A Pilot Study of Two Techniques for Wound Debridement

Purpose
The purpose of this study was to obtain some initial data comparing the VERSAJET™ Hydrosurgery System (Smith & Nephew, Inc.; Largo, FL) to traditional methods of traumatic wound debridement.

Methods
A total of 20 patients between the age of 18 and 65 with an open soft tissue or an open fracture wound were to be evaluated. The VERSAJET Hydrosurgery System was directly compared to sharp Debridement in conjunction with pulsatile lavage using the Zimmer Pulsavac system. Patients presenting with open soft tissue wounds or open fracture wounds were randomized to one of two treatment groups—VERSAJET or Pulsavac. A number of parameters were evaluated, including number of procedures required, time required for debridement, length of time to closure of the wound and the amount of saline that was used.

Results
At the time of this summary, the study had enrolled eight patients for a total of 15 debridements. Four patients with four wounds were enrolled for the VERSAJET system and four patients with eight wounds were enrolled for the Pulsavac. The table shown summarizes many of the parameters studied.

Conclusions
At this time, all but one patient has been released from the hospital with no documented complications to the debridement procedures. There is a trend for fewer debridement procedures, using less saline and faster time to closure using the VERSAJET Hydrosurgery System. The study size was too small to draw conclusions with high levels of statistical significance and therefore a larger study would be needed to confirm these findings.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>VERSAJET™</th>
<th>Pulsavac</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debridement Time in Min</td>
<td>7.68 ± 4.51</td>
<td>8.92 ± 6.39</td>
</tr>
<tr>
<td>Debridement Time/Wound Size</td>
<td>0.70 ± 0.37</td>
<td>0.83 ± 1.0</td>
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<tr>
<td>Saline Used in cc</td>
<td>930 ± 489.5</td>
<td>2878.3 ± 1434.5</td>
</tr>
<tr>
<td>Saline Used/Wound Size in cc/cm²</td>
<td>108.07 ± 77.32</td>
<td>167.5 ± 136.9</td>
</tr>
<tr>
<td>Time to Closure in Days</td>
<td>2.25 ± 2.86</td>
<td>6 ± 4.92</td>
</tr>
<tr>
<td>Number of Procedures</td>
<td>1.33 ± 0.47</td>
<td>2.25 ± 1.20</td>
</tr>
<tr>
<td>Contamination Level*</td>
<td>2 ± 0**</td>
<td>1.75 ± 0.83</td>
</tr>
</tbody>
</table>

* Average contamination levels were determined by assigning 1 to high, 2 to medium, 3 to low.
** Contamination levels for the VERSAJET were calculated from two patients as other data were not available.
***Test results shown were derived from an earlier generation device trademarked as TraumaJet.
Traumatic and Chronic Wound Debridement With A Novel Fluidjet Device: The VERSAJET® Hydrosurgery System

Introduction

Standard surgical debridement of traumatic wounds is tripartite. First, gross debridement is performed utilizing a scalpel and scissors to remove obviously necrotic or devitalized tissue. Second, the wound area is subjected to a pulsed saline lavage of several liters. Third, sharp debridement of any tissue now shown to be devitalized is completed.

This three-step standard approach can be time-consuming. Further, the irrigation phase is often accompanied by saturation of the operative field, splashing of irrigant onto the floor and droplet aerosolization. These unwanted events can create significant hazards within the operating suite.

A novel fluidjet device has been introduced that is designed to address these concerns with a single instrument. The VERSAJET® Hydrosurgery System (Smith & Nephew, Inc. Largo, FL) enables the surgeon to hold, cut and remove damaged tissue and contaminants while simultaneously irrigating the wound. Surgical debridement is accomplished in a single step. Further, the device utilizes a relatively small amount of irrigant which is immediately evacuated, minimizing saturation of the operative field and reducing the risk of splashing and aerosolization.

To date, we have treated over twenty-five (25) patients with the VERSAJET Hydrosurgery System. This paper presents our clinical results using this novel instrument.

Methods

The patients included in our 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 VERSAJET Hydrosurgery System consists of a reusable power console and a disposable handpiece (Figure 1).

The HydroDrive Console is activated by a foot pedal and utilizes a fluid supply bag for irrigant and a standard waste receptacle for effluent. The VERSAJET Hydrosurgery Handpiece is a fluidjet-powered surgical tool available with a 14 mm operating window with a choice of a 15° or 45° angle tip, as well as an 8 mm operating window with a 45° angle tip.

The VERSAJET System is based on HydroDrive technology. A high velocity stream of sterile saline created by the Console jets across the operating window of the Handpiece and into an evacuation collector. This creates a localized vacuum—a Venturi effect—which can hold the tissue within the operating window (Figure 2).
Handpiece orientation relative to the tissue determines the tissue effect. When the operating window is oriented parallel to the tissue, the result is controlled, precise excision with concomitant aspiration (Figure 3A). When the operating window is oriented obliquely to the tissue, wound irrigation and contaminant removal is the primary effect (Figure 3B).

