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Paper

MEDICAL APPLICATIONS OF THE HIGH POWERED PARALLEL WATERJET

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ABSTRACT

Acute and chronic wounds are a major medical problem. Preparing a wound bed is an essential feature of their treatment. Wound bed preparation requires the removal of unhealthy and necrotic tissue as well as foreign bodies. The purpose of this study was to develop an improved surgical debridement instrument (VersaJet™, Smith and Nephew, Hull, UK) using fluidjet technology and to evaluate its applications in clinical medicine.

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INTRODUCTION

Skin is the tissue that envelops the body and protects the internal environment. When the skin is disrupted a physiologic wound healing mechanism is immediately triggered. Initially bleeding is controlled and a clot is formed. An *inflammatory phase* then ensues during which inflammatory cells migrate into the wound to digest debris and set up for the next phase. During the *proliferative phase* new protein is elaborated and a scar is formed. The scar then undergoes a variety of changes during the post healing *maturation phase*. When a wound consists of a laceration the edges can be opposed and the wound healing process is optimal. In situations that develop from burns, large acute wounds, or from various disease processes wounds can develop and fail to heal properly. This condition is referred to as a chronic wound.

During the past decade, the treatment of chronic wounds became focused on wound bed preparation. Essentially, this process consists of manipulating a wound to bring it into a physiologic state that is compatible with healing. This process has been codified with the acronym *TIME*. The *T* refers to *tissue necrosis*. All unhealthy tissue including tissue with inadequate blood supply, severely damaged tissue, and dead tissue must be removed from the wound. All foreign material must be cleared from the wound. The *I* is for *infection*. Bacterial burden must be below 100,000bacteria/gm in order for a wound to heal. The *M* stands for *moisture balance*. Wounds heal best in a moist environment. Desiccation inhibits the healing process. Finally, the *E* means *edge*. The advanced edge of the tissue at the wound perimeter must now be primed for healing. Healing can be facilitated by means of appropriate dressings, application of advanced technological wound coverage systems, or by surgery.

Effective debridement is the key to advancing through the *TIME* cascade. Various means can be employed to debride wounds, but this manuscript will focus on surgical debridement. Historically, surgeons have cut away unhealthy tissue using sharp instruments. Lasers, ultrasound, electrocautery, and radiofrequency devices have been employed but all have major drawbacks. The VersaJet® is a high powered parallel oriented fluidjet debridement instrument which was developed by HydroCision (Andover, MA) and brought into clinical use by Smith and Nephew (Hull, UK). This study will review the mechanics of the device, the developmental hurdles, and the clinical applications.

MAIN BODY OF PAPER

Water, an incompressible fluid, when forced through a tiny orifice at very high-pressure forms a jet that demonstrates remarkable abilities to cut materials. In industry, pressures of up to 100,000 psi are routinely employed. Nozzle orifices of only 0.1-0.5mm in diameter are used to generate these powerful jets. With properly designed nozzles the waterjet is highly collimated and can cut through a wide range of material with clean, smooth cut surfaces, with no thermal damage to the material. This technique is used industrially to cut soft materials such as candy, chicken, and fish. It is also used to cut harder materials like textiles and circuit boards and very dense materials such as concrete and glass, particularly if abrasives are added to the fluid. The performance features related to the industrial use of this technology are high throughput (cutting speed), avoidance of thermal damage, safety (especially 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. Except for 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" of fluid (exemplified by the simple "squeeze bottle", but sometimes enhanced by automation, as in pulsed lavage devices) have proven adequate for many medical applications, such as in wound cleaning. Why, therefore, introduce a complicated high-pressure technology into such a demanding field as surgery?

The fact that fluidjets can cut tissues ranging in hardness from fat to fascia cleanly and rapidly without any thermal effects is highly desirable, but not sufficiently beneficial *per se* to justify abandoning the scalpel. A phenomenological description of fluidjet cutting of biological tissue in air forms the theoretical basis for the effectiveness of the VersaJet. Visualize a homogeneous material such as a 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 the kinetic energy is $1/2mv^2$, 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 nozzle. Of equal importance is the ability to achieve very high jet velocities by generating high pressures (up to 15,000 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, 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. If there is insufficient energy in the jet beam to cut through even softer tissue, it will lose its directional momentum and be deflected randomly into the surrounding tissue. This emphasizes the importance of having sufficient energy in the beam to penetrate the tissue completely before losing enough directional momentum for the cutting phenomenon to take place. Given sufficient energy in the jet beam, it is more likely to cut through the tissue and continue on its way. In general, jet pressures in the range of 10,000-15,000 psi are required to remove wound related soft tissue.

There are two attributes of waterjet devices that represent potential advantages over other incisional modalities. These are:

<u>Tissue Differentiation:</u> 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. However, the surgeon is using the scalpel to dissect through tissue planes and if these planes are not actually planar, but are topographically irregular, he is unlikely to achieve an exact separation. A great advantage therefore accrues to a device that can be pre-set to precisely remove layers of soft tissue to an exact level, even in surgical sites which are inhomogeneous, 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 precision tissue excision, a capability which is particularly useful in wound debridement.

