

Negligible particle aerosolization and bacterial dispersion limited to treatment area during debridement with the VERSAJET[®] II Hydrosurgery System in an ex vivo model of infected tissue

+ Plus points

Negligible aerosolization of debridement particles¹

Minimal bacterial dispersal that was **limited to the treatment area**¹

Decreases in bacterial colony counts in the treatment area as debridement progresses may be due to successful removal of infected tissue¹

Study aims and background

The VERSAJET Hydrosurgery System is used for debridement of acute and chronic wounds, burns and soft tissue, as well as for cleansing surgical sites that require sharp debridement and pulsed lavage irrigation.²

The VERSAJET System enables a surgeon to hold, cut and remove damaged tissue and contaminants while simultaneously irrigating a wound using a high velocity stream of sterile saline.^{3,4} Irrigation fluid from the wound is immediately evacuated into a container, minimizing saturation of debridement area and reducing the risk of splashing and aerosolization.^{3,4}

The aim of these laboratory studies using the VERSAJET II System was to understand the potential for spray, bacterial contamination, aerosol particle production and dispersal during and after debridement of infected tissue, specifically:¹

- Extent of particle aerosolization during debridement (assessed using aerosol particle monitors)
- Bacterial spread within the treatment area (assessed using agar settle plates)

Methods

Aerosolization and bacterial dispersal studies

A porcine ex vivo tissue model was used in this study to simulate a patient with an infected wound.¹ Wounds (100x100mm) were created using scalpels, and within the wound area, gentle scoring was used to create a grid pattern of 10x10mm squares.¹ The entire wound area was inoculated with 5mL of streptomycin-dependent *Escherichia coli* (50µL/10mm² of 1x10⁶ colony forming units/mL) and then the tissue was incubated at 37°C (human body temperature) for 16 to 18 hours.¹

After incubation, a single user performed debridement using a conventional scalpel or the VERSAJET II System at each of three power settings low (level 4), medium (level 7) and high (level 10) on the wound areas for 30min. Another person opened agar settle plates at 0, 5, 10, 15, and 30min during debridement and 45, 105 and 165min after debridement, and activated aerosol particle monitors (5min exposure time for all).¹

There were eight agar settle plates for each zone (one per time point). One extra agar settle plate was used before debridement to assess background levels.¹ All agar settle plates were incubated at 37°C within 30min of the experiment and checked for growth after 24 and 48 hours.¹

The aerosol particle monitor was placed directly in front of the treatment (debridement) area. Experiments were performed in triplicate.¹ The study room set up is shown in Figure 1.

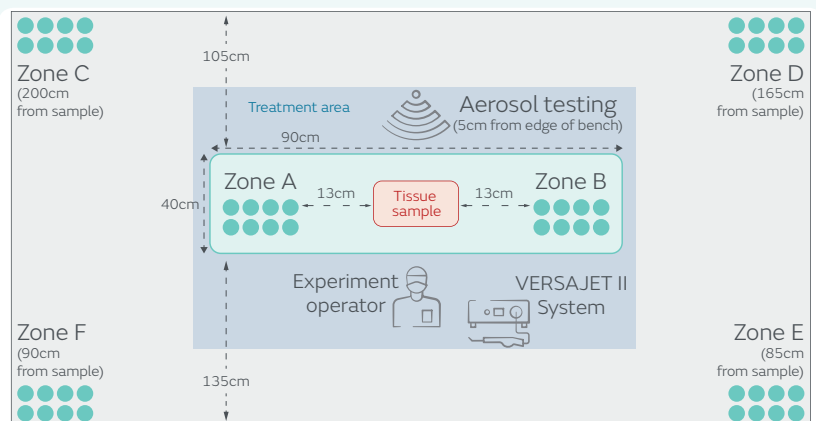


Figure 1. Schematic representing the room layout (3.3x2.8m; not to scale) for aerosolization (particle monitor) and bacterial dispersal studies (agar settle plates; Zones A to F)¹

Key findings

Aerosolization

- The weights of the aerosol particle monitor membrane filters were recorded before and after conventional sharp debridement and use of the VERSAJET[®] II System¹
- There were no noteworthy changes to mass of the membrane filters indicating no substantial aerosolization of debridement particles using conventional sharp debridement with a scalpel or using the VERSAJET II System (Figure 2)¹
- Most changes in mass were small (<0.001g) and negative, suggesting reductions in weight¹
 - This may have been due to the membrane filters drying out or mass changes below the limit of detection for the scales¹

