



Australian Government
Department of Health and Ageing



Horizon Scanning Technology
Prioritising Summary
The Versajet hydrosurgery system
February 2007



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Mr. Irving Lee from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

PRIORITISING SUMMARY

REGISTER ID: S000004

NAME OF TECHNOLOGY: THE VERSAJET™ HYDROSURGERY SYSTEM

PURPOSE AND TARGET GROUP: BURN PATIENTS REQUIRING WOUND BED PREPARATION/DEBRIDEMENT

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input checked="" type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|--------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 106594 |
| <input type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States		✓	
United Kingdom		✓	

IMPACT SUMMARY:

Smith & Nephew (United Kingdom) provides the Versajet hydrosurgery system for the debridement of burn wounds. The technology is available through burns specialists for patients requiring wound debridement prior to treatment to accelerate the healing process.

BACKGROUND

Wound bed preparation (wound debridement) is the process of managing a wound to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures (Granick et al. 2006b). Wound bed preparation was initially developed as a method of managing chronic wounds; however it is now clear that it can be applied to acute and surgical wounds as well. The TIME concept utilised by healthcare professionals provides a systematic approach to assessing and treating wounds, with the aim of restoring a biochemical environment that stimulates healing or provides a wound bed that can be treated with advanced therapeutic measures: Necrotic tissue (T) and foreign bodies must be cleared from the wound. Infection (I) must be controlled and corrected. Moisture (M) balance must be restored to prevent maceration and desiccation which will physically impede healing and wound contraction. The migrating epithelial edge (E) of the wound is a sign of healing, if this is not present, the patient and the wound need to be reassessed (Granick et al. 2006a, Granick et al. 2006b).

Wound debridement has been shown to accelerate wound healing compared to conservative treatment, and the reduction of bacterial load and bioburden achieved is considered critical for undisturbed wound healing and successful skin grafting (Rennekampff et al. 2006). Sharp debridement is the standard of care to which all other forms of wound debridement are compared. However, despite the effectiveness of this method, the treated patient is often subjected to substantial pain. Furthermore, the knives utilised for sharp debridement are not well suited for debridement of several crucial areas, including the eyelids, ears and web spaces. Sharp excision in these areas are often imprecise and may result in inadequate debridement or excessive removal of tissue (Klein et al. 2005). A new device, known as the Versajet hydrosurgery system, offers an alternative method of wound debridement utilising water/saline. The Versajet system uses pressurised saline in a sterile circuit that is forced into a nozzle. The water executes an 180° turn and is forced out of a miniscule nozzle which is less than 5/1,000 inches in diameter, forming a focused water jet. The water jet is directed to pass parallel to the wound and is captured by an evacuator port which is located 8 to 14 mm from the nozzle. The resultant Venturi effect creates a local vacuum on the surface of the debriding area and therefore carries the water, ablated tissue and debris into the evacuator port without the need for a separate suction mechanism. The Versajet has an adjustable power level (12,800 psi to 15,000 psi) which allows it to plane down the wound to the level desired.

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, an estimated 46,611 people were hospitalised as a result of burn or scald-related injury during the 5-year period of 1999/00 to 2003/04. This equates to an age-adjusted rate of 47.9 cases per 100,000 population per year. Of the 46,611 cases requiring hospitalisation during this period, almost half (49%) were classified as burns of partial thickness, whilst less than a quarter (24%) were reported as full thickness burns (AIHW: Burns and Scalds 2006).

Approximately 1484 dressing of burn procedures were recorded in 2004 to 2005 while dressing of other wounds accounted for 6598 procedures (AIHW: National Hospital Morbidity Database 2006).

DIFFUSION

The management of wounds is an important aspect of wound healing. If the Versajet is proven to be safe and effective it is likely to be widely diffused in Australia as a viable alternative to standard sharp debridement. Although this device has received TGA approval, the extent of its use in Australia is not known. In addition, the Versajet has received marketing approval from the FDA and the European CE mark.

