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Original Article

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

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Abstract: The aim of this study was to assess the efficacy of an alternative debridement technology in the treatment of Gustilo & Anderson grade III A and III B open tibia fractures. The objective was to explore whether improvements to the debridement using tangential hydrosurgery (VERSAJET™ Plus Smith & Nephew) could reduce the number of debridement episodes and the days before closure. A pilot scale randomized controlled trial was conducted against conventional surgery. A total of 40 patients were recruited. Sixteen patients received hydrosurgery and 24 patients were treated with standard surgical debridement. Baseline characteristics were well balanced. There was significant evidence ($p < 0.001$) that VERSAJET patients required fewer debridement procedures than standard surgical debridement prior to wound closure (ratio standard: VERSAJET = 1.747). The median time to wound closure was 3 days (95% CI 3 days, 5 days) for VERSAJET and 5 days (95% CI 4 days, 8 days) for standard debridement, although the difference was not statistically significant ($p = 0.275$). There were no instances of post-operative infection.

Keywords: Open fracture, debridement, hydrosurgery, VERSAJET

Introduction

Whilst the importance of debridement and irrigation followed by delayed closure is established practice in the treatment of open fracture injuries [1-3], the timing of closure is still uncertain and actively debated [4]. Early closure could reduce the level of subsequent infection through the protection against nosocomial hospital acquired infections which evidence suggests are the most likely sources of subsequent open fracture complications [5, 6]. Recent studies have provided evidence that that a strategy of early use of Negative Pressure Wound Therapy (NPWT) prior to surgical closure is able to limit rates of infection in open fracture wounds, most probably through the reduction in oedema, management of wound drainage and the conversion of an open wound to a wound under temporary closure [7, 8]. Pursuing a strategy for early closure demands high confidence that debridement was adequately performed, yet relatively few studies have looked to improve the efficiency of the debridement process.

In a recent case report the alternative debridement technology VERSAJET™ Hydrosurgery was described for the excision of a contaminated upper extremity fracture [9]. A case series of 17 open fracture patients in which VERSAJET hydrosurgery was used in combination with nanocrystalline sliver dressings has also been reported [3]. The VERSAJET™ Hydrosurgery system offers a unique way of performing debridement: a high pressure fluid jet running parallel to the surface draws devitalized soft tissues into a cutting chamber for excision and evacuation. It is highly suited to excising concave and convex surfaces. VERSAJET Hydrosurgery has been studied in burns and chronic wounds with both case series [10, 11] and randomized studies [12, 13] having been reported. However, there have been no randomized studies to test

