant difference between the duration of surgery (excluding anaesthetic time) between the VersaJet™ hydrosurgery (median 40 min) and conventional groups (median 35 min; $p=0.6$).[25, level I]

5.3.3 Secondary Outcome: Scar Quality Assessment/ Efficacy in Dermal Plane

Duteille F et al. (2012) conducted a **prospective, case series** to validate the efficacy of VersaJet™ hydrosurgery system and to define its role in the therapeutic arsenal with respect to intermediate second-degree burns. Twenty patients with second-degree intermediary burns, need to be hospitalised in the burns unit and have 10% body surface area minimum affected were included. Each burn was evaluated by at least two senior physicians within 48 hours after the initial accident. The burn area represented at least 15% of all the face (ears included but scalp excluded) and all burns were of thermal origin. Children under 16 years of age and cases in which the

short-term prognosis was life-threatening were excluded from the study. An early surgery was performed between day six and 10, involving use of the VersaJet™ hydrosurgery system. All patients were then followed up for two weeks, three-, six- and 12-months. At 12 months, the study showed the inflammatory phase had regressed for 90% of patients. Meanwhile, the two patients with ectropion were operated successfully and showed no functional problems.[10, level III]

A **case study** by Slocombe PD et al. (2011) was conducted to study the efficacy and safety of VersaJet™ hydrosurgery in the treatment of mature hypertrophic scars in children. A 13-year old girl presented with a mature hypertrophic scars on the dorsal aspect of her left hand and second, third and fourth digits. This scar had resulted from a hot iron full thickness contact burn at 12 months of age. There were no hand contractures, but the patient was unhappy about the cosmetic appearance of the scar and wished treatment to make it less noticeable. The scar was debrided to the desired level. Twelve months later the patient was happy with the result and there were no signs of recurrence of the hypertrophic scars **(see Figure 5).**[21, level III]

(a) **(b)**

Figure 5: a) Pre-operative image of hand showing an irregular hypertrophic scars. b) Six-months post-operative image of hand.[21, level III]

5.3.4 Secondary Outcome: Need for Grafting

A **retrospective, cohort study** was conducted by Legemate CM et al. (2018) to evaluate the outcome of patient treated with hydrosurgery in specialised burn care centres in the Netherlands. All 2113 patients with a burn-related admission in the burn centres in the Netherlands; Maasstad Hospital in Rotterdam, Martini Hospital in Groningen and Red Cross Hospital in Beverwijk between January 2009 and 31 December 2016 were included. Out of the 2113 patients, 1105 were treated with the VersaJet™ hydrosurgery, (with 506 was exclusively treated with hydrosurgery, and 599 was treated along with unstated conventional treatment), while 1008 received the conventional treatment. The result showed the patients in the group exclusively treated with VersaJet™ hydrosurgery were less often treated with dermal substitutes.[9, level II-2]

Matsumura H et al. (2012) in a **case series** reported that most of the patients (34/47; 72%) were able to receive surgical closure (skin graft, flap, skin substitute, or suture) of their wounds immediately after the debridement procedure. Only one patient further underwent a flap procedure during the 15-days follow-up phase. A follow up assessment at day 15 confirmed that all 35 patients had received successful surgical closure. Percentage ‘‘take’’ at day 15 for skin graft, flap, and skin substitute wounds (n=34) was recorded as a median of 100% (range, 70-100%).[6, level III]

The effectiveness of VersaJet™ hydrosurgery system was summarised as follows **(see Table 4)**.

Table 4: The effectiveness of VersaJet™ hydrosurgery system.