In addition to alteration in Handpiece orientation, we controlled depth and speed of debridement via three mechanisms. First, we adjusted console power settings as necessary. Second, we varied the speed at which we moved the Handpiece across the tissue plane. Finally, we altered the contact pressure applied to the tissue with the Handpiece. In each case, all debridement was performed under direct vision.

Results
In all cases debridement was rapidly performed using this device alone. In no case was more than one (1) liter of irrigant required, despite extensive utilization of the device. These points are illustrated by the case reports that follow.

Case Reports
Rapid Burn Eschar Resection
A 19-year-old woman was alighting from her disabled vehicle on the shoulder of an interstate highway when her vehicle was struck, wedging her between the vehicle and the guardrail. In this position, the dorsum of her foot was held in contact with the catalytic converter thus inflicting a full thickness burn (Figure 4).

During surgical burn excision, the wound was circumscribed with a scalpel, and the VERSAJET System was used to develop the plane between burned skin and viable subcutaneous tissue (Figure 5). Light Handpiece contact pressure rapidly removed eschar; concurrently, injury to the veins of the foot dorsum was avoided, minimizing bleeding (Figure 6). A split thickness skin graft was applied with subsequent 100% successful incorporation.
This patient also sustained a crush-type degloving wound of the ipsilateral thigh that extended well down into the soft tissue of the thigh. As the wound was beyond the reach of the Handpiece, traditional sharp debridement and pulsed lavage were required to treat this wound. Compared to wound treatment with the VERSAJET™ System, this traditional approach was more time-consuming.

**Deep Debridement of Foot Gunshot Wound**

An 18-year-old male sustained a through-and-through gunshot wound to the foot. The wound was grossly contaminated as the bullet went through the patient's sneaker. In order to minimize risk of infection, the wound was surgically debrided.

After the removal of grossly visible sneaker cloth remnants, the VERSAJET Handpiece was inserted into the wound (Figure 7). During advancement, the device was rotated 360°. Full rotation was also carried out during device withdrawal. As a result, a thorough, circumferential deep debridement of the wound was achieved.

In this case, traditional local wound exploration would have required enlargement of the wound via dorsal and plantar incision. If this approach had been necessary, there would have been a substantial increase in postoperative morbidity due to pain and risk of infection—consequences which were avoided by the use of the VERSAJET System. The patient made an uneventful recovery and was discharged with a cane on postoperative day 3.

**Complete Defatting of Full Thickness Scalp Replant**

A 47-year-old male was the unrestrained driver in a high-speed motor vehicle crash. His face and frontal scalp were propelled through the windshield by the deceleration, which resulted in avulsion of a “skull cap” shaped, 3 cm x 5 cm injury at the vertex. The tissue was physically attached to the remaining scalp by a bridge of obviously devitalized tissue.

In the operating room, the avulsion was completed by dividing the skin bridge. The amputated scalp was then inspected. The viability of the tissue was uncertain but it was felt reasonable to attempt reattachment. The VERSAJET System was used to rapidly and completely defat the scalp tissue, leaving no islands of subcutaneous fat. Using this device, we were able to keep the dermis intact, avoiding “button hole” defects in the skin.

Subsequent inspection of the replanted area showed the tissue to be non-viable and a plastic surgery consult was initiated. The replanted tissue was removed and a scalp advancement flap was performed to achieve wound closure.

**Resection of Necrotic Muscle Compartment through Minimal Incision**

A 35-year-old morbidly obese woman was the front seat, unrestrained passenger in a high-speed motor vehicle crash. She sustained an anterior dislocation of the right knee severing the popliteal artery and vein. Vascular reconstruction of both the artery and vein was completed and an anterior compartment fasciotomy was performed through a 10 cm incision. At the time of surgery, the other compartments were open due to the injury.

The arterial repair was patent but subsequent ultrasound studies showed venous thrombosis. Anticoagulation was initiated and inspection of the anterior compartment revealed the muscle to be non-viable.

Using the VERSAJET System, the entire anterior compartment was simultaneously debrided, lavaged and resected. 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. A KCI
Vacuum-Assisted Closure® System was used to promote wound healing.

Debridement of Necrotizing Soft Tissue Infection
A 55-year-old man “picked” at a pimple on the back of his neck. Three days later, his neck, shoulders and upper chest were profoundly edematous and he was in impending respiratory distress.

In the operating room, generous debridement was performed through parallel incisions extending from the back of the neck onto the chest in a collar-like, curvilinear fashion. He was subsequently taken back to the operating room for placement of a tracheostomy and further debridement of necrotic tissue (Figure 8).

During the second operative debridement, the VERSAJET™ System was used. 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.

After two additional operative debridements performed with the VERSAJET System, split thickness skin grafts were placed to cover the wounds which could not be primarily closed. The patient made a full recovery.

Debridement of Sacral Decubitus Pressure Ulcer
A 79-year-old male—a long time nursing home resident—presented with pneumonia. He was treated in the medical intensive care unit with mechanical ventilation and antibiotics. His recovery was slow and he experienced prolonged, ventilator-dependent respiratory failure. During this time, he developed a large sacral decubitus ulcer and a consult with the surgical service was initiated.