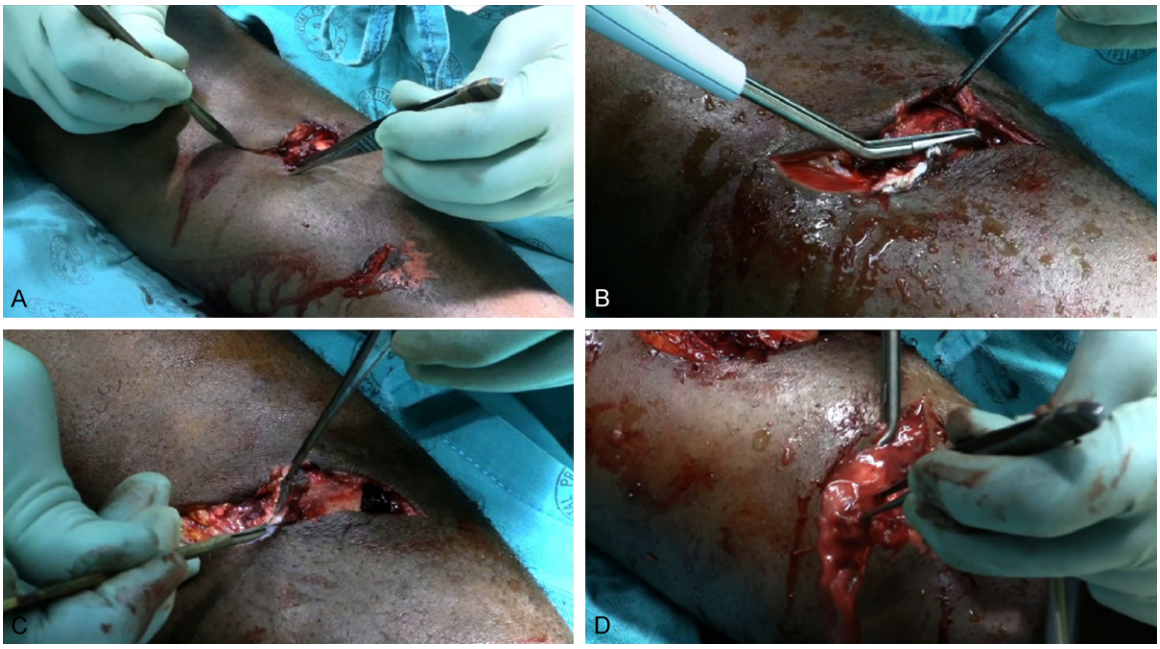

Figure 1. Illustration of the use of VERSAJET in this study: A. In both Standard and VERSAJET groups the wounds were extended with a scalpel where necessary. B. VERSAJET debridement was applied to all exposed areas of soft tissue. In the Standard group a scalpel was used to remove non-viable or contaminated tissue. C. In both Standard and VERSAJET groups where necessary the wound edges were formalized with a scalpel in preparation for delayed surgical closure. D. VERSAJET debridement was again applied to all exposed areas of soft tissue and bone ends following debridement of the medullary canal with a Volkman spoon. The image is a single frame taken from a video of the procedure at the point of contact with the bone end. This intercepts the fluid jet resulting in the momentary "gush" of fluid which is aspirated by the suction a few seconds later.

Table 1. Baseline patient characteristics

	VERSAJET	Standard
n	16	24
Age (y)	30.9	37.1
% male	81.3	83.3
% contaminated	26.7	29.2
IIIA	68.8%	37.5%
IIIB	31.3%	62.5%
Wound area cm^2 (median)	12.3	9.6
Time to 1st debridement (median)	1 day	1 day

the effectiveness of VERSAJET hydrosurgery in orthopaedic trauma.

The aim of this study was to assess the outcome of the VERSAJET hydrosurgery system in the treatment of Gustilo & Anderson grade III A and III B open tibia fractures using a pilot scale prospective randomized controlled trial against conventional surgery. The primary variable was the total number of debridements until wound closure. Secondary variables included time to wound closure and the total number of surgical procedures.

Materials & methods

VERSAJET hydrosurgery

The VERSAJET™ Hydrosurgery device (Smith & Nephew, St Petersburg, USA) consists of an electrically powered console and single use, disposable handpieces. The device operates at power settings of between 1-10; the higher the setting,the more aggressive the cut. Both 14 mm and 8 mm cutting windows are available on a 45° angle handpiece. A 14 mm cutting window is available on a 15° angle handpiece. VERSAJET tangentially excises tissues and removes soft tissue debris allowing good vision of the surgical field. VERSAJET will not cut hard tissue such as bone. VERSAJET Plus is a higher performance handpiece with more rapid and aggressive surgical cutting power than standard VERSAJET. In this study the 14 mm 45° VERSAJET Plus handpiece was employed.

Clinical protocol

A standard clinical protocol was employed for all patients. Surgical debridement was aimed

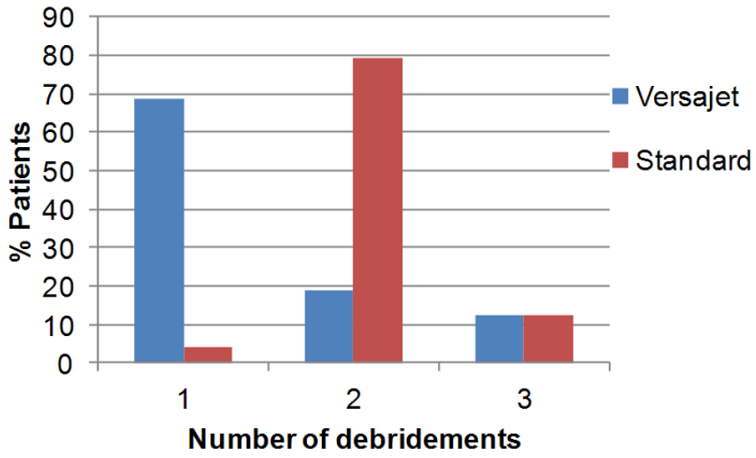

Figure 2. Number of debridements. Proportions of patients that achieved stable closure following 1, 2 or 3 debridement procedures as described in Materials and Methods in the VERSAJET or standard debridement groups.