No.	Study/ Year	Study Design	Outcome
Primary outcome: Healing time			
1.	Hyland EJ et al./ 2015[25, level I]	Prospective, RCT	There was **no significant difference between** time to healing after-skin grafting (p=0.6) or time to healing after-burn (p=0.2).
2.	Liu J et al./ 2013[26, level I]	Prospective, RCT	Nine (42.9%) subjects in **the VersaJet™ hydrosurgery group achieved stable wound closure during the study period** compared with seven (26.8%) in the conventional group. However, there was **no difference in time to achieve stable wound closure between the treatment groups** (p=0·77).
3.	Matsumura H et al./ 2012[6, level III]	Case series	Twelve patients’ wounds were allowed to heal by secondary intention. Of these wounds, **6 (46.2%) were closed at day 15**.
4.	Tortella BJ et al./ 2014[27, level III]	Case series	The length of the VersaJet™ handpiece permitted the surgeon to access the entire compartment without the need to enlarge the initial wound, sparing the patient **increased morbidity and prolonged wound healing**.
Primary outcome: Operative time			
1.	Oosthuizen B et al./ 2014[28, level I]	Prospective, open label, RCT	There was significant evidence (p<0.001) that **VersaJet™ patients required fewer debridement procedures** than standard surgical debridement prior to wound closure.
2.	Hyland EJ et al./ 2015[25, level I]	Prospective, RCT	There was **no significant difference** between the duration of surgery (excluding anaesthetic time) between the VersaJet™ hydrosurgery (median 40 min) and conventional groups (median 35 min; p=0.6).
3.	Tortella BJ et al./ 2014[27, level III]	Case series	Due to the simultaneous performance of three parts of standard debridement (initial gross debridement, lavage and final sharp debridement), the **operative time of VersaJet™ hydrosurgery system was**

			decreased. This was a critical advantage for the unstable patient during the intervention.
Secondary outcome: Scar quality assessment/ Efficacy in dermal plane			
1.	Duteille F et al./ 2012[10, level III]	Case series	At 12 months, the study showed the **inflammatory phase had regressed** for 90% of patients. Meanwhile, the two patients with ectropion were operated successfully and showed no functional problems.
2.	Slocombe PD et al./ 2011[21, level III]	Case study	Twelve months later, the patient was happy with the result of the debridement and there were **no signs of recurrence of the hypertrophic scars**.
Secondary outcome: Need for grafting			
1.	Legemate CM et al./ 2018[9, level II-2]	Retrospective, cohort study	The patients in the group exclusively treated with VersaJet™ hydrosurgery were **less often treated with dermal substitutes**.
2.	Matsumura H et al./ 2012[6, level III]	Case series	Most of the patients (34/47; 72%) were able to receive surgical closure (skin graft, flap, skin substitute, or suture) of their wounds immediately after the debridement procedure. Only one patient further underwent a flap procedure during the 15-days follow-up phase. **A follow up assessment at day 15 confirmed that all 35 patients had received successful surgical closure**. Percentage ‘‘take’’ at day 15 for skin graft, flap, and skin substitute wounds (n=34) was recorded as a median of 100% (range, 70-100%).

*RCT: Randomised controlled trial

5.4 Safety

There were three studies reported on safety of VersaJet™ hydrosurgery system for debridement, of which one randomised controlled trial, one cohort study and one case series.

The studies reported that, there was/were:

- A significant evidence that the **blood loss and transfusion** for overall excision procedures was less for the VersaJet™ hydrosurgery group subjects than for the conventional group subjects[26, level I; 9, level II-2];
- Lower mean **infection rate** in the VersaJet™ hydrosurgery group compared to conventional group.[9, level II-2];
- One serious adverse event was recorded which was hip dislocation, but this was not related to the VersaJet™ system[6, level III];
- Seventy-three mild or moderate adverse events in total were recorded, however none of which related to the VersaJet™ system device or procedure.[6, level III]

The latest version of VersaJet™ hydrosurgery system had received 510(k) from United States Food and Drug Administration[31] and was Conformité Européenne (CE) marked

in 2011 before the system was launched in 2012.[15] The hydrosurgery system also had been approved by Medical Device Authority Malaysia in 2018.[31]

5.5 Cost analysis/ Cost-effectiveness

There was one study reported on cost-analysis of VersaJet™ hydrosurgery system for debridement **(see Table 5)**.

Table 5: Cost-analysis of VersaJet™ hydrosurgery system for debridement.[26, level I]

Cost	Treatment group	Control group	Remark
First operative procedure	[redacted]	[redacted]	p=0.278
The surgical procedures	[redacted]	[redacted]	p=0.513
The study treatment: the mean (surgical procedures and hospital stay)	[redacted]	[redacted]	p =0.287
Cost to achieve stable wound closure	No information	No information	p=0.851

Source: Liu J, Ko JH, Secretov E et al. 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. International Wound Journal. 2013; 456-461.