The decubitus pressure ulcer was 12 cm x 15 cm and required operative debridement. First, the wound was circumscribed with a scalpel and the VERSAJET System was used to detach the necrotic skin and subcutaneous tissue. After this tissue was removed, the surgery proceeded rapidly with efficient debridement of necrotic fat to the required depth using continued, gentle strokes with the VERSAJET Handpiece. Importantly, the device simultaneously lavaged the wound, thus saving the operative time usually required for that component of traditional debridement.

Discussion
Clinical Benefits
Significant clinical benefits derive from the ability of the VERSAJET System to effect surgical debridement while providing concurrent lavage. In our experience with this new system, wound debridement is efficient and straightforward, reducing operative time.

With the VERSAJET System, tissue excision is precise, avoiding damage to healthy tissue or vasculature. In addition, the design of the VERSAJET Handpiece allows access for debridement without the need to enlarge the wound, reducing postoperative morbidity and promoting wound healing.

The VERSAJET System also requires significantly less irrigant than traditional lavage techniques, confines the irrigant to the wound area, and provides immediate fluid evacuation. With the VERSAJET System, the need to frequently change large saline irrigant bags and multiple suction reservoir waste canisters is substantially reduced. Immediate evacuation of the irrigant also eliminates soaking of the operative field.

In this era of concern about communicable disease, prevention of droplet aerosolization is a critical goal within the operating room suite. This is especially true when treating trauma patients—a population known to have a higher incidence of viral infection. The design of the VERSAJET Handpiece reduces the risk of aerosolization thereby offering another important benefit to the surgical staff and patients alike.

The Learning Curve
We have found the VERSAJET System to be a very intuitive device, allowing operative debridement to progress in the same manner as traditional approaches. Very little formal training is needed since the surgeon is not required to learn any new operative principles. The only requirement is mastery of a new instrument—not a new procedure. This process proceeds rapidly, even for
less experienced surgeons and residents.

It is important, however, for the surgeon to develop a “feel” for debridement and lavage energy at low (3–5), moderate (5–8), and high (9–10) power settings. It is also essential that the surgeon develop skill in rapid manipulation of the contact pressure applied to the tissue with the Handpiece. Contact pressure that is too light will produce lavage with little debridement. Contact pressure that is too heavy will cause overly deep debridement and device clogging.

When performing the first case with the VERSAJET® System, the Console should initially be set to low power settings (3–5). Early use of high power should be avoided as it will result in unintended, overly aggressive debridement. As the case progresses, however, and the surgeon gains a feel for the level of debridement and lavage energy, the power setting can be increased to moderate power settings (5–8). For the next case, the Console can be initially set to moderate power settings (5–8). Typically, by the end of that case or during the next, there is rapid progression to comfort with utilization of high power settings (9–10).

**Learning Tip: Laboratory Practice**

Laboratory practice is an excellent way to master operation of the VERSAJET System. An illustrative model is easily assembled by using chicken pieces from the grocery store. First, a grater is used to shred the chicken tissue. Then particulate matter such as pepper, soot or India ink is applied. The preliminary grating allows placement of the particles into all the “nooks and crannies” to more accurately represent a grossly contaminated traumatic wound.

**Conclusion**

The VERSAJET Hydrosurgery System has substantially simplified the debridement of wounds. Using the VERSAJET System, debridement of traumatic wounds, chronic wounds and other soft tissue lesions is accomplished rapidly and precisely, sparing healthy tissue and promoting healing. Additionally, use of the system minimizes exposure to droplet aerosolization in the operating suite.

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1 The FDA cleared indications for the VERSAJET System state “this device is not intended to be used on burns.”
High Pressure Parallel Fluid Flow for Debridement of Contaminated Wounds in a Pig Model

Purpose
Contaminated wounds must be meticulously debrided to ensure removal of all foreign particles and necrotic tissue; any residual particles or necrotic tissue can become a nidus for infection. The current standard of care is sharp (scalpel) debridement with pulsatile saline lavage washes. Debridement of large or heavily contaminated wounds is labor and time intensive. A novel debridement device that uses high-pressure, parallel flow fluid was evaluated for its ability to debride wounds deliberately contaminated with bacteria and particulate material in a pig model.

Methods
Four 25 kg white Chester pigs were procured. The animals were anesthetized and four pairs of 5 cm x 5 cm wounds were created in two parallel rows, one on each side of the spine. The wounds extended through the skin and fascia to the deep back muscles. 108 Staph. aureus organisms, 0.5 gram talc, and 1.0 gram of iron particles were placed into the wound. All wounds were dressed and allowed to 'mature' for 24 hours. After this time, the animals were reanesthetized. Surgeons (n=5) were instructed to debride one wound of each pair with scalpel and pulsatile lavage, the other with the parallel fluid flow device. Wounds not being treated were covered with a thin film dressing to prevent cross contamination.