No substantial aerosolization

with the VERSAJET II System

(no meaningful changes in membrane filter mass)¹

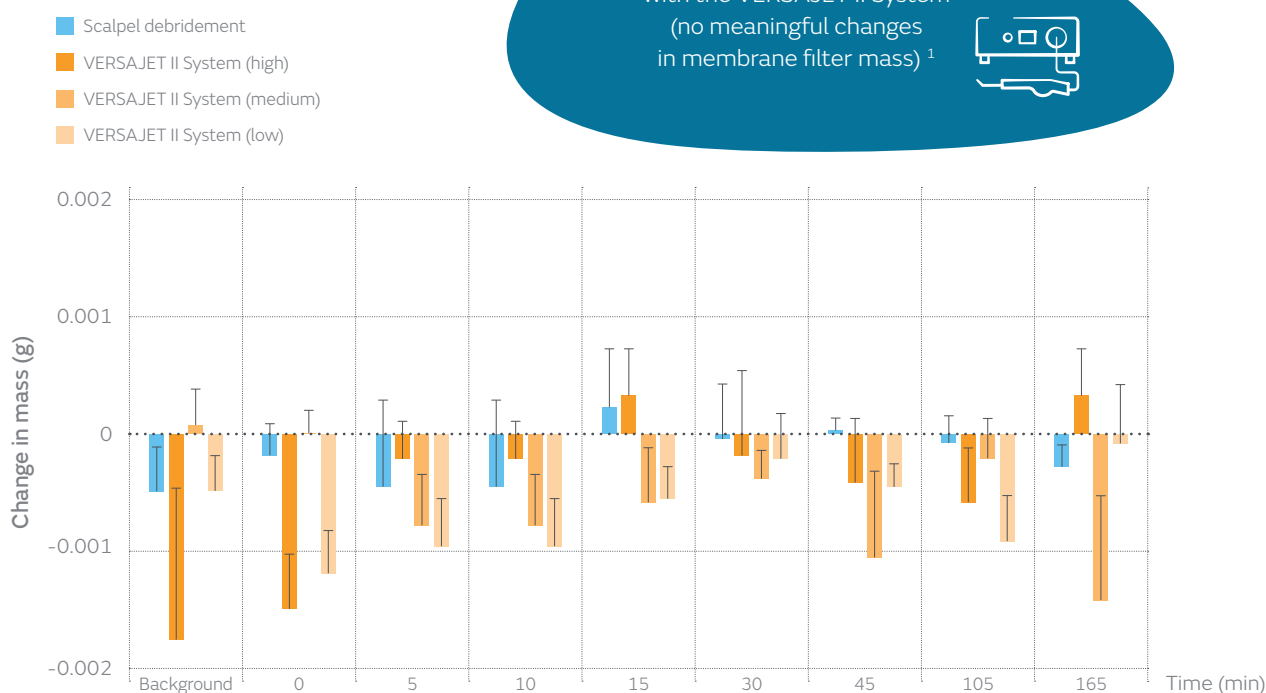


Figure 2. Mean (standard deviation) changes in membrane filter mass over time using conventional sharp debridement and the VERSAJET II System at three power settings (low, medium and high). Most changes were small and negative suggesting reductions, rather than increases, in weight¹

Bacterial dispersal

- At all debridement power settings evaluated (low, medium and high) and at all time points assessed, no colonies were isolated on agar settle plates in the corners of the room (Zones C to F; Figure 1) using the VERSAJET II System¹
 - Any aerosolization that did occur was unable to disperse viable bacterial colonies to the outer corners of the room¹
- Some colony growth was detected in close proximity to the treatment area (Zones A and B; Figure 1) with use of the VERSAJET II System¹
 - Overall, bacterial dispersal in the treatment area (Zones A and B) was greatest using the low power setting for the VERSAJET II System (level 4) compared with the other two power settings tested (levels 7 and 10; Figure 3)¹
 - Colony counts were slightly greater in Zone B than in Zone A and were greatest within the first 10min of starting debridement¹
 - No further bacterial dispersal was observed after the period of debridement using the VERSAJET II System (on agar settle plates opened after 30min)¹

+ Evidence in focus

Preclinical evaluation

Bacterial dispersal only occurred during debridement **within the treatment area** and mostly when using the low VERSAJET® II System setting¹