Meanwhile, the price for the system in the market was summarised as follow:

Table 6: Price according to each component of the latest version of VersaJet™ hydrosurgery system.[29]

Component	Price (United States Dollars)
Hydrosurgery Handpiece, Plus, 8mm, 45?, 5/cs	[redacted]
Hydrosurgery Handpiece, Plus, 14mm, 45?, 5/cs	
Hydrosurgery Handpiece, Plus, 14mm, 15?, 5/cs	
Hydrosurgery Handpiece, Exact, 8mm, 45?, 5/cs	
Hydrosurgery Handpiece, Exact, 14mm, 15?, 5/cs	
Hydrosurgery Handpiece, Exact, 8mm, 45?, 5/cs	
Hydrosurgery Handpiece, Exact, 14mm, 45?, 5/cs	
Versajet II Cart, 1/cs	[redacted]
Multi-function Footswitch, 1/cs	[redacted]
Replacement Shelf, 1/cs	[redacted]
Total	[redacted]

cs: pieces

Source: Product price for Smith and Nephew Versajet II hydrosurgery system. Available from https://qpsmedicals.com/products/smith-nephew-versajet-ii-hydrosurgery-system?_pos=9&_sid=d4640ae18&_ss=r. Accessed on 25 August 2021

5.6 Organisational Issue

There was no retrievable study on organisational issue regarding VersaJet™ hydrosurgery system.

5.7 Limitations

This review has several limitations. The selection of the studies and appraisal was done by one reviewer. Although there was no restriction in language during the search, only English full text articles were included in the report. The most important limitation was the methodological quality of the included trials which had some concern of bias.

6.0 CONCLUSION

There was substantial evidence on VersaJet™ hydrosurgery system for debridement. However, some studies have high risk of bias due to inappropriate randomisation sequence generation and selective measurement of the outcome, hence varying the quality of the included trials. Nevertheless, the evidence showed that VersaJet™ may reduce the healing and operative time to treatment, improve quality of scar or dermal plane efficacy, and optimise the need for grafting.

As per safety, the VersaJet™ hydrosurgery system may reduce the blood loss and transfusion, and decrease the infection rate. Even though there was one serious adverse event and some mild or moderate adverse events were reported, none of them were related to VersaJet™ hydrosurgery system. The latest version of VersaJet™ hydrosurgery system had received 510(k) from United States Food and Drug Administration and was Conformité Européenne (CE) marked in 2011 before launched in 2012. The hydrosurgery system also had been approved by Medical Device Authority Malaysia in 2018.

There was no significant difference between the two 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. Approximately, the price for one set of the latest version of VersaJet™ hydrosurgery system was [redacted] (United States Dollars).

7.0 REFERENCES

1. Attinger CE, Janis JE, Steinberg J et al. Clinical approach to wounds: de´bridement and wound bed preparation including the use of dressings and woundhealing adjuvants. Plast Reconstr Surg. 2006;117: 72SY109S DOI: 10.1097/01.prs.0000225470.42514.8f. PMID: 16799376.

2. National Diabetes Registry Report 2013-2019. Ministry of Health Malaysia.

3. Jones T, McDonald S, Deitch EA. Effect of graft bed on long-term functional results of extremity skin grafts. J Burn Care Rehabil. 1988;9: 72Y74.

4. Mensı´k I, Lamme EN, Brychta P. Depth of the graft bed influences split-skin graft contraction. Acta Chir Plast. 2003;45: 105Y108.

5. Dunkin CS, Pleat JM, Gillespie PH et al. Scarring occurs at a critical depth of skin injury: precise measurement in a graduated dermal scratch in human volunteers. Plast Reconstr Surg. 2007;119: 1722Y1732; discussion 1733Y4.

6. Matsumura H, Nozaki M, Watanabe K et al. The Estimation of Tissue Loss During Tangential Hydrosurgical Debridement. Annals of Plastic Surgery. 2012; 5(69): 521-525.

7. Manna B, Nahirniak P, Morrison CA. Wound debridement. Available from https://www.ncbi.nlm.nih.gov/books/NBK507882/. Accessed on 16 August 2021.