Factors examined include: tissue bacteria counts; time required for debridement; volume of saline used; particulate matter (measured with x-ray); particulate removal (histology); and scanning laser Doppler imaging.

Observations
Wounds debrided with the parallel fluid flow device required significantly less time (11:14 +/- 3:52 minutes) than scalpel and pulsatile lavage (17:08 +/- 3:13 minutes) (p<0.001). Wounds debrided with the parallel fluid flow device required significantly less saline (1.92 +/- 0.58 liters) than scalpel and pulsatile lavage (5.04 +/- 1.66 liters) (p<0.001). Both techniques were equally effective in removing bacteria and particulate matter from the wounds as determined by quantitative bacteriology, x-ray and histologic analysis. Scanning laser Doppler images showed similar levels of perfusion following both treatments.

Conclusions
The novel high-pressure parallel fluid flow device was as effective for debridement of bacterial and particulate contaminated wounds as the scalpel and pulsatile lavage, the current gold standard for wound debridement. The parallel fluid flow device required significantly less time and less saline than debridement with scalpel and pulsatile lavage. With current budget concerns related to medical care, the high-pressure parallel fluid flow device shows great promise. It effectively debrided wounds in less time and required less materials than the current standard of care.

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A Phenomenological Description of Fluidjet Cutting

To our knowledge, there has been no scientific study of how fluidjets cut and ablate biological tissues, how the mechanism may vary among different tissues, and how that mechanism compares to other methods of cutting and ablating. The following is our best understanding of the phenomena involved, based on extensive experience with fluidjets by HydroCision:

Homogeneous Materials in Gaseous Environments

Visualize a homogeneous material such as plastic. Obviously, a jet of fluid at low power (governed by the pressure forcing the jet through a tiny orifice) will merely bounce off the surface of the material. As the pressure is increased, the jet will reach a power level that exceeds the cohesive force between the molecules of the material, such that the material will begin to erode and a hole will be started. The power in the jet beam will be dissipated as energy is converted into momentum of the ablated particles of material, as well as in separating the particles initially. In addition, some energy will be dissipated by recoil of the jet from the bottom of the hole. The power of the jet beam must be sufficient to exceed the "ablative energy threshold" of these dissipational modes through the full thickness of the material to be cut.

The jet beam cutting ability is best characterized by its energy per unit area, where kinetic energy is \( \frac{1}{2}mv^2 \), with \( m \) as the mass of the fluid/unit time and \( v \) as the velocity of the beam. As this formula implies, a higher velocity of the jet is more important than a high mass. Therefore, a very small diameter beam, traveling at a high velocity, is more effective than a larger diameter beam traveling at a lower velocity. It is therefore desirable to maintain the jet diameter as small as possible. Further, it is important to maintain the beam as coherent as possible, i.e., to avoid divergence of the jet beam as it travels away from the jet-emitting orifice (nozzle). Of equal importance is the ability to achieve very high jet velocities by generating very high pressures (typically 10,000 to 20,000 psi) to force the jet beam through the nozzle. Simply stated, device designs that achieve a small diameter, highly coherent, high-velocity jet result in the ability to cut thicker materials. The maximum thickness will be proportional to the pressure behind the jet of fluid.

Other methods of cutting involve very different mechanisms. If the material is brittle, a mechanical method such as a blade can cut by cracking the material. Thermal methods such as a laser, can cut by melting, or by spalling, or by a combination of both. In any case, however, the energy in the cutting method, translated into force per unit area, is the critical parameter. Fluidjets can develop substantial energy (capability of doing work). If one assumes a jet orifice cross sectional area of 100 mm\(^2\), a jet pressurized to 10,000 psi will then contain 4.7 megawatts of power, assuming that the nozzle is frictionless. Since, as noted above, it is desirable to minimize the diameter of the jet, most effective devices utilize nozzle areas much smaller than 100 mm\(^2\), with about 0.01 mm\(^2\) being typical. In this configuration (still assuming a frictionless nozzle) the power at 10,000 psi will be approximately 600 watts or about 0.8 horsepower.

Inhomogeneous Materials in Gaseous Environments

Most surgical applications of fluidjets involve inhomogeneous (at least at the microscopic level) biological tissues. Wound debridement, skin resurfacing and several laparoscopic procedures exemplify applications in gaseous media. Fluidjets
cut inhomogeneous materials by following the path of least resistance through the material. A simplistic example is a garden hose directed onto gravelly soil. The water does not cut through the rocks; it goes around the rocks and penetrates through the softer soil. Similarly, when cutting tissue, the jet, if it contains sufficient energy, will find its way between materials of higher density.

It is instructive to consider the difference between a blade and a fluidjet in this sense. Consider hypothetically, a local “inclusion” of higher density tissue embedded in softer tissue. A blade has no ability to find its way around that inclusion, so it either, 1) stops the cutting action because the blade has insufficient energy to cut through it, or 2) pushes the inclusion to one side, thus creating damage in the softer tissue impacted by the inclusion, or 3) pushes the inclusion ahead of it through the tissue, thus creating damage in a cross-section of tissue larger than the cross-section of the blade. The worst case is represented by an inclusion that is connected to an additional tough tissue (such as stromal matrix), such that dragging of that inclusion can also drag tissue from distances quite remote from the blade.