to be performed within six hours of injury and administration of Cefazolin (1 g intravenously) was initiated in the casualty department and then 8 hourly thereafter for 5 days or till wound closure. Gentamycin at 1.5 mg/kg was administered intravenously as a single dose. The limb was washed with Hibiscrub™ mixed 1:10 with sterile water and hosed with 10 litres of sterile water. Patients were randomised to receive either surgical debridement (scalpel) or VERSAJET Hydrosurgery. The technique for use of VERSAJET Hydrosurgery is illustrated in **Figure 1**. 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). Note this resulted in an uneven number of IIIA and IIIB since randomisation to receive either VERSAJET or standard surgical debridement had already been made. 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 debridement, the wound was again washed with chlorhexidine solution and packed with gentamycin loaded polymethylmethacrylate (PMMA) beads and covered with an occlusive film dressing and wrapped with gauze dressings between 48 hour inspections. 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.

Statistical analysis

Accelerated failure time models were applied separately to the number of debridement procedures before wound closure, number of operating room surgical procedures before wound closure, and the number of days until wound closure to test for a difference between VERSAJET Plus and standard surgical debridement. Treatment, Gustilo and Anderson classification, area of devitalised tissue and surgeon were included as covariates in each of the models. The acceleration factors and corresponding 95% intervals were generated where appropriate. A Kaplan-Meier estimate was also used separately for the median number of debridement procedures to achieve wound closure and the median time to achieve wound closure by evaluation completion. The corresponding 95% confidence intervals were also presented. All data was summarised using summary statistics and 95% confidence intervals were generated where appropriate.

Results

A total of 40 patients were recruited. Sixteen patients were randomised to VERSAJET Plus™ hydrosurgery and 24 patients to standard surgical debridement. **Table 1** shows that baseline characteristics were well balanced with respect to the age (30.9 v 37.1 years; gender (81.3% v 83.3% males); contamination (26.7% v 29.2%) and wound area (12.3 cm^2 v 9.6 cm^2). There was some imbalance between treatment groups where more (68.8%) VERSAJET patients had III A classification; vs. (37.5%) standard surgical debridement patients which arose because debridement preceded final classification.

Figure 2 shows that the number of debridement procedures before wound closure was for VERSAJET: 1 procedure for 11 (69%) patients, 2 for 3 (19%) patients and 3 for 2 (12.5%)

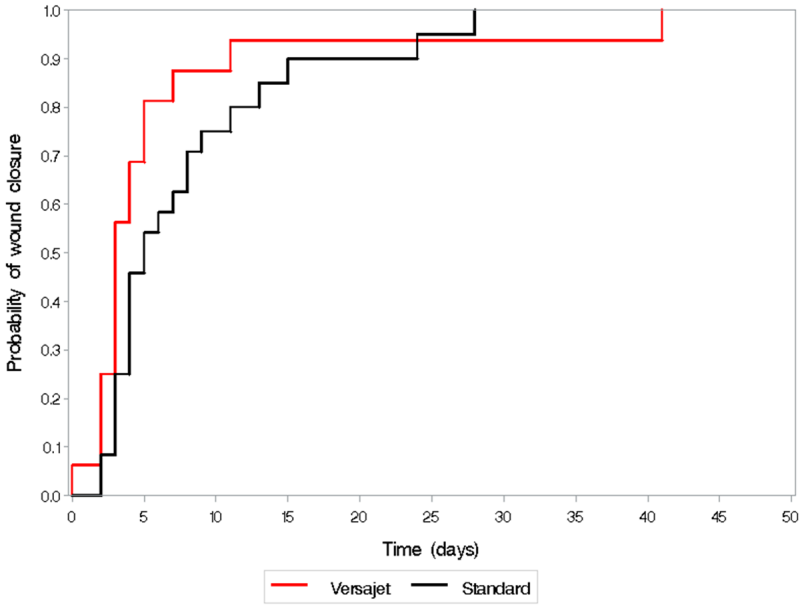

Figure 3. Kaplan-Meyer analysis of median time to closure. The estimates of the median time to wound closure was 3 days (95% CI (3 days, 5 days)) for VERSAJET and 5 days (95% CI (4 days, 8 days) for standard surgically debrided wounds, but the difference was not statistically significant (p = 0.275).