8. Choo J, Nixon J, Nelson A et al. Autolytic debridement for pressure ulcers. Cochrane Database Syst Rev. 2019;6. DOI: 10.1002/14651858.CD011331.pub2. PMCID: PMC6573093CD011331.

9. Legemate CM, Goei H, Gostelie OFE et al. Application of hydrosurgery for burn wound debridement: an 8-year cohort analysis. Burn. 2018; https://doi.org/10.1016/j.burns.2018.08.015.

10. Duteille F, Perrot P. Management of 2nd-degree facial burns using the Versajet™ hydrosurgery system and xenograft: a prospective evaluation of 20 cases. Burns. 2012;38: 724Y729.

11. Granick M, Boykin J, Gamelli R, et al. Toward a common language: surgical wound bed preparation and debridement. Wound Repair Regen. 2002; 14(Suppl 1): S1YS10.

12. HydroCision wins another patent for its fluidjet surgery systems. Mass High Tech. 2004. Available from https://www.bizjournals.com/boston/blog/mass-high-tech/2004/02/hydrocision-wins-another-patent-for.html. Accessed on 16 August 2021.

13. *Garis Panduan Perkhidmatan Penjagaan Luka di Fasiliti Kesihatan Primer*. Ministry of Health Malaysia. 2019. Available from https://www.moh.gov.my/moh/resources/Penerbitan/Garis%20Panduan/Garis%20Panduan%20Umum(KKM)/Garis_Panduan_Perkhidmatan_Penjagaan_Luka_di_Fasiliti_Kesihatan_Primer.pdf. Accessed on 17 August 2021.

14. Klein MB, Hunter S, Heimbach DM, Engrav LH, Honari S, Gallery E, et al. The Versajet water dissector: a new tool for tangential excision. J Burn Care Rehab 2005;26: 483-487.

15. The Versajet II hydrosurgery system for surgical debridement of acute and chronic wounds and burns. NICE Medtech Innovation Briefing: National Institute for Health Care Excellence; 2014: 1-23.

16. Sainsbury DC. Evaluation of the quality and cost effectiveness of Versajet hydrosurgery. Int Wound J 2009;6: 24-29.

17. Kimble RM, Mott J, Joethy J. Versajet hydrosurgery system for the debridement of paediatric burns. Burns 2008;34: 297-298.

18. Caputo WJ, Beggs DJ, DeFede JL et al. A prospective randomised controlled clinical trial comparing hydrosurgery debridement with conventional surgical debridement in lower extremity ulcers. Int Wound J 2008;5: 288-294.

19. Mosti G, Iabichella ML, Picerni P et al. The debridement of hard to heal leg ulcers by means of a new device based on Fluidjet technology. Int Wound J. 2005;2: 307Y314.

20. Vanwijck R, Kaba L, Boland S, et al. Immediate skin grafting of sub-acute and chronic wounds debrided by hydrosurgery. J Plast Reconstr Aesthet Surg. 2010;63: 544Y549.

21. Slocombe PD, Simons MA, Kimble RM. A modification of the Hynes procedure: a surgical innovation in the treatment of mature hypertrophic scars in children. Burns. 2011; 37: 1265-1267.

22. VersaJet™ hydrosurgery system: System overview. Smith and Nephew. Available from https://www.smith-nephew.com/key-products/advanced-wound-management/versajet/. Accessed on 19 August 2021.

23. Smith & Nephew. Versajet II Exact & Plus hydrosurgery system handpiece system installation. Smith & Nephew Inc. 2012.

24. Gurunluoglu R. Experiences with waterjet hydrosurgery system in wound debridement. World J Emerg Surg. 2007;2: 10.

25. Hyland EJ, D'Cruz R, Menon S et al. Prospective, randomised controlled trial comparing versajettm hydrosurgery and conventional debridement of partial thickness paediatric burns. Burns. 2015; 41: 700-707.

26. Liu J, Ko JH, Secretov E et al. 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. International Wound Journal. 2013; 456-461.

27. Tortella BJ. Traumatic and chronic wound debridement with a novel fluidjet device: the Versajet™ hydrosurgery system. Smith & Nephew. 2014.