The above considerations also apply with a fluidjet cut, but with some differences. Notably, if there is insufficient energy in the jet beam to cut through even the softer tissue, it will lose its directional momentum and be deflected randomly into the surrounding tissue. Whereas this may not cause significant damage, it will still result in “edematizing” a surrounding area, i.e., swelling the area by capture of the jet fluid. This emphasizes the importance of having sufficient energy in the beam to penetrate the tissue completely before losing enough directional momentum for this phenomenon to take place. Given sufficient energy in the jet beam, if the jet beam impinges in the tougher inclusion, it can either cut through it, or find its way around the inclusion with a minimum of damage. In particular, a fluidjet beam has a very high momentum, so it is more likely to cut through the inclusion and continue on its way, whereas a blade (which has a very low momentum) is more likely to push the inclusion through the softer tissue rather than cutting through it, thus creating a track of damage through the tissue.

Jet pressures well in excess of 10,000 psi are required to cut cleanly through about four millimeters of relatively soft tissue (up to the toughness of meniscal tissue). At greater thickness of tissue, the beam energy is insufficient to maintain its directional momentum. Nevertheless, the softer the tissue the greater the thickness that may be cut, so it is feasible to contemplate cutting tissues effectively well over a centimeter in thickness, particularly if it is quite soft, as in the case of parenchyma tissue.

Considering other methods, thermal effects generally dominate laser cutting, with excimer lasers (so-called “cold lasers”) being the least damaging type of laser. Excellent cuts may be achieved with lasers in homogeneous materials, but since lasers depend on the absorptive and thermal diffusivity properties of the material to be cut, it is very difficult to predict the extent of damage in a laser cut, unless those properties are taken into account for each of the different materials making up the inhomogeneous material to be cut. For example, if the inclusion in the above hypothetical model is highly absorptive at the laser wavelength, the inclusion can reach a very high temperature. If the inclusion is non-absorptive, the laser beam can be deflected and create thermal damage in the contiguous areas.

Radiofrequency (RF) devices can also cut. The electrosurgical pencil is very capable of cutting tissue, but also creates considerable thermal damage at the site. (Such thermal damage can, of course, be desirable when cautery is needed.) Multiple electrode RF devices are not effective for cutting but can perform ablation at some risk of thermal damage to the underlying tissue. Ultrasonic scalpels create less damage, but do not appear to be capable of ablation and are most useful over a scalpel when mild cautery is required. It is evident that when thermal damage to surrounding tissue is an issue, the totally non-thermal fluidjet is an option requiring consideration.

**Materials in Liquid Environments**

Applications in liquid environments are exemplified by arthroscopic, urological and gynecological procedures that are conventionally carried out under irrigation fluid. When fluidjets are operated...
under liquids, they exhibit perhaps their most remarkable characteristic. When the above general parameters of operation are employed, the jet velocity approaches the speed of sound in water. This extreme velocity creates enormous shear forces as it travels through the surrounding liquid. These forces give rise to the well-known phenomenon of “cavitation,” i.e., the creation of microscopic bubbles of fluid vapor that form and collapse in microseconds. The collapse of these microbubbles result in tremendous abrasive action on any material they touch. An example is the erosion of ship propellers by cavitation, a well-known phenomenon. The fluidjet therefore displays an even more effective cutting and ablating action when utilized under fluid.

The cavitation yields two additional beneficial effects. First, it makes the fluidjet beam visible, since the surrounding cavitation reflects light and causes the beam to appear white. Secondly, when the cavitation is “captured” as with VERSAJET’s proprietary designs, it provides a secondary maceration of any material removed in the cutting or ablation, so the excised tissue is reduced almost to a cellular level and therefore does not give rise to clogging of effluent conduits, even if the very small diameters required for many difficult to access surgical applications.

Finally, when operated in liquid environments, fluidjets can be designed to act as “eductor pumps” and thus create a vacuum at the point where the fluidjet is captured along with the cavitation. Because of the shear forces, surrounding irrigation fluid is drawn into the jet and this enhances the aspiration of detritus, when the device is properly designed. Commonly, about two-thirds of the aspirated fluid will be irrigation fluid and one-third will be jetfluid (usually sterile saline). Compared to other methods of cutting and ablating, fluidjet devices conforming to VERSAJET’s proprietary design parameters appear to be far more capable of removing excised material from a surgical site at precisely the point where it is generated, thus decreasing the risk of visually obstructing the site and, importantly, the risk of leaving unwanted biological contamination in the surgical field.

Summary
It is instructive to view the various cutting methods discussed above in a negative light and consider the disadvantages that each may engender. The most important disadvantage of fluidjet cutting is that high-beam energy is required to fully penetrate tissue without losing is directional momentum. With insufficient beam energy, the tissue will not be fully penetrated and edema may be caused in surrounding tissue. This disadvantage is not present with VERSAJET’s very high energy fluidjet when used for cutting and/or ablating most tissues involved in surgery.