COMPARATORS

- *Sharp debridement*
This technique utilises handheld knives (Goulian/Weck or Watson) and is the current standard for wound debridement.
- *Autolytic debridement*
Autolysis uses the body's own enzymes and moisture to re-hydrate, soften and finally liquefy hard eschar and slough. It is often a slow and unpredictable process. Patients with ongoing necrosis can get septic, develop invasive infection, become malnourished and experience pain.
- *Enzymatic debridement*
This technique utilises chemical enzymes, fast acting products that produce slough of necrotic tissue. It appears to be effective in patients with minimal necrotic load but is time consuming and labour intensive.
- *Mechanical debridement*
Utilising the 'wet to dry' technique where a moist dressing is applied and peeled off when dry to remove debris and tissue. This is a painful and non-specific process.
- *Laser debridement*
Lasers appear to be efficient and precise when utilised in tissue ablation, however this technique carries the risk of thermal damage to healthy tissue.
- *Maggot therapy*
Maggots are utilised to ingest and break down necrotic tissue. While this technique is effective, it carries a high level of patient and nursing non-acceptance.
- *Ultrasound debridement*
Utilises ultrasound to cause cavitation and micro streaming to achieve wound debridement.

Granick et al. 2006a, Rennekampff et al. 2006

SAFETY AND EFFECTIVENESS ISSUES

Mosti et al. (2005) examined the efficacy of the Versajet in 68 patients affected by chronic, hard-to-heal leg ulcers stuck in the inflammatory phase compared to 99 control patients who underwent traditional debridement with moist dressings. Adequate debridement was achieved with the Versajet in all 68 patients, with 46/68 (68%) patients requiring only one operative procedure with the device. Overall, utilisation of the Versajet was faster (mean time per treatment: 5 minutes) compared to controls and resulted in shorter hospital stays as a result of quicker healing. Furthermore, this study reported that the Versajet was capable of reducing the bacterial load of the ulcer bed (Mosti et al. 2005).

The case series conducted by Klein et al. (2005) utilised the Versajet in 44 patients as an adjunct to Watson and Guilian knives (sharp debridement) or electrocautery for burn excision in a variety of anatomic areas (e.g. eyelids, fingers and web spaces). No patients required repeat grafting as a result of inadequate excision with the Versajet. In addition, no patients experienced graft loss due to excessive tissue excision. The authors concluded that the Versajet is a useful adjunct in burn wound excision and reduces the risk of inadequate debridement and unnecessary damage to critical and fragile anatomic structures, however it is not suitable for the debridement of large areas due to the small nozzle (Klein et al. 2005).

Granick et al. (2006a) retrospectively reviewed 40 patients (45 wounds) whose wounds were debrided with the Versajet system and compared them to 22 control patients (22 wounds) who underwent conventional sharp debridement. Both treatment groups were comparable with regards to gender, age, admitting diagnosis and wound type. However, the control group had a significantly larger median wound area ($p = 0.016$). Multiple regression analysis revealed that there was no evidence of statistically significant differences for debridement time after adjusting for patient age and wound area (mean time for pooled sample: 65 minutes). However, the mean number of surgical procedures was significantly less in the Versajet group ($p = 0.0002$), which required 1.18 procedures per wound. In contrast the control patients required 1.91 procedures per wound. In addition to this, Granick et al. (2006a) reported that the odds of having a lower number of procedures were significantly greater for the Versajet group compared with conventional sharp debridement ($p = 0.01$). No statistically significant association was found between the odds of having a lower number of procedures and patients age or wound area (Granick et al. 2006a).