28. Oosthuizen B, Mole T, Martin T et al. Comparing of standard surgical debridement versus the versajet plustm hydrosurgery system in the treatment of open tibia fractures: a prospective open label randomised controlled trial. Int J Burn Trauma. 2014; 4(2): 53-58.

29. Product price for Smith and Nephew Versajet II hydrosurgery system. Available from https://qpsmedicals.com/products/smith-nephew-versajet-ii-hydrosurgery-system?_pos=9&_sid=d4640ae18&_ss=r. Accessed on 25 August 2021.

30. VersaJet II Hydrosurgery System. United States of Food and Administration (USFDA). Available from https://gpsmedicals.com/products/smith-nephew-versajet-ii-hydrosurgery-system?_pos=9&_sid=d4640ae18&_ss=r. Accessed on 16 August 2021.

31. VersaJet II Hydrosurgery System. Malaysia Medical Device Register (MMDR). Available from https://mmdr.mda.gov.my/frontend/web/index.php?r=carian%2Fview&id=51146. Accessed on 30 August 2021.

8.0 APPENDICES

8.1 Appendix 1: Search strategy

Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to 13 August 2021

1 DEBRIDEMENT/ 16936
2 debridement*.tw. 27665
3 1 or 2 35255
4 Versajet hydrosurgery system.mp. 24
5 Versajet hydrosurgery system.tw. 24
6 waterjet*.tw. 155
7 waterjet*.mp. 161
8 WOUND HEALING/ 98478
9 wound healing*.tw. 71038
10 HYDROTHERAPY/ 2595
11 hydrotherap*.tw. 1059
12 whirlpool bath*.tw. 68
13 WOUNDS.mp. and INJURIES/ [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 79353
14 injur*.tw. 858869
15 injur*.mp. and wound*.tw. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 60605
16 research* related injur*.tw. 39
17 trauma*.tw. 387791
18 wound*.tw. 215748
19 wound*.mp. and injur*.tw. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 101918
20 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 1329219
21 OCCLUSIVE DRESSINGS/ 3859
22 occlusive bandage*.tw. 44
23 occlusive dressing*.tw. 853
24 Enzymatic debridement.tw. 208
25 Biological debridement.tw. 8
26 Conservative sharp debridement.tw. 7
27 21 or 22 or 23 or 24 or 25 or 26 4545
28 3 and 20 and 27 437
29 limit 28 to (yr="2011 -Current") 136

OTHER DATABASES	
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to July 27, 2021	Same MeSH, keywords, limits used as per MEDLINE search
Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations 1946 to July 27, 2021	
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 2017 to July 27, 2021	
Ovid MEDLINE(R) 1946 to July Week 3 2021	
Ovid MEDLINE(R) 1996 to July Week 3 2021	
Ovid MEDLINE(R) Epub Ahead of Print July 27, 2021	
Ovid MEDLINE(R) Daily Update July 27, 2021	
Ovid MEDLINE(R) 2017 to July Week 3 2021	
Cochrane Library	

PubMeD

(((DEBRIDEMENT[MeSH Terms]) OR (debridement[Text Word])) AND ((((((((((((Versajet hydrosurgery system[Text Word]) OR (waterjet[Text Word]))) OR (WOUND HEALING[MeSH Terms])) OR (wound healing[Text Word])) OR (HYDROTHERAPY[MeSH Terms])) OR (hydrotherapy[Text Word])) OR (whirlpool bath[Text Word])) OR (WOUNDS and INJURIES[MeSH Terms])) OR (injury[Text Word])) OR (research related injury[Text Word])) OR (trauma[Text Word])) OR (wound[Text Word])) OR (wound[Text Word] AND injury[Text Word]))) AND ((((((OCCLUSIVE DRESSINGS[MeSH Terms]) OR (occlusive bandage[Text Word])) OR (occlusive dressing[Text Word])) OR (Enzymatic debridement[Text Word])) OR (Biological debridement[Text Word])) OR (Conservative sharp debridement[Text Word]))

8.2 Appendix 2: Hierarchy of evidence for effectiveness/ diagnostic

I Evidence obtained from at least one properly designed randomised controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

