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Surgical Debridement with SonicOne® O.R.: an Initial Look at the Bacterial Load Pre- and Post- Low Frequency Direct Contact Ultrasound

Daria Abolghasemi, D.O., Karen D. Szymanski, D.O., Michael Baruch M.D., Jamshed Zuberi M.D.

Affiliations
1 Resident Department of General Surgery, St Joseph Hospital and Medical Center, Paterson, New Jersey
2 Fellow Section of Plastic and Reconstructive Surgery, St Joseph’s Hospital and Medical Center, Paterson, New Jersey, USA
3 Chief Section of Plastic and Reconstructive Surgery, St Joseph’s Hospital and Medical Center, Paterson, New Jersey, USA
4 Trauma and Critical Care Surgeon, Department of Surgery, St Joseph’s Hospital and Medical Center, Paterson, New Jersey, USA

Abstract Presented at The Diabetic Limb Salvage Meeting, March 2016

Background
A retrospective study was done to determine the impact low frequency direct contact ultrasound debridement (SonicOne O.R., Misonix Inc.) has on the bacterial load of a variety of wound types.

Methods
20 patients with wounds of all regions of the body were treated with the SonicOne O.R. 32 anaerobic/aerobic cultures were taken before and after the wound was treated with the SonicOne O.R.

The second part of the study involved sampling quantitative bacterial cultures from a subset of the group, taking 10 quantitative bacterial cultures before and after SonicOne O.R. debridement.

Results
The cultures identified a broad spectrum of bacteria present in the wounds, including Staphylococcus Aureus, Pseudomonas Aeruginosa, Streptococci Beta Hemolytic Group C, Escherichia Coli and Stenotrophomonas Maltophilia. The cultures classified an approximated range of bacteria present: Many, Moderate, Few and Rare. Prior to treatment, 36% of the cultures were classified as “Many.” Post-treatment with the SonicOne O.R., 14% were classified as “Many.”

Quantitative bacterial cultures before treatment showed an average bacterial count of 10⁹ CFU per gram of tissue. Post-treatment the average bacterial count was 10⁴, or a log 5 reduction in bacterial count as a result of the low frequency ultrasonic debridement. Three of the five samples post-treatment showed a bacterial count of zero. The cultures and quantitative bacterial cultures indicate the ability for SonicOne O.R. ultrasonic debridement to reduce bacterial load in a variety of wound types and with a broad spectrum of bacteria present.
The use of split thickness skin grafts (STSG) to treat chronic diabetic foot wounds is well-documented. Crucial to STSG success is appropriate wound bed preparation. Sharp surgical debridement of the wound bed is the traditional gold standard, but this technique has notable drawbacks including non-selectivity. This purpose of this study is to review the use of an alternative method of wound bed preparation with ultrasonic debridement prior to STSG application in diabetic foot wounds. A six month retrospective chart review (05/15 – 11/15) was conducted at a single institution with a single surgeon using the Sonic One Misonix Ultrasound debridement system. Twelve patients were reviewed with two excluded for non-compliance and/or more proximal amputation during the study period. Of the 10 remaining patients, 7 were male and 3 were female with an average age of 70.6 years old (range: 46-88). The average percent area of STSG incorporation in our population was 97.5%. Ninety percent (9/10) were noted to achieve graft success with greater than 90% closure after routine follow-up. Compared to the STSG success rates reported in the literature following traditional wound bed preparation—which demonstrate 78% (range: 65-93.75%) success at achieving 90% closure—the result of this study with ultrasonic debridement exists at the high end of this reported range. Overall, this study demonstrates that ultrasonic debridement is a viable procedure for wound bed preparation prior to STSG application in the diabetic population. Strength to the study could be added through a longer retrospective review and a larger patient population.
The Clinical Implications of a New Wound Debridement Device That Combines Low Frequency Direct Contact Ultrasound and Vacuum Aspiration

Mark S. Granick M.D.¹, Michael Baruch M.D.², Wayne J. Caputo M.D.³, Paul M. Glat M.D.⁴