The most important disadvantage of mechanical cutting methods, such as blades either manually employed or automated (as in “shaver” cutters), is a tendency to damage a greater volume of contiguous tissue by pulling, dragging, or pushing harder portions of tissue through softer regions. Whereas fluidjets having the ability to penetrate several millimeters of tissue certainly have sufficient energy to rupture cells, it is speculated that there will be less cell damage by virtue of the jet beam’s tendency to follow the intercellular “path of least resistance.” This, however, is difficult to prove histologically, since an intact cell count would be required before and after a fluidjet cut. An interesting (but also difficult) study, however, would be to compare the quantity of an intracellular component (like DNA) that is liberated in a mechanical cut versus that liberated in a fluidjet cut. The most important disadvantage of laser cutting is thermal damage and the possibility of extensive local damage due to deflection of the laser beam. The nature of this disadvantage varies widely with laser beam wavelength and power, together with the detailed nature of the tissue being addressed, so cannot be adequately summarized here.

Clearly, no method of cutting is ideal, we believe, however, that when properly configured and operated, fluidjet cutting is significantly better for many tissue cutting and (particularly) ablating applications. In addition, although not discussed above, the proprietary “jet/collector” combination configurations utilized by VERSAJET allow “differential ablation,” i.e., the removal of a softer tissue, such as infected or necrotic tissue, from a tougher tissue, such as healthy tissue, with minimal damage to the substrate tissue.
Fluidjets in Surgery

Abstract
High-pressure jets of water have been used in industry for cutting a wide variety of materials. In recent years, the advantages of this technology have been explored and validated in a number of medical applications. This paper describes how the technology has been adapted to the specialized requirements of surgical use and how fluidjets may be used advantageously in some of those applications. Recent enhancements of this technology lead to the expectation that it will see widespread use in surgery.

Introduction
Incompressible fluids (usually water, with or without additives) when forced through a tiny orifice under very high pressure, form jets that demonstrate remarkable abilities to cut materials. In industry, pressures of up to 100,000 pounds per square inch (psi) are routinely employed and orifice (nozzle) sizes are usually only a few thousandths of an inch (0.1–0.5 mm) in diameter. With properly designed nozzles, the fluidjet is highly collimated and can cut a wide range of materials with clean, smooth cut surfaces, with no thermal damage to the material. This technique is used to cut soft materials, such as candy and fish, to somewhat harder materials such as textiles and circuit boards, to very hard materials like glass and concrete, if abrasives are added to the working fluid.

The uses of fluidjets in industry have been well documented. The performance features most emphasized in industry have been high throughput (cutting speed), avoidance of thermal damage, safety (e.g., in mines, where electrical equipment can be hazardous) and high reliability. High-pressure pumps, hoses, valves, etc., are a natural extension of the same components used in hydraulic heavy machinery; thus, with the exception of specialized areas like nozzle design, a considerable body of supporting engineering knowledge lies behind this technology.

Despite its success in numerous industrial applications, one must ask if there is any basis for utility of this technology in surgical applications. After all, the scalpel (enhanced, in some cases, with heat or with ultrasonic vibrations) is a well-established cutting device—both simple and inexpensive. Furthermore, low-pressure “jets” (exemplified by the simple “squeeze bottle,” but sometimes enhanced by automation, as in pulsatile lavage devices) have proven adequate for many medical applications, such as in wound cleaning, or separation of tissue planes in surgery. Why, therefore, introduce the major complication of high-pressures into such a demanding field as surgery?

Potential Advantages in Surgery
The facts that fluidjets can cut tissues ranging in hardness from fat to bone cleanly and rapidly without any thermal effects are highly desirable, but not sufficiently beneficial per se to justify abandoning the scalpel. There are, however, three attributes of fluidjet devices that represent potential advantages not easily attained (certainly in combination) over other modalities. These are:

Tissue Differentiation
Whereas a conventional scalpel, in the hands of a skilled surgeon, can “differentiate” certain tissues (e.g., can resect fatty tissue away from stromal, or muscular tissue), a great advantage accrues to a device that can be preset to remove only soft tissue without resecting harder tissues, even in surgical sites that are difficult to access and/or difficult to visualize. Fluidjet devices can be “tuned” by proper
nozzle design and operating parameters to do just this. In fact, the earliest fluidjet devices were indicated for use in dissecting away soft, parenchymal tissue in the liver and for dissecting tumors in the brain. More advanced technology, coupled with the use of higher fluid pressures, provides the potential for exquisite control of tissue differentiation, a capability that is useful in a variety of surgical procedures.

