USAGE OF ULTRASOUND IN WOUND MANAGEMENT

COMPARISON BETWEEN ULTRASONIC WOUND DEBRIDEMENT AND SHARP DEBRIDEMENT IN DIABETIC FOOT ULCERS: A RANDOMIZED CLINICAL TRIAL

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Mahmud Merican Award for best research paper and presentation

This paper was also presented at the The 3rd ASEAN-AAOS Instructional Course and the Combined 28th Annual Meeting of the Royal College of Orthopaedic Surgeons of Thailand (3rd ASEAN-AAOS/28th RCOST) 20th -23rd October 2006
ABSTRACT

An estimated 15% of patients with diabetes will develop a foot ulcer sometime in their life, making them 30 to 40 times more likely to undergo amputation than the non-diabetic population. This study is designed to determine the efficacy of a new, non-contact, kilohertz ultrasound debridement therapy for the healing of diabetic foot ulcers as compared to sharp/surgical debridement. This randomized clinical trial was conducted at University Malaya Medical Centre. 59 patients with 60 ulcers of Wagners Type 1 and 2 received standard care in their respective wards, debridement of the ulcers, wound assessment using the leg ulcer measurement tool, measurement of actual ulcer size and evaluation of pain during procedure. The intervention was either active 24 KHz ultrasound delivered by a saline mist for debridement or bedside sharp surgical debridement. After 2 weeks of care, the improvement in the wounds in the active ultrasound therapy device group was significantly higher than that in the sharp debridement group (P = 0.001, Mann Whitney Test). There was also significant reduction in the size of the ulcers statistically. The pain experienced during the debridements (measured with visual analog scale) was significantly lower in the group that underwent ultrasound debridement. The ultrasound treatment was easy to use. Compared to control, this therapeutic modality was found to increase the healing rate of recalcitrant, Wagners Type I and 2 diabetic foot ulcers, increase patient satisfaction and at the same time cause less pain. KEYWORDS: ultrasound debridement, diabetic foot ulcer, randomized trial, leg ulcer measurement tool.
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ABSTRACT

An estimated 15% of patients with diabetes will develop a foot ulcer sometime in their life, making them 30 to 40 times more likely to undergo amputation than the non-diabetic population. This study is designed to determine the efficacy of a new, non-contact, kilohertz ultrasound debridement therapy for the healing of diabetic foot ulcers as compared to sharp/surgical debridement. This randomized clinical trial was conducted at University Malaya Medical Centre. 59 patients with 60 ulcers of Wagners Type 1 and 2 received standard care in their respective wards, debridement of the ulcers, wound assessment using the leg ulcer measurement tool, measurement of actual ulcer size and evaluation of pain during procedure. The intervention was either active 24 KHz ultrasound delivered by a saline mist for debridement or bed side sharp surgical debridement. After 2 weeks of care, the improvement in the wounds in the active ultrasound therapy device group was significantly higher than that in the sharp debridement group (P = 0.001, Mann Whitney Test). There was also significant reduction in the size of the ulcers statistically. The pain experienced during the debridements (measured with visual analog scale) was significantly lower in the group that underwent ultra sound debridement. The ultrasound treatment was easy to use. Compared to control, this therapeutic modality was found to increase the healing rate of recalcitrant, Wagners Type I and 2 diabetic foot ulcers, increase patient satisfaction and at the same time cause less pain. KEYWORDS: ultrasound debridement, diabetic foot ulcer, randomized trial, leg ulcer measurement tool.
ABBREVIATIONS

UAW   - Ultrasound assisted wound debridement
LUMT  - Leg Ulcer Measurement Tool
TPRD  - Total Patient Rated Domain
TCRD  - Total Clinician Rated Domain
VAS   - Visual Analog Scale
NTA   - Necrotic Tissue Amount
GTA   - Granulation Tissue Amount
NDA   - Neuropathy Disability Score
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INTRODUCTION

Epidemiology

Diabetes Mellitus is a common disease affecting 30 million people world-wide. In Malaysia, the prevalence rate has been reported to have increased from 6.3% in 1986 to 14.6% in 1996. Fifteen percent of patients with diabetes mellitus will develop a lower extremity ulcer during the course of their disease. The prevalence of foot ulceration in patients attending a diabetic outpatient clinic in Malaysia has been reported as 6%. Diabetic foot complications is a substantial problem in the Malaysian diabetic population. They are a major source of morbidity, a leading cause of hospital bed occupancy and account for substantial health care resources. Foot complications have been found to account for 12% of all diabetic hospital admissions, which in turn made up 17% of all hospital admissions at Hospital Kuala Lumpur, Malaysia.