Affiliations
¹Division of Plastic Surgery, Rutgers New Jersey Medical School, Newark, New Jersey, USA
²Division of Plastic and Reconstructive Surgery, St Joseph’s Hospital and Medical Center, Paterson, New Jersey, USA
³Clara Maass Medical Center, Barnabas Health, Belleville, New Jersey, USA
⁴Division of Plastic Surgery, Division of Burn Unit, St. Christopher's Hospital for Children, Philadelphia, Pennsylvania, USA

Abstract Presented at The Diabetic Limb Salvage Meeting, March 2016

Background
Low frequency direct contact ultrasonic (LFDCU) debridement is a newly introduced technology to the surgical marketplace. The device has many advantages including: ease of use, selective debridement of necrotic tissue, preservation of vital tissues, and a variety of interchangeable tips. It has an antibacterial effect as well. One of the disadvantages of this technology has been the need for a vapor interface at the dissection field. This preliminary study was performed to determine if the use of LFDCU debridement combined with vacuum aspiration eliminates vapor dispersion without impairing the function of LFDCU alone.

Methods
Fifteen patients were treated at four centers. A rating scale was used to compare the effectiveness of combining vacuum aspiration with LFDCU against LFDCU alone. Vapor dispersion was grossly assessed. The amount of irrigant and the amount of collected fluid was measured.

Results
The users rated the combined therapy better than the stand-alone ultrasound 100% of the time. The use of vacuum did not impede debridement function and no safety issues were reported. The vapor did not disperse beyond the tip of the device.

The effectiveness of the vacuum was measured in 10 cases. The mean quantity of irrigant used in those cases was 334.67ml (100-1000ml). The mean fluid capture was 415.33 ml (100-1300ml). The use of vacuum in combination with LFDCU resulted in 31.64% more fluid captured than used as irrigant. Anaerobic/aerobic cultures indicated removal of a broad spectrum of bacteria including serratia marcescens, escherichai coli, staphylococcus epidermidis and enterococcus avium group D.
Spray Containment for Surgical Debridement Tools

Mark S. Granick M.D.¹, Liel Rubinsky PhD²

Affiliations
¹Division of Plastic Surgery, Rutgers New Jersey Medical School
²Tipul Biotechnology, El Cerrito, Ca.

Abstract Presented at The Diabetic Limb Salvage Meeting, March 2016

Background
Three commercially available wound debridement devices were tested to determine how effective they were in containing spray during treatment.

Materials and methods
Three commercially available wound debridement devices were tested. A new device, the SonicVac® (Misonix, Inc.) was compared to two commercially available wound debridement devices, the VersaJet 2 (Smith and Nephew, Inc.) and the Qoustic Wound Therapy System (Arobella Medical, LLC).

Contact plates (Valiteq) were placed at designated distances ranging from 12 - 24 inches away and at heights of 17 - 30 inches to capture spray. For each test, a wound model (beef ~1-3 inches) was topically inoculated on the surface with 6x10⁴ 100 μl of Escherichia coli (E.coli) (ATCC # 54288) prior to debridement.

Results
The SonicVac and the VersaJet devices both averaged less than one CFU per collection plate (range 2-7 CFU) when debriding a wound. The Qoustic averaged over 16 CFU’s per plate (range 2-88 CFU).

For both the SonicVac and VersaJet devices, the spray collection of any bacteria was incidental and extremely small. We found that incidental spray for both the VersaJet and the SonicVac are similar and well contained. The Qoustic contained the spray less effectively. This is to be expected for a device that does not use vacuum aspiration. We conclude the use of wound debridement devices that incorporate aspiration with tissue removal have a greatly reduced chance of spraying bacteria from infected wound surfaces.
Evaluation of low frequency contact ultrasound assisted debridement (LFCUD) on wound healing outcomes of a complex wound population.

Research Questions:
- Does LFCUD improve WSA reduction and improve wound bed quality?
- Is LFCUD well tolerated by patients?
- Is LFCUD feasible to use in a nurse-led outpatient wound clinic?
- What are the complications associated with LFCUD?