8.3 Appendix 3: Evidence tables

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
1. Hyland EJ, D'Cruz R, Menon S et al. Prospective, Randomised Controlled Trial Comparing Versajet™ Hydrosurgery and Conventional Debridement of Partial Thickness Paediatric Burns. Burns. 2015; 41: 700-707. AUSTRALIA	**Prospective, Randomised Controlled Trial** **Objective:** To compare conventional tangential burn wound debridement with Versajet™ (Smith and Nephew) in children with partial thickness burns. **Method:** All subjects underwent standard general anaesthesia and received anti-septic povidone–iodine operative site preparation prior to sterile draping. A two-mm punch biopsy was then taken at the site of the unhealed partial thickness burn to be grafted. Subjects were then randomised into receiving debridement using the Versajet II Exact™ (Smith and Nephew) hydrosurgical system or conventional tangential burn wound	I	Total 61 children. 31 underwent conventional treatment; 30 underwent debridement using Versajet™ (Smith and Nephew).	Versajet™ hydrosurgery	Conventional treatment	Three and six months	**Healing time** There was no significant difference between time to healing after-skin grafting (p=0.6) or time to healing after-burn (p=0.2). **Operative time** There was no significant difference between the duration of surgery (excluding anaesthetic time) between the hydrosurgery (median 40 min) and conventional groups (median 35 min; p=0.6). <u>Author's conclusion</u> The findings suggested that hydrosurgery may be a more precise method of burn wound debridement ensuring maximal dermal preservation, however there was no significant difference between hypertrophic scarring at three and six months after-burn.	

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	debridement using a Goulian knife (6–8 thousandths of an inch).							

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
2. Oosthuizen B, Mole T, Martin T et al. Comparing of Standard Surgical Debridement Versus the Versajet Plus™ Hydrosurgery System in the Treatment of Open Tibia Fractures: a Prospective Open Label Randomised Controlled Trial. Int J Burn Trauma. 2014; 4(2): 53-58. SOUTH AFRICA	**Prospective, Open Label Randomised Controlled Trial** **Objective:** To assess the efficacy of an alternative debridement technology in the treatment of Gustilo & Anderson grade III A and III B open tibia fractures. **Method:** Sharp incision with a scalpel was used to extend the wound where necessary and to create linear edges in both groups. The final definition of the Gustilo & Anderson classification was made in the operating room after the debridement (IIIA adequate soft tissue; IIIB soft tissue defect). Versajet Hydrosurgery was used on the soft tissues in both proximal and distal soft tissue injuries and to clear the bone ends as thoroughly as possible, after the medullary canal was debrided with a Volkman	I	40 patients. 24 underwent surgical treatment; 16 underwent debridement using Versajet Plus™ (Smith and Nephew).	Versajet Plus™ hydrosurgery	Surgical treatment		**Operative time** There was significant evidence ($p<0.001$) that Versajet patients required fewer debridement procedures than standard surgical debridement prior to wound closure: ratio standard to Versajet=1.747).	

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	spoon in order to get any debris out that entered the wound at the moment of injury. Following assessment, debridement and closure or debridement and application of further gauze dressings was performed using either Versajet or standard surgical techniques as appropriate for each group.							

Evidence Table : Efficacy, Safety, Cost
Question : What is the effectiveness, safety issue and cost of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
3. Liu J, Ko JH, Secretov E et al. 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. International Wound Journal. 2013; 456-461. UNITED STATES	**Prospective, Randomised Controlled Trial** **Objective:** To assess clinical efficacy and cost-effectiveness when treating subjects with chronic wounds. **Method:** Forty evaluable subjects were recruited for the primary investigation on the time to closure of delayed healing dehisced incisions and traumatic or chronic cutaneous defects. The first subject was recruited on November 2007 and the last subject completed the study on September 2011. The study protocol received approval from the Institutional Review Boards at Northwestern University (project number STU0020035).	I	40 subjects. 19 underwent conventional treatment; 21 underwent debridement using Versajet.	Versajet™ hydrosurgery	Conventional treatment		**Efficacy** **Healing time** Nine (42.9%) subjects in the hydrosurgery group achieved stable wound closure during the study period compared with seven (26.8%) in the conventional group. There was no difference in time to achieve stable wound closure between the treatment groups (p=0·77). **Safety** There was significant evidence (p=0·003) that the maximum blood loss for overall excision procedures was less for the hydrosurgery group subjects than for the conventional group subjects. Similarly, it was observed that there was less blood loss for hydrosurgery group during the first excision procedure than for the conventional group. **Cost** • The mean cost of the first operative procedure was $4411.70 for the hydrosurgery group and $6014.10 for the conventional group subjects (p=0·278). • There was no significant difference in the mean cost of the surgical procedures for hydrosurgery group ($13,689.10) compared with the conventional group ($12,869.40) (p=0·513). • The mean cost of study treatment (surgical procedures and hospital stay) was $44,290.10 for the hydrosurgery group and $39,940.50 for the conventional group subjects (p =0.287). • There was no evidence (p=0·851) of a difference in the cost to achieve stable wound closure	