In the United States, an estimated 15% of patients with diabetes will develop a foot ulcer some time in their life. Diagnosed diabetes is most prevalent in the middle-aged and elderly populations, with rates estimated at 11% for those persons aged 65 years and older. Being the seventh leading cause of death (sixth-leading cause by disease) in the United States, diabetes contributes to more than 193,000 deaths per year. This fact, coupled with the myriad of treatment options available, ensures that
managing diabetic foot ulcers will continue to be a major clinical problem for years to come.

As the number of people with diabetes grows worldwide, the disease takes an ever-increasing proportion of national health care budgets. Without primary prevention, the diabetes epidemic will continue to expand. Currently cardiovascular complications are the most common cause of premature deaths among patients with diabetes\textsuperscript{17,18,19,20}. Even worse, diabetes is projected to become one of the world’s main disablers and killers within the next twenty-five years.

Much of this increase will occur in developing countries and will be due to population growth, ageing, unhealthy diets, obesity and sedentary lifestyles. By 2025, while most people with diabetes in developed countries will be aged 65 years or more, in developing countries most will be in the 45-64 year age bracket, people who are in their most productive years\textsuperscript{9,10}.

For WHO and the International Diabetes Federation (IDF), this increase can and must be prevented with the right measures. Costs for ulcer care in the United States have been estimated in the range of US$4,595 per ulcer episode to nearly US$28,000 for the 2 years after diagnosis\textsuperscript{11}. One report estimates 800,000 prevalent ulcer cases in the United States with costs averaging US$5,457 per year per patient or total national annual costs of US$5 billion\textsuperscript{13}. Over the past few decades the length of hospitalizations for lower extremity amputations in the United States has decreased,
but the overall direct costs have remained high\textsuperscript{14}. Direct and indirect costs of lower extremity amputation vary greatly by year, financer, level of amputation, length of stay, or attendant co morbidities and can range from US$20,000 to US$40,000\textsuperscript{14} with an estimated overall total costs of US$6 billion annually in the United States. On a similar calculation, the cost of diabetic foot care in Singapore will be about 2.4 billion dollars in the year 2010 with a population of 400,000 diabetics \textsuperscript{12}.

\textbf{Pathogenesis}

Foot complications result from a complex interplay of ischaemia, ulceration, infection and diabetic Charcot’s joint. They can be reduced through appropriate prevention and management. Each patient however should be treated according to the individual’s clinical, socioeconomic and domestic situation. The objectives are to prevent limb loss and life threat; maintain quality of life through the prevention, early recognition and treatment of foot complications; prevent recurrence; and provide patient and health provider education \textsuperscript{21}. One of the most common complications of diabetes in the lower extremity is the diabetic foot ulcer. It is estimated that 15\% of patients with diabetes will develop a lower extremity ulcer during the course of their disease \textsuperscript{14}. Several reports from population-based studies indicate an annual cumulative incidence for diabetic foot ulcers of 2–3\% \textsuperscript{22,23}.

While most ulcers can be successfully treated in the office or outpatient setting, infected and/or ischemic foot ulcers are a major cause for diabetes-related
hospitalization \(^{24}\). National hospital discharge data indicate that the average hospital length of stay in diabetic patients with ulcer diagnoses was 59% longer than in those diabetes discharges without them \(^{14}\). While 14–20% of patients with foot ulcers will subsequently require an amputation, foot ulceration is the precursor to approximately 85% of lower extremity of amputations in persons with diabetes \(^{25,26,27}\). Following one lower extremity amputation, there is a 50% incidence of serious contra lateral foot lesion and a 50% incidence of contra lateral amputation within 2–5 years \(^{14,25}\).

**Identification of risk factors**

Foot ulceration is the most common single precursor to lower extremity amputations among persons with diabetes \(^{25,26,27}\). Treatment of infected foot wounds accounts for up to one-quarter of all diabetic admissions in the United States and Britain. This staggering figure makes it the single most common reason for diabetes-related hospital admission in these nations \(^{14,24,28,29}\). The multifactorial nature of diabetic foot ulceration has been elucidated by numerous observational studies \(^{14,30,31,32,33,34,35,36,37}\). Risk factors identified include peripheral neuropathy, vascular disease, limited joint mobility, foot deformities, abnormal foot pressures, minor trauma, a history of ulceration or amputation, and impaired visual acuity. These and other putative causative factors are listed in Table 1. Identification of risk factors predisposing to foot ulceration, amputation, infection and Charcot’s arthropathy in the history taking and physical examination is important in the treatment and prevention of diabetic foot problems.
Table 1. Risk Factors For Developing Foot Ulcers