Table 2. Number of operating room surgical procedures before closure

Number of OR surgical procedures to wound closure	VERSAJET (N = 16)	Standard debridement (N = 23)*	Total (N = 40)
1	1 (6.3%)	0	1
2	13 (81.2%)	19 (79%)	32
3	2 (12.5%)	4 (17%)	6

*One patient switched to NPWT and with drew from the study before closure.

patients, whereas for standard surgical patients: 1 procedure for 1 (4.3%) patient, 2 for 19 (83%) patients and 3 for 3 (13%) patients (One standard patient switched to NPWT in view of a larger tissue defect and withdrew from the study before closure). There was no evidence that the number of debridement procedures to achieve wound closure differed between the Gustilo and Anderson grade IIIA and grade IIIB classifications (p = 0.692). 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). **Figure 3** shows the results of a Kaplan-Meyer analysis to estimate the median time to wound closure. Median days before closure was 3 days (95% CI (3 days, 5 days)) for VERSAJET debrided patients and 5 days (95% CI (4 days, 8 days) for standard debrided wounds but the difference was not statistically significant (p = 0.275). **Table 2** shows the number of surgical operating room (OR) procedures for both groups. There was no evidence (p = 0.397) of a difference in the total number of surgical operating room (OR) sessions required to close the wound (standard surgical debridement: VERSAJET = 1.040; 95% CI (0.950, 1.137) with typically wounds in both groups being closed in the second OR procedure. There were no instances of post-operative infection in either group.

Discussion

This study has compared the treatment of a group of Gustilo & Anderson grade IIIA and grade IIIB wounds treated with an existing standard protocol randomised between VERSAJET Hydrosurgery and standard surgical debridement. Although VERSAJET use was not exclusive; scalpel excision was used in both groups to extend the wounds and create wound edges suitable for primary closure, the majority of VERSAJET treated wounds needed only the initial debridement procedure prior to delayed closure and at inspection no further debridements were judged to be clinically necessary. In contrast, in the patients treated with standard debridement techniques, typically a further debridement was judged to be clinically necessary and most of the standard debridement patients received two excisions. The difference was statistically significant at (p < 0.001).

With respect to the timing of closure there was a trend towards the possibility of earlier closure following the use of VERSAJET compared with standard surgery but this was not significant in this study. In general this was because VERSAJET and standard wounds were both closed at the next scheduled operating room procedure. Although no further VERSAJET debridement was required, both VERSAJET and standard surgically debrided wounds were

closed at this OR session. The ability to proceed to immediate closure with skin grafting following debridement with VERSAJET has been previously described in contaminated and infected chronic or sub-acute wounds [11, 14, 15] but not in wounds typically closed with a delayed primary procedure. Vanwijck *et al.,* describe a series of 167 contaminated sub-acute and chronic wounds from 155 patients that were treated with VERSAJET Hydrosurgery, of these cases 95% were subject to immediate STSG grafting [14]. Comparable rates of 94% of wounds adequately debrided in one procedure were also observed by Matsumura and colleagues [15]. Furthermore, a large study of 469 chronic wounds by Mosti and colleagues [11] concluded that only 1 procedure was required in 108 patients, whereas 2 and 3 procedures were required in 27 and 7 patients respectively resulting in a shorter overall treatment time for debridement with Versajet (1.3 days) compared to standard moist dressings (4.3 days). Similarly, in burns, Klein et al. [16] reported successful excision using Versajet in one debridement procedure followed by grafting, with no repeat grafting in 44 patients.

The high degree of tissue preservation along with a significant reduction of necrotic tissue as demonstrated across patients with a variety of acute and chronic wounds by Matsumura and colleagues [15] provides further evidence to support the effectiveness of this type of debridement. Further randomised studies would be required to show whether the efficiency of the VERSAJET procedure would allow earlier closure as part of a pathway for the accelerated management of open fractures.

A criticism of the present study is that although randomised the decision of whether the wound required further debridement was made by surgeons knowledgeable of whether this patient had received VERSAJET or standard debridement. An improvement would have been to arrange to have an independent surgeon to make the judgement of whether further debridement was necessary. However, this would present many units with considerable logistical challenges and ours would be no exception. On a practical basis we found VERSAJET Plus generally to be easy to use and offered protection against tearing of surgical gloves when trying to carryout conventional surgical debridement in deep open fractures; a reassuring benefit in a population likely to be at risk for HIV infection. On the negative side the VERSAJET Plus was sometimes a little difficult to manipulate in small area wounds. An alternative would be to use the standard VERSJAT Exact handpiece which uses a smaller head. The spray that resulted from the high pressure water contacting the bone was a problem to some surgeons regarding HIV and Hepatitis risk. Surgeons should wear surgical masks and protective eyewear when using the VERSAJET.

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