Method:
- Ten patients with lower extremity wounds.
- Vascular Surgery Clinic Population.
- Four weekly 22.5kHz LFCUD treatments.
- Wound surface area (WSA) measured weekly by an independent assessor.
- Wound scored using revised Photographic Wound Assessment Tool (revPWAT).
- Adverse events, changes in health status, hospital admissions, and ER visits recorded.

Results:
- LFCUD improved WSA reduction and wound appearance in the majority of patients.
- No patients wounds deteriorated during the study period.
- Median difference in VAS pain scores between pretreatment and during treatment =5mm(0-20mm. 95%CI) Related Samples Wilcoxon Signed Rank Test.
- There were no treatment-related adverse events, episodes of excessive bleeding, wound-related hospital admissions or ER visits.

Conclusion:
LFCUD applied by the ET RN was well tolerated, improved healing response with minimal complications, and is a promising mode of therapy to support healing in a complex, hard-to-heal vascular clinic population.
Ultrasonic Tangential Burn Excision Reduces Blood Loss

Abraham P. Houng MD MSE FACS, Sylvia J. Petrone MD FACS, Robin A. Lee MD, Christina Lee MD, Michael A. Marano MD FACS
Department of Surgery, Division of Burn Surgery
Saint Barnabas Medical Center, Livingston, New Jersey
Abstract Presented at the American Burn Association Meeting, April 2015

Introduction
The gold standard treatment of third-degree burns is surgical excision and skin grafting. Surgical excision is composed of tangential excision and fascial excision. Tangential excision can be performed using the Goulian knife, Watson knife, or the hydrosurgery water dissector. We are using a novel ultrasonic surgical debridement tool for tangential excision of third-degree burns. Ultrasound technology has been used in orthopedic and neurosurgery with good success. We are reporting a case series of 10 patients that had excision using this novel technique. Calculated blood loss was found to be less than standard excision methods.

Methods
A retrospective chart review of 10 patients with third-degree burns requiring surgical excision and split thickness skin graft (STSG) was performed. These patients all had ultrasonic debridement. Some of these same patients had separate staged procedure with tangential excision.

A high intensity, low frequency ultrasound device with a titanium alloy probe was used to excise third-degree burns in the ultrasonic group (UG). The device uses standard electrical signal and converts the energy to mechanical vibration via crystals. This energy is transferred to a titanium tip which is used to debride the third-degree burn. A Goulian knife was used in the standard debridement group (SDG). Selection was based on wound characteristics; wounds with granulation tissue and fine coagulum were excised using the ultrasound device. Patients with eschar were excised via standard technique. Split thickness skin was grafted onto the excised area during the same operation. Blood loss was calculated and compared using patient’s weight, preoperative hematocrit and postoperative hematocrit via the following formula:

Calculated Blood Loss = PreOp RBC volume – PostOp RBC volume
PreOp RBC volume = Body weight (kg) x 80 (mL/kg) x PreOp HCT (%)  
PostOp RBC volume = Body weight (kg) x 80 (mL/kg) x PostOp HCT (%)

Results
All patients tolerated the surgical procedure well and did not have any significant graft loss. Operative time was similar to standard excision. Injuries ranged from 3% total body surface area (TBSA) to 53% TBSA. There were 6 patients with flame burns, 2 with scald burns, 1 with electrical burns, and 1 with contact burns. A total of 32 excision and split thickness graft procedures were performed on these 10 patients: 20 SDG and 12
Discussion

Ultrasonic surgical debridement appears to be safe and effective for use in tangential excision of third-degree burn wounds. Since the device is bladeless, it reduces sharps injury in the operating room. Wound selection is important. A limitation of this device is that it does not debride eschar well. This technique is most suited for granulation tissue or wound beds with fine coagulum as shown in the figure below. The calculated blood loss in UG was 0.54 ml/cm², which was less than 0.94 ml/cm² in SDG. The UG blood loss is also significantly less than published blood loss in burn excision: 0.75-1.19ml/cm². Although not statistically significant due to limited sample size, the results suggest that ultrasonic debridement reduces blood loss. A prospective study is needed to validate these initial findings.

Can Ultrasound Debridement Facilitate Biofilm Removal From Diabetic Foot Ulcers?