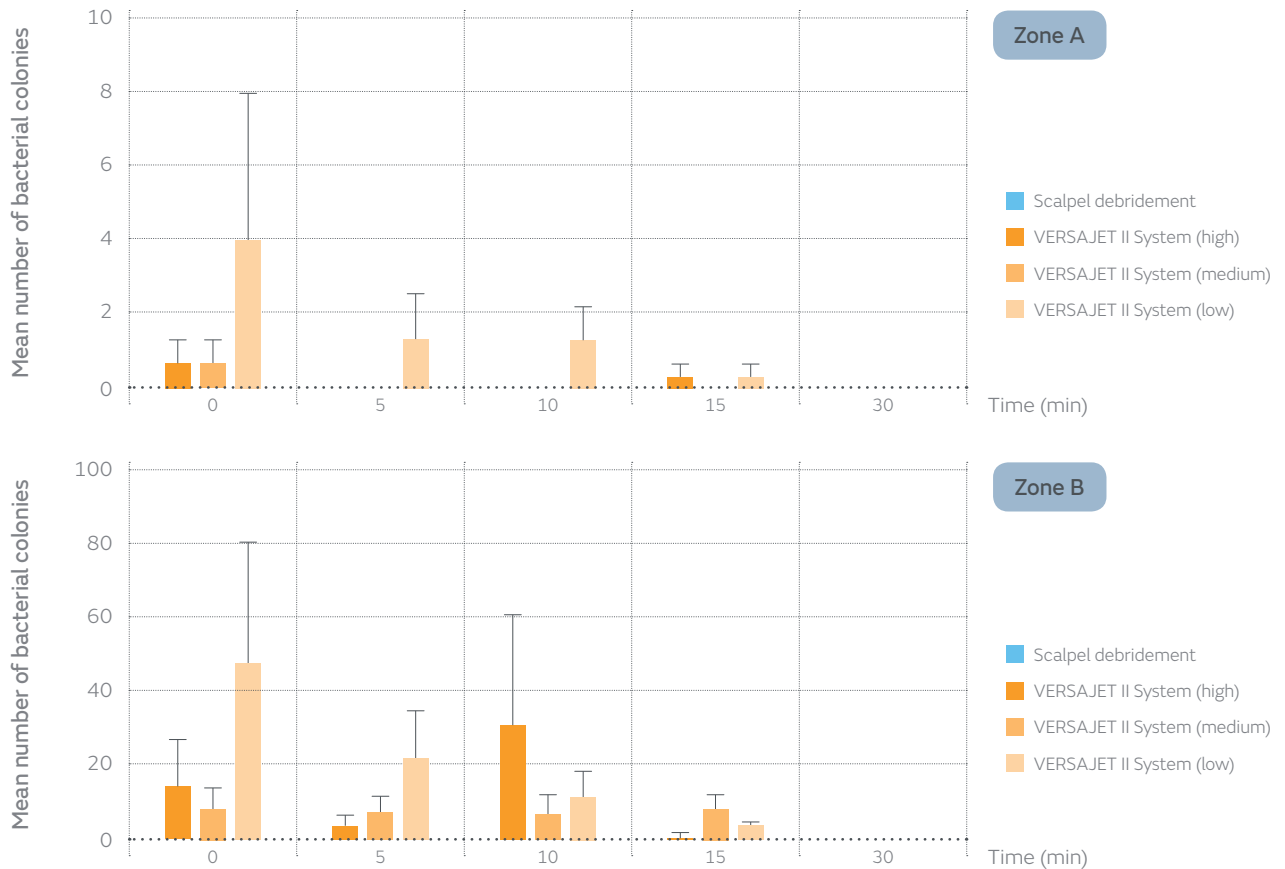


Figure 3. Mean (standard deviation) bacterial colony count in Zones A and B (closest to the debridement area) over time using the VERSAJET II System. No colonies were detected on agar settle plates in either zone at any time point with scalpel debridement or after 30min (end of debridement) using the VERSAJET II System¹

Considerations

Decreases in bacterial colony counts in the treatment area (Zones A and B; Figure 1) as debridement progressed may have been due to successful removal of infected tissue leaving uninfected tissue for the remainder of the debridement period.¹

Dispersal of bacteria may have been the result of spray during saline bag changes due to priming of the headpiece, which in clinical practice may be changed less frequently than was done in these experiments.¹

During the study, direction of the spray and distribution of colonies may have been influenced by user technique and the hand used (left or right) to perform debridement, which may indicate areas of likely contamination and inform cleaning protocols.¹

The investigators noted that spray was more likely to occur when the headpiece of the VERSAJET II System came into contact with fat or fascia rather than lean tissue.¹

Summary

- Aerosolization of bacteria in the treatment room during debridement with the VERSAJET II System was negligible.¹
- Localized dispersal of bacteria occurred only within the treatment area, mostly within the first few minutes of use.¹
- These findings suggest that appropriate training to optimize user technique may help to minimize bacterial dispersal when using the VERSAJET II System in the clinical setting; they also help to inform appropriate infection control measures (eg, high hygiene standards and adapted cleaning protocols).¹

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use

References

1. Motion E. The ex-vivo assessment of the potential bacterial aerosolization and spray when using VERSAJET® II Hydrosurgery System. Data on file, report DS/20/289/R Version 1, 23 April 2020.
2. VERSAJET® II Hydrosurgery System user guide. PI3926A. September 2012. Available at: <https://www.smith-nephew.com/global/assets/pdf/products/surgical/versajet%20ii%20hooper%20user%20guide%20pi03926a%20final.pdf>. Accessed 24 April 2020.
3. Granick MS, Posnett J, Jacoby M, Norrthun S, Ganchi PA, Datsishvili RO. Efficacy and cost-effectiveness of a high-powered parallel waterjet for wound debridement. *Wound Repair Regen.* 2006;14(4):394-397.
4. Mosti G, Iabichella ML, Picerni P, Magliaro A, Mattalino V. The debridement of hard to heal leg ulcers by means of a new device based on Fluidjet technology. *Int Wound J.* 2005;2(4):307-314.