Ablation

A major disadvantage of the early, lower pressure fluidjet devices for liver and kidney dissection was the fact that the fluidjet tended to disperse the tissue removed at the site, so that various means of incorporating an external vacuum had to be utilized in an attempt to retrieve the dispersed tissue. Obviously, failure to accomplish this completely could represent some hazard, depending on the nature and the area of dispersion for the resected cells. In addition, great care needed to be taken to avoid inadvertently directing the fluidjet against uninvolved contiguous areas.

A major advance ensued from the recognition that the fluidjets form the basis of the very old technology of “eductor pumps.” (Such pumps have been used in mines for centuries to pump out slurries of coal, for example). By the addition of a “collector” device, designed according to very specific criteria, it is possible to capture the fluidjet itself, while concomitantly creating a vacuum at the point of capture. When properly designed, this configuration results in intense cavitation at the collection point, so not only is the excised tissue drawn into the collector, but it is macerated almost to the cellular level and driven out of the collector tube, without need to any external vacuum connection. This effect occurs whether the device is operated immersed in irrigation fluid (in which case some of the fluid is also drawn into the collector) or also when operated in a gaseous environment (in which case, a flow of gas is drawn into the collector along with the excised tissue or other debris). This phenomenon, which effectively removes the material cut by the fluidjet, allows the use of such devices not only for cutting, but also for “ablation”, or “sculpting” of tissue surfaces. An important further advantage of the collector configuration is that the jet is fully controlled, i.e., its action is constrained to the region between the jet nozzle and the collector, greatly minimizing the danger of impinging on uninvolved contiguous.

Accessibility

The two previous advantages are greatly facilitated and enhanced by the fact that fluidjet devices can be configured to place the working region of the fluidjet at the distal end of a tiny device, consistent with the dimensions required for minimally invasive surgery. It should be noted that the fluidjet device can be configured with the working jet parallel to the axis of the device or perpendicular to the axis of the device. In the latter device, the length of the fluidjet can be varied while in use so as to change the “gap” between the nozzle and the collector, thus allowing tissue of varying thicknesses to be safely addressed, while minimizing the “envelope” dimensions of the distal tip in sites that are difficult to access.

The above three principle advantages of advanced fluidjet technology are very synergistic; for example, the capability of tissue differentiation in an ablation device that can access the surgical site via minimally invasive techniques represents a much more advantageous methodology than any of the three alone. In summary, we believe these advantages, in addition to the inherent speed, precision and non-thermal nature of this technology, justify potential position as a versatile, general-purpose modality in the surgical armamentarium. Nevertheless, a number of technical challenges needed to be surmounted before that potential could begin to be realized.

Technical Hurdles

The operating parameters of greatest importance for surgical applications are quite different from those for industrial applications. First, it is essential that the working fluid be sterile, since it is exposed to the site of surgery. This is a substantial hurdle, since power must be transmitted to the working fluid without the transmission of bacterial or viral contamination. This immediately gives rise to the question of re-sterilization of those components that carry the working fluid. Realizing that most fluidjet surgical devices will incorporate very small diameter tubes and very fine nozzles leads to the conclusion that re-sterilization of such devices is
extremely difficult to validate to the degree required by a responsible supplier and FDA Good Manufacturing Practices. In particular, the need for sterilization is compounded by the need for absolute cleanliness, since a single minute particle (even though sterile) can clog a jet orifice. It is thus evident that the best strategy is to provide that part of the system which carries the sterile working fluid as a pre-sterilized, single-use, device. This strategy, of course, imposes the need for low manufacturing costs, consistent with those for disposable devices, but does alleviate the need for the long useful lifetimes that would be required for reusable devices. For example, if the device is disposable, there is no need for the expensive sapphire nozzles used in industry to provide months of useful life. A second technical hurdle is the need to reduce the size of a complete fluidjet system from the typical floor-mounted or truck-mounted industrial system to a size which allows mounting in typical operating room “towers” or on typical instrumentation carts. This hurdle is mitigated by the fact that the pressures required for surgical applications are not as high as typically used in industry. Generally, pressures from several thousand psi to 35,000 psi are sufficient, since the latter pressure can cut bone (without abrasive additives), as opposed to the 50,000 to 100,000 psi range used for industrial applications.

Similarly, it is essential to reduce the size of the “working end” of the system to millimeter dimensions—a realm unheard of in industry. Finally, it is obviously necessary to ensure that the stringent safety requirements consistent with operating room use are incorporated into the fluidjet system. This includes meeting well-prescribed electrical safety regulations, but also involves overcoming any hazard from fluids under high pressure, as well as from the spread of infective contamination from spray generated by the device. Other considerations, such as noise and ease of use, which are exacerbated in the often frenetic OR environment, cannot be ignored.

These hurdles can be overcome in different ways, but as an example, we describe HydroCision’s approach. The overall system concept was to develop a reusable power and control console for pressurizing fluids up to 30,000 psi, in a wide variety of different handpieces.

**The Console**
The console may then be “instructed” by the handpiece as the pressure (or pressure range) required for application. The console, in addition to meeting international regulatory requirements for electrical and mechanical safety, was required to have a low noise level, minimum operator interaction, and a size commensurate with “tower” mounting in the operating room.