<u>Ablation:</u> 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. As a result 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 area of dispersion of the resected tissue. In addition, great care must be taken to avoid inadvertently directing the waterjet against uninvolved contiguous areas.

A major advance ensued from the recognition that waterjets 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 for any external vacuum connection. When operated in a gaseous environment a flow of gas is drawn into the collector, by means of the Venturi effect, 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, so the danger of impinging on uninvolved contiguous areas is greatly minimized. Furthermore, bacteria and wound contaminants will likely be removed along with the ablated tissues. By designing an appropriately contoured handle, the cutting edge of the fluidjet can effectively reach relatively inaccessible areas of a wound.

The above principal advantages of advanced fluidjet technology are very synergistic. These advantages, in addition to the inherent speed, precision and non-thermal nature of this technology, justify a potential place as a versatile, general-purpose modality in the surgical armamentarium. Nevertheless, a number of technical challenges needed to be surmounted before that potential could be realized.

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. All surgical procedures are performed under sterile conditions. 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. In particular, the need for sterilization is compounded by the need for absolute cleanliness, since a single residual particle (even though sterile) can clog a jet orifice. Consequently, that part of the system which carries the sterile working fluid is 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 15,000 psi are sufficient for wound debridement 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 Operating Room environment are essential.

The VersaJet has resolved these hurdles. The overall system consists of a reusable power and control console for pressurizing normal saline (a biologically compatible isotonic fluid) up to 15,000 psi. The pressure required for the particular wound is adjusted on the console. The console, in addition to meeting international regulatory requirements for electrical and mechanical safety, has a low noise level, minimal operator interaction, and a size commensurate with “tower” mounting in the operating room. Handpieces are disposable, including the entire sterile fluid path from saline bag, through the integral “pump cartridge” to the high-pressure nozzle via high-pressure flexible tubing. The pump cartridge was designed to be easily inserted into a receptacle in the console and incorporates a sterile barrier, so that contamination from the non-sterile console is avoided. A foot pedal operates the handpiece that comes with either an 8 or 14mm working area.

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. 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 a hand held surgical device. Finally, the design of the fluidjet nozzle (.005inch diameter) and the jet collector was found to be critical in order to achieve optimal cutting, ablating and tissue removal characteristics in an air environment.

For centuries the debridement of wounds has been the hallmark of surgery. In the preanesthetic era amputation was the preferred method of debriding an extremity wound. The standard of operative management evolved into a radical excision of wounds. Extensive surgery of that nature widely removes all necrosis and debris, but at the same time sacrifices a large amount of healthy collateral tissue. In burn surgery it was recognized that tangential excision of burn wounds led to earlier wound closure and less scarring. Tangential excision consists of slicing through thin layers of dense burned skin until punctate bleeding is seen. At this level, the advancing edge of the wound is present and skin grafting is possible. VersaJet debridement affords the same type of precision and control over wound surgery. The hand piece sculpts tissue in an orientation parallel to the direction of the water jet. Consequently, the device debrides tissue when the waterjet moves parallel to the wound surface with no pressure exerted on the wound itself. By removing necrosis and debris from within the wound and working towards the healing edge of the wound, surgeons employing the VersaJet can readily identify the edge of healthy tissue and remove only the unwanted matter. There is minimal collateral damage, no thermal injury, and less bleeding. In spite of the less extensive nature of VersaJet debridement, patient outcomes are improved and it takes significantly fewer debridements to prepare the wound bed.

There are numerous recognized applications for the waterjet in surgery (1-8). The VersaJet has FDA approval as a wound debridement instrument. It is effective in removing granulation tissue, fibrinous debris, or frank necrosis in all wound types, including fasciitis wounds. In very severe and extensive wounds near important anatomical structures, the VersaJet is capable of delicately and precisely removing tissue to an almost microscopic level so as not to injure the aforementioned structures. In combination with a negative pressure wound therapy system, a healthy wound can often be achieved in cases that were not possible with scalpel debridement. This is also true in patients with loss of abdominal domain. We have found that the VersaJet can clean off exposed viscera in cases of open abdomens. This allows more rapid closure with less risk of fistula. The VersaJet is much more accurate and rapid than scalpel surgery in debriding necrotic muscle in compartment syndrome.

In burn wounds, VersaJet is not useful for the removal of dry eschar, which is too dense for it to cut. However, in chemical burns, friction burns, scald burns, and more superficial flame burns, it is a fast, less bloody, and very effective debridement tool. At this writing the VersaJet does not have FDA approval for burn debridement in the United States, but has been used extensively for this purpose in the United Kingdom. The VersaJet is exceptionally useful in cleaning up acute traumatic wounds. Patients who have crush injuries, electrical burns, compartment syndromes, gunshot wounds and open comminuted fractures are traditionally treated with serial debridements and wound irrigations in the operating room prior to any attempt at closure. The VersaJet enables the surgeon to more accurately clean the wound so that the number of debridement sessions required to get to a properly prepared wound bed is significantly reduced.