1. Peripheral sensory neuropathy
2. Structural foot deformity
3. Trauma and improperly fitted shoes
4. Callus
5. History prior ulcers/amputations
6. Prolonged, elevated pressures
7. Limited joint mobility
8. Uncontrolled hyperglycemia
9. Duration of diabetes
10. Blindness/partial sight
11. Chronic renal disease
12. Older age

Peripheral sensory neuropathy in the absence of perceived trauma is the primary factor leading to diabetic foot ulcerations\(^{30,31,32,38}\). Approximately 45–60% of all diabetic ulcerations are purely neuropathic, while up to 45% have neuropathic and ischemic components\(^{31}\). A recent prospective multicenter study of diabetic patients revealed that sensory neuropathy was the most frequent component cause in the causal sequence to ulceration\(^{31}\).

Other forms of neuropathy may also play a role in foot ulcerations. Motor neuropathy resulting in anterior crural muscle atrophy or intrinsic muscle wasting can lead to foot deformities such as foot drop, equinus, hammertoes, and prominent plantar metatarsal
heads. Autonomic neuropathy may commonly result in dry skin with cracking and fissuring, thus creating a portal of entry for bacteria. Autosympathectomy with attendant sympathetic failure, arteriovenous shunting, and microvascular thermoregulatory dysfunction impairs normal tissue perfusion and microvascular responses to injury. These alterations can subsequently be implicated in the pathogenesis of ulceration. Foot deformities resulting from neuropathy, abnormal biomechanics, congenital disorders, or prior surgical intervention may result in high focal foot pressures. This may lead to vulnerable areas on the foot predisposing to ulcerations. These areas are primarily located plantarly, although medial and dorsal ulcerations may occur from footwear irritation. Such deformities might include prior partial foot amputations, prominent metatarsal heads, hammertoes, Charcot arthropathy, or hallux valgus.

Trauma to the foot in the presence of peripheral sensory neuropathy is an important component cause of ulcerations. While trauma may include puncture wounds and blunt injury, a common injury leading to ulceration is moderate repetitive stress resulting from walking or day to day activity. This is often manifested by callus formation under the metatarsal heads. Shoe-related trauma has been identified as a frequent precursor to foot ulceration. Peripheral vascular disease rarely leads to foot ulcerations directly. However, once an ulceration develops, arterial insufficiency will result in prolonged healing and imparts an elevated risk for amputation.
Attempts to resolve any infection will be impaired due to lack of oxygenation and difficulty in delivering antibiotics to the site of infection. Early recognition and aggressive treatment of lower extremity ischemia is therefore vital to lower limb salvage. 27,36,40

Limited joint mobility has recently been described as a potential risk factor for ulcerations. 36, 41. Glycosylation of collagen as a result of long-standing diabetes may lead to stiffening of capsular structures and ligaments (cheiroarthropathy). The subsequent reduction in ankle, subtalar, and first metatarsophalangeal (MTP) joint mobility has been shown to result in high focal plantar pressures with increased risk of ulceration. Other factors often associated with heightened risk for ulceration include: nephropathy, poor diabetes control, blindness, advanced age, and poor nutrition. 28,36,38

Mechanisms of Injury

The multifactorial etiology of diabetic foot ulcers is evidenced by the numerous pathophysiological pathways which can potentially lead to this disorder. 31,29. Notwithstanding, there are two common mechanisms by which foot deformity and neuropathy may bring about skin breakdown in persons with diabetes: injuries due to continuous low pressure, typically from ill-fitting shoes, and injuries due to chronic repetitive trauma from walking. 21.
The first mechanism of injury refers to prolonged low pressure over a bony prominence (i.e., bunion or hammertoe deformity). This generally causes wounds over the medial, lateral, and dorsal aspects of the forefoot and is associated with tight or ill-fitting shoes. Studies have shown that shoe trauma, in concert with loss of protective sensation and concomitant foot deformity, are major precipitating events leading to foot ulceration in persons with diabetes\textsuperscript{25,31}.