**The Handpieces**
Handpieces were specified to be disposable, including the entire sterile fluid path from saline bag, through the integral “pump cartridge” to the high-pressure nozzle via high-pressure flex tubing. The pump cartridge was designed for easy insertion into a receptacle in the console and incorporates a sterile barrier, so that contamination from the non-sterile console is avoided. The Handpieces are designed for operation by a foot pedal, although hand operation is quite feasible.

Considerable innovation was required to meet these overall system objectives. For example, the cost requirements imposed by disposability of the sterile fluid path resulted in a unique pump cartridge design that is simple, while allowing ease of use. For this approach, special high-pressure tubing was required, so as to allow safe containment of the pressure, while still allowing high flexibility for ease of use. Obviously, the design of the handpieces needed to meet stringent cost requirements, while also meeting the weight and size requirements consistent with minimally invasive devices. Finally, the design of the fluidjet nozzle and the jet collector was found to be critical in order to achieve optimal cutting, ablating and tissue removal characteristics.

Each surgical indication added an additional set of design requirements. For example, HydroCision’s early ArthroJet System for arthroscopic surgery needed to incorporate a capability for cauterizing bleeding vessels and a capability for “burring” bone. The latter requirement was met with the design of a unique, fluidjet-powered turbine as a driver for the bone burr, illustrating another facet of the versatility of this technology. Whereas the ArthroJet, now on the market as the Exojet Fluid-Jet Resection System,
operates while immersed in irrigation fluid, HydroCision's former TraumaJet™, now on the market as the VERSAJET™ Hydrosurgery System for traumatic wound debridement must operate in air, representing yet another example of the fluidjet technology's versatility.

Conclusions
Despite the well-developed and proven body of technology underlying industrial fluidjet applications, the adaptation of this technology to surgical applications has not been easy. Each market involves quite different operating parameters and different feature advantages. Just as in the case of industrial use, this versatile technology has already tended to segment into specialized areas of application. Fluidjets used in ophthalmology1 in cardiovascular intervention, in arthroscopy and other minimally invasive surgical indications all have different performance criteria, different advantages vs. conventional techniques, and their own set of technical problems in implementation.

Nevertheless, as this brief description attempts to show, enough of these problems have now been solved to lend credence to the authors' belief that current, state-of-the-art, high-pressure fluidjet technology represents a versatile, powerful surgical modality that will increase rapidly in usage as its benefits become validated and more widely recognized.

Wound Debridement: A Comparison of Two Techniques for Particle Clearance

Introduction
Retained foreign particles in wounds may potentiate wound infections. High pressure pulsatile lavage (HPPL) is used in most centers as an aid to wound debridement. Questions about the efficacy and the potential role of pulsatile lavage in cell injury have arised. In this study, we utilized a vacuum jet technique (VJT) VERSAJET® Hydrosurgery System (Smith & Nephew, Inc.; Largo, FL) in which a high-pressure fluid flow is directed parallel to the wound surface. The high-pressure, parallel flow creates a vacuum by the Bernoulli effect, lifting loose particles and tissue into the flow stream for removal (Figure 1). The VJT was compared to HPPL for efficiency in removing particles from deliberately contaminated wounds.

Particles were pressed into the tissue by application of a 15 kg weight for 30 seconds.

The VJT was used to debride the wound on the right leg and HPPL was used to debride the wound on the left leg. Wounds were debrided for 3-minute intervals for a total of 15 minutes. Radiographs were taken prior to the start of debridements, and were also taken at the end of each interval. The radiographs were digitized and blinded, and the number of metallic particles present in each wound were counted by 3 observers. The means (± standard deviation) were calculated and compared for statistical significance using Sigmastat with p<0.01.

Methods
12 cm by 12 cm wounds, increasing in depth from 1 cm (superior) to 3 cm (inferior) were created in paired fresh cadaveric human thighs (3). Two grams of fine metallic particles (-20 mesh; Grade A-172; lot #0468009) and two grams of larger particles (1-3 mm diameter; Grade M-932; Lot #04810005) (both from OMG Americas, Research Triangle Park, NC) were evenly disbursed over each wound. The
Results
Both wounds had similar number of particles prior to the start of debridement (Figures 3 and 4). At 3 minutes, VJT had removed 45% (± 3%) of particles compared to HPPL which removed 7% (± 5%) of particles (Figures 5 and 6). At 9 minutes, the VJT had removed 73% (± 4%), while the HPPL had removed 18% (± 8%) (Figures 7 and 8). At 15 minutes, VJT had removed 88% (± 1%) of particles, while HPPL had removed 22% (± 6%) of particles (Figures 9 and 10). The vacuum jet technique was significantly more effective at removing particles than HPPL at all time points (Figure 2).

Conclusion
Removal of metallic particle wound contaminants in a paired fresh human cadaveric model is more thoroughly and quickly accomplished with the vacuum jet technique than with high pressure pulsatile lavage. Faster, more effective removal of particles from contaminated wounds should decrease the potential for infections associated with foreign particles.