Volume 27 - Issue 8 - August 2014 Podiatry Today Author(s): Melinda Bowlby, DPM, and Peter Blume, DPM, FACFAS

Key Excerpt:

Researchers have shown that ultrasound kills bacteria on wound surfaces. The two main mechanisms are cavitation and microstreaming. Cavitation is the creation of microbubbles in a fluid medium. With low frequency contact ultrasound, these bubbles emanate from the device’s operative vibrating tip touching the tissue itself. This creates some gaseous bubbles and then the bubbles collapse rapidly once they leave the proximity of the distal tip surface. Others are actually gas bubbles present in the tissue, which grow and shrink within the pulsating pressure field until they collapse on their own. Microbubbles affect bacteria by increasing temperature, inducing mechanical stress and/or free radical production. When either type of microbubbles collapse, they release pressure and energy very quickly. This energy release is bactericidal as it disrupts cell walls and otherwise renders the bacteria unviable.
Key Excerpts:

Ultrasonic debridement is a form of mechanical debridement. It employs an electrical current, which piezoelectric crystals then convert to mechanical vibrations. The mechanical vibrations stimulate a probe, which in turn amplifies the vibrations. This mechanical energy converts into acoustic energy, which subsequently transfers to the tissue in the wound bed and peri-wound tissue. The process involves the application of a saline solution. Given that ultrasound does not travel easily through air, the saline solution serves as a contact media for the ultrasound waves to travel from the probe into the tissues via direct contact.

During this process, there is additional acoustic phenomena, including cavitation, which is the creation and destruction of small bubbles within the fluid surrounding the probe. During cavitation, the bubbles oscillate in size and shape. The oscillation of the bubbles is dependent on the frequency of the ultrasound wave. The bubbles expand and rapidly collapse, causing shockwave formation. This implosion due to cavitation causes erosion of tissues. Ultrasonic debridement provides both mechanical and hydrodynamic effects directly in the wound bed. This method causes necrotic tissue disruption, fragmentation and emulsion.

On average, we found that wounds that underwent ultrasonic debridement healed at a faster rate than those that underwent standard sharp debridement. All patients received standard wound care with a non-adherent primary dressing and standard compression therapy with either a three- or four-layer bandage.

Of equal importance is the total number of procedures performed. We found that debridement with high intensity ultrasound lasted significantly longer than debridement performed with a curette. In a 12-week period, we recorded performing an average of 3.5 debridements per patient with the SonicOne® O.R. in comparison to an average of 5.8 sharp debridement procedures per patient.
Ultrasonic Debridement: An Effective and Superior Method of Wound Debridement

John M. Hiebert MD, FACS. FACN – Director Wound Care Centers, Saint Luke’s Health System, Clinical Professor Plastic Surgery, University of Kansas

Abstract presented at Spring SAWC 2013

Introduction

Surgical debridement is often an essential part of effective complex wound management. Many methods of debridement are available. The essential goals of the procedure are to:

1. Achieve specificity in removal on non-viable from viable wound tissue
2. Achieve bacterial reduction
3. Achieve minimal blood loss
4. Improve time efficiency and cost effectiveness

Methods

40 consecutive hospitalized infected or heavily contaminated wound center patients with a variety of wound types (stage III & IV) but all requiring wound debridement were studied. Repeated ultrasonic debridements (SonicOne® O.R. Misonix, Inc.) were surgical carried out and compared with other debridement methods. Careful measurements of blood loss, intra operative time efficiency and selective specificity of devitalized tissue removal was observed and recorded. Appropriate adjunctive treatment, e.g. HBP when indicated), antibiotic management and wound dressing management methods were compared in all patients.

Results

All patients were pretreated in the OR with methylene blue dye staining (penetration 3 mm) before debridement. Measured average blood loss was 40-80 cc. Time efficiency of average ultrasound debridement was 38 sq. cm/min.

Conclusions

We conclude that contact ultrasound is a measurably superior method of debridement due to its OR specificity and OR efficiency.
If you would like further information or would like to evaluate the SonicOne® O.R. please contact us at +1.631.694.9555