Evidence Table : Efficacy, Safety, Cost
Question : What is the effectiveness, safety issue and cost of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
							between the treatments. The estimate for the ratio of the cost to achieve stable wound closure, hydrosurgery : conventional, was 0.851.	

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
4. Tortella BJ. Traumatic and Chronic Wound Debridement with a Novel Fluidjet Device: the Versajet™ Hydrosurgery System. Smith & Nephew. 2014. PHILADELPHIA, UNITED STATES	**Case series** **Objective:** To study the efficacy of Versajet™ hydrosurgery system in treating wounds. **Method:** The patients included in the study ranged in age from 18 years to 79 years and presented with a myriad of wounds. Specifically, the Versajet™ hydrosurgery system was used to treat traumatic wounds and burns, to resect necrotic muscle, and to debride decubitus pressure ulcers.	III	Five patients. 19-year old woman with rapid burn and eschar formation, 18-year old man with foot gunshot wound, 35-year old woman with necrotic muscle wound, 47-year old male with full thickness scalp replant, 55-year old man with necrotic soft tissue infection, 79-year old male with sacral decubitus pressure ulcer.	Versajet™ hydrosurgery system			**Healing time** The length of the Versajet™ handpiece permitted the surgeon to access the entire compartment without the need to enlarge the initial wound, sparing the patient increased morbidity and prolonged wound healing. **Operative time** • Versajet™ hydrosurgery system approach was less-time consuming. • Because this device simultaneously performed the three parts of standard debridement - initial gross debridement, lavage, final sharp debridement - operative time was decreased. This was a critical advantage as the patient was quite unstable at the time of this intervention. <u>Author's conclusion</u> This system was efficient, straightforward and reducing operative time for wound debridement.	

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
5. Slocombe PD, Simons MA, Kimble RM. A Modification of the Hynes Procedure: a Surgical Innovation in the Treatment of Mature Hypertrophic Scars in Children. Burns. 2011; 37: 1265-1267. AUSTRALIA	**Case Study** **Objective:** To study the efficacy and safety of Versajet™ hydrosurgery in the treatment of mature hypertrophic scars in children. **Method:** A 13-year old girl presented with a mature hypertrophic scars on the dorsal aspect of her left hand and second, third and fourth digits. This scar had resulted from a hot iron full thickness contact burn at 12 months of age. There were no hand contractures, but she was unhappy about the cosmetic appearance of the scar and wished treatment to make it less noticeable.	III	One patient. A 13-year old girl presented with a mature hypertrophic scars.	Versajet™ hydrosurgery		12 months	**Efficacy** **Scar quality assessment** The scar was debrided to the desired level. Twelve months later the patient was happy with the result and there were no signs of recurrence of the hypertrophic scars.	