Rennekampff et al. (2006) evaluated the clinical efficacy of debridement of burn wounds in 17 patients with the Versajet system (face, arm, leg, hand and foot). The authors reported that superficial partial thickness burn wounds were successfully debrided with a single pass of the Versajet system (pressure settings from 3 to 5). No complications were observed in this subgroup and there were no post-operative infections or complications. Meanwhile, mid-dermal level burns were also effectively debrided with the Versajet system. Higher settings (5 to 7) were needed to obtain complete debridement and several passes were required. These wounds were successfully treated with a skin substitute (Biobrane) and healed without sequelae. For deep partial thickness wounds, Rennekampff et al. (2006) reported that multiple passes with settings from 5 to 8 were required to attain complete debridement. However it was noted that dry, leathery necrotic skin could not be sufficiently debrided with the Versajet system, and these areas were debrided using a Goulian knife. After debridement, all deep partial thickness wounds were grafted with split thickness skin grafts and the results of engraftment and healing were comparable to conventional sharp debridement. Microbiological analysis demonstrated that of the 4 wounds that had pre-debridement bacterial load, 2 exhibited no bacterial growth and one demonstrated a reduction of bacterial load post-Versajet debridement. This indicates that the Versajet is capable of reducing or clearing bacteria from the wound. However, of the 3 wounds with no pre-debridement bacterial growth, one exhibited growth post-debridement.

Cubison et al. (2006) reported that when Versajet was utilised to treat a series of 7 children with burns, it was very effective at cleaning and debriding superficial and intermediate depth burns prior to the application for biological dressings. However, the authors cautioned that higher settings are required for debridement in older children possibly due to the thickness or inherent quality of their dermis. Versajet excision of these burns could cause an uneven groove bed (as noted in one patient) and therefore caution is advised. Meanwhile, although Versajet is not able to debride full thickness injuries, it can be utilised as an adjunct to conventional sharp debridement, particularly at the edges of the burn (Cubison et al. 2006).

COST IMPACT

Klein et al. (2005) reported that the price of the Versajet console is USD\$9500, while the handpieces cost USD\$355. Alternatively, Smith & Nephew will provide the console free of charge but the cost per handpiece will be raised to USD\$395 (Klein et al. 2005).

The mean cost per debridement procedure at the University Hospital, Newark, in 2002/2003 was USD\$3393. However, due to the reduction in the number of procedures per patient in the Versajet group reported by Granick et al. (2006a), the average debridement cost was almost USD\$2000 lower than patients debrided by conventional methods (Granick et al. 2006b).

Table 1: Medical Benefits Schedule of fees for procedures related to wound debridement (Medicare Australia 2006)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Debridement of wound of soft tissue, traumatic, deep or extensively contaminated, under general anaesthesia or regional or field nerve block, including suturing of that wound when performed.	30023	\$288.10	13798
Debridement of extensively infected post-surgical incision or Fournier's Gangrene, wound of soft tissue, under general anaesthesia or regional or field nerve block, including suturing of that wound when performed.	30024	\$288.10	207

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

Rennekampff and Tenehaus, two authors from the Rennekampff et al. (2006) study, have participated in an advisory board meeting coordinated by Smith & Nephew. The cost for color reproduction in this study was covered by Smith & Nephew.

Smith & Nephew supplied the Versajet handpieces utilised by Cubison et al. (2006) and funded the colour reproduction of the study article. In addition, Smith & Nephew contributed to travel expenses for the authors to present their findings at an international conference.

HEALTHPACT CONCLUSION

The evidence available on the Versajet system unanimously concludes that the device is capable of effective wound debridement and is particularly useful in anatomical sites where conventional debridement is difficult to perform. However, its efficacy is limited in full thickness injuries or dry necrotic leathery skin (Cubison et al. 2006, Granick et al. 2006a). Preliminary evidence also suggests that Versajet may lower bacterial load on burn wounds (Rennekampff et al. 2006) and ulcer beds (Mosti et al. 2005).

HealthPACT has recommended that further assessment of this technology is no longer warranted.

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input checked="" type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

SOURCES OF FURTHER INFORMATION:

Stetter C, Plaza T, von den Dreisch P. Skin grafting of a chronic leg ulcer with combined Versajet™-V.A.C. therapy. *Journal der Deutschen Dermatologischen Gesellschaft* 2006; 4(9): 739-742.

LIST OF STUDIES INCLUDED

Total number of studies 4
Level III-3 and IV intervention evidence

SEARCH CRITERIA TO BE USED:

Wound debridement
Versajet
Water jet debridement
Debridement*/instrumentation
Burns/therapy

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