The VersaJet is extremely useful for the removal of particulate foreign bodies such as "road dirt". Road dirt consists of soil and grit that is ground into the tissues when an injured person is dragged against the ground. Unless road dirt is removed from the wound early after the injury it gets incorporated into the healing skin and forms a traumatic tattoo. At that point it is almost impossible to get rid of it other than by directly excising it. The VersaJet readily and completely removes this material from an acute wound leaving a healthy wound bed. Similarly the VersaJet facilitates removalof silicone gel following implant rupture.

The VersaJet is useful for defatting flaps and skin grafts. When a full thickness skin graft is required, a piece of skin is cut away from one area of the body, all of the underlying fat is removed and it is then placed elsewhere on the body. The waterjet is a quick effective way to remove the excess fat from the underside of the graft.

Orthopedic surgeons have found the VersaJet to be a quick and effective way of debriding infected prostheses. When a patient who has a total joint prosthesis becomes infected, the prosthesis is generally removed and a spacer impregnated with antibiotics is placed in the joint space for a period of months prior to replacing the prosthesis. With the VersaJet, the infected prosthesis can be removed, the wound completely cleaned and a new prosthesis inserted in one sitting. That saves multiple operations and months of disability for the patient. The Versajet is used to remove osteomyelitic bone and metallosis from worn out prostheses.

CONCLUSION

The VersaJet, a high-powered parallel cutting water jet, was developed for the purpose of wound debridement. The process of development required solutions to many challenging technical problems. The result however is a device with remarkable accuracy and precision. As we gain more experience with this new approach to surgery, more applications for this device will undoubtedly develop. There are many potential applications that can be realized as well by adapting the instrumentation to different surgical environments. The VersaJet has empowered the surgeon to achieve better outcomes for patients while saving scarce economic resources for the hospitals at the same time. It has led to a paradigm shift in surgical thinking.

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GRAPHICS

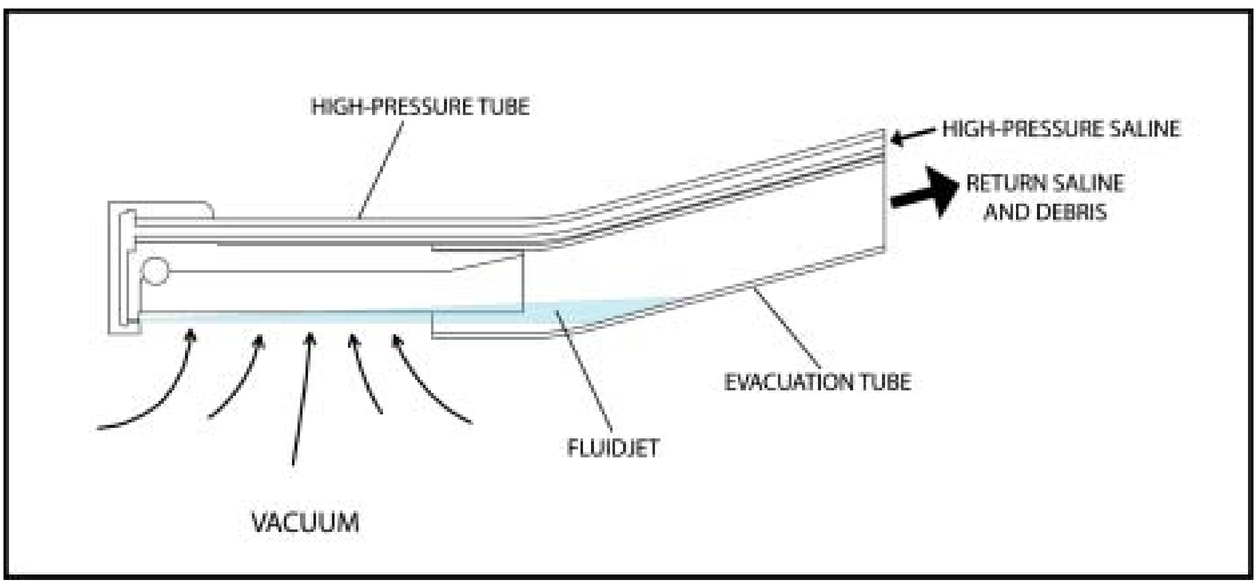

Figure 1. Sterile saline is directed through a high pressure tube into the handpiece of the VersaJet where it is redirected 180 degrees and ejected through the nozzle. The waterjet is collected across an 8-14mm gap creating a suction (Venturi) effect on the surrounding tissue.

Figure 2. Side view of the tip of the handpiece.

Figure 3. The waterjet is seen emerging from the nozzle and being captured in the eductor port.

Figure 4. The Versajet in use in an Operating Room. An abdominal wound is being debrided in preparation for a skin graft. Note the VersaJet console on a OR cart behind the surgeon.