Evidence Table : Efficacy, Safety
Question : What is the effectiveness and safety issue of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
6. Legemate CM, Goei H, Gostelie OFE et al. Application of Hydrosurgery for Burn Wound Debridement: an 8-year Cohort Analysis. Burn. 2018; https://doi.org/10.1016/j.burns.2018.08.015. NETHERLANDS	**Retrospective, Cohort Study** **Objective:** To gain insight in which patients hydrosurgery is used in specialised burn care in the Netherlands. **Method:** All patients with a burn-related admission in one of the burn centres in the Netherlands (Maasstad Hospital in Rotterdam, Martini Hospital in Groningen, and Red Cross Hospital in Beverwijk) between January 2009 and 31 December 2016 were included. Data were collected using the national Dutch Burn Repository R3.	II-2	2113 patients. Hydrosurgery group, n=1105 *Only hydrosurgery: 506* *Hydrosurgery plus conventional: 599* Conventional group, n=1008	Versajet™ hydrosurgery			**Efficacy** **Need for grafting** Patients in the group exclusively treated with hydrosurgery were less often treated with dermal substitutes. **Safety** Patients in the group exclusively treated with hydrosurgery had a lower mean volume of blood transfusion and infection rates compared to other groups.	

Evidence Table : Efficacy, Safety
Question : What is the effectiveness and safety issue of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
7. Matsumura H, Nozaki M, Watanabe K et al. The Estimation of Tissue Loss During Tangential Hydrosurgical Debridement. Annals of Plastic Surgery. 2012; 5(69): 521-525. JAPAN	**Case series** **Objective:** To determine the proportion of wounds that had been appropriately debrided. **Method:** The study was conducted in six surgical centres between June 2008 and June 2009. Patients older than 16 years, with a burn, dehisced wound, skin or pressure ulcer, contused wound, or traumatic skin loss requiring debridement were included. Each patient underwent debridement using the Versajet system with a 45 degree/8 mm and/or a 45 degree/14 mm handpiece. Power settings on the one to 10 scale were at the discretion of the investigator. Wound assessment and photography were carried out before and immediately after the	III	47 patients with history of failure to heal.	Versajet™ hydrosurgery		15 days	**Efficacy** **Healing time** • Twelve patients' wounds were allowed to heal by secondary intention. Of these wounds, 6 (46.2%) were • closed at day 15. • The percentage reduction in wound area observed by day 15 of wounds closed by secondary intention or sutured (n=13) was a median of 96.9%. **Need for grafting** • Most of the patients (34/47; 72%) were able to receive surgical closure (skin graft, flap, skin substitute, or suture) of their wounds immediately after the debridement procedure. • One patient further underwent a flap procedure during the 15-day follow-up phase. A follow up assessment at day 15 confirmed that all 35 patients had received successful surgical closure. Percentage ''take'' at day 15 for skin graft, flap, and skin substitute wounds (n=34) was recorded as a median of 100% (range, 70-100%). **Safety** • One serious adverse event was recorded during the study, although this was not related to the Versajet system (hip dislocation). • A further 73 mild or moderate adverse events in total were recorded, none of which related to the Versajet system device or procedure.	

Evidence Table : Efficacy, Safety
Question : What is the effectiveness and safety issue of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	debridement procedure. Wound dimensions were measured using computerised planimetry of wound tracings to assess area and a graduated probe to assess depth.							

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
8. Duteille F, Perrot P. Management of 2nd-degree Facial Burns Using the Versajet™ Hydrosurgery System and Xenograft: a Prospective Evaluation of 20 Cases. Burns. 2012; 38: 724-729. FRANCE	**Case series** **Objective:** To validate the efficacy of this form of management and to define its role in the therapeutic arsenal with respect to intermediate second-degree burns. **Method:** Twenty patients were included in the prospective study. These patients had second-degree intermediary burns, need to be hospitalised in the burns unit and have 10% body surface area minimum. Each burn was evaluated by at least two senior physicians within 48 h after the initial accident. The burn area represented at least 15% of all the face (ears included but scalp excluded) and all burns were of thermal origin. Children under 16 years of age and cases in which the short-term prognosis was life-threatening were excluded from the study.	III	20 patients.	Versajet™ hydrosurgery		Two weeks, three, six and 12 months	**Efficacy** **Scar quality assessment** • At 12 months, the inflammatory phase had regressed for 90% of patients. • The two patients with ectropion were operated successfully and showed no functional problems.	

Evidence Table : Efficacy
Question : What is the effectiveness of Versajet Hydrosurgery System for Debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Early surgery was performed between day six and 10, involving use of the Versajet™ hydrosurgery system.							

e ISBN 978-967-2887-39-3