Regions of high pedal pressure are directly associated with foot deformity\textsuperscript{36,42}. When an abnormal focus of pressure is coupled with lack of protective sensation, the result can be the development of a callus, blister, and ulcer. The other common mechanism of ulceration involves prolonged repetitive moderate stress. This normally occurs on the sole of the foot and is related to prominent metatarsal heads, atrophied or anteriorly displaced fat pads, structural deformity of the lower extremity, and prolonged walking. Rigid deformities such as hallux valgus, hallux rigidus, hammertoes, and limited range of motion of the ankle, subtalar, and metatarsophalangeal joints have been associated with the development of diabetic foot ulcers\textsuperscript{43}. Sensory neuropathy is the predisposing factor which allows progression to ulceration in each of these mechanisms of injury.
Risk for Amputation

The reported risk of lower extremity amputations (LEA) in diabetic patients ranges from 2% to 16% depending on study design and the population(s) under investigation. Rates of LEA in persons with diabetes can be 15–40 times higher than those found in persons without diabetes. The risk factors for amputation are similar to those responsible for ulceration. Overall, people with diabetes account for 60% of all amputations performed in the US annually. The same risk factors which predispose to ulceration can also generally be considered as contributing causes for amputation, albeit with several modifications (Table 2). The most common single factor to lower limb amputations among diabetics is foot ulcer and peripheral sensory neuropathy is the primary factor responsible for diabetic foot ulcerations.

Whereas peripheral vascular disease (PVD) may not always be an independent risk factor for ulceration when controlling for neuropathy, it can be a significant risk factor for amputation. PVD affecting the feet and legs is present in 8% of adult diabetic patients at diagnosis and in 45% after 20 years. The incidence in diabetic men and women is four to seven times greater than their non diabetic counterparts. Since this impairment of arterial perfusion can be an isolated cause for amputation as well as a predisposing factor leading to gangrene, arterial insufficiency must be diagnosed early and managed by revascularization procedures to avoid limb loss.
Infection is a significant risk factor in the causal pathway to amputation, while it is not often implicated in the pathway leading to ulceration. Lack of wound healing, systemic sepsis, or unresolved infection can lead to extensive tissue necrosis and gangrene requiring amputation to prevent more proximal limb loss. This includes soft-tissue infection with severe tissue destruction, deep space abscess, or osteomyelitis. Adequate debridement may require amputation at some level as a means of removing all infected material.

Another frequently described risk factor for amputation is chronic hyperglycemia. The association between degree of glucose control and incidence or progression of
numerous diabetic complications has consequently been well established by studies 20,48,49. Such complications include peripheral neuropathy, microangiopathy, impaired leukocyte phagocytosis, and glycosylation of tissue proteins. Each has adverse effects on the diabetic foot, can contribute to the etiology of foot ulceration, delay normal wound healing, and subsequently lead to amputation 36. Several studies have reported significant associations between elevated glucose and lower extremity amputation 22,45. Amputation has also been associated with other diabetes-related co-morbidities such as nephropathy, retinopathy, and cardiovascular disease 19,36. Aggressive glucose control, management of associated comorbidities, and appropriate lower extremity care coordinated in a team environment may indeed lower overall risk for amputation 14,27,36,40.

The best predictor of amputation is a history of previous amputation. A past history of a lower extremity ulceration or amputation increases the risk for further ulceration, infection, and subsequent amputation 19,26,33,44. It may also be inferred that patients with a past history of ulceration possess all the requisite risk factors necessary to produce another ulceration, having demonstrated that they already have the component elements in the causal pathway 31,25,37. This data is substantiated by the fact that up to 34% of patients develop another ulcer within 1 year after healing an index wound, while the 5-year rate of developing a new ulcer is 70% 50. The rate of recurrence is always higher in those patients who have previously undergone amputation. Recurrence of pedal ulceration is due to abnormal distribution of plantar pressures, and changed osseous architecture following amputation. The cumulative
identified risks of neuropathy, deformity, high plantar pressure, poor glucose control, and male gender are all additive factors for pedal ulceration in these diabetic patients. Re-amputation can be attributed to progression of the disease process, nonhealing wounds, and the development of additional risk factors for limb loss that develop as a result of the first amputation. Tragically, the 5-year survival rate after a diabetes-related lower extremity amputation has been reported as low as 28%.

Risk for Infection

Infections in patients with diabetes are not only common but are often more severe than those found in nondiabetic persons. It is well documented that diabetic foot infections are polymicrobial in nature. Hyperglycemia, impaired immunological responses, neuropathy, and peripheral vascular disease are the main predisposing factors leading to limb-threatening diabetic foot infections. Uncontrolled diabetes results in impaired ability of host leukocytes to fight bacterial pathogens, while ischemia will also affect the ability to fight infections since delivery of antibiotics to the site of infection will be impaired. Consequently, infections can develop and spread rapidly and produce significant and irreversible tissue damage. Even in the presence of adequate arterial perfusion, underlying peripheral sensory neuropathy will often allow the progression of infection through continued walking or delay in recognition. Infection is a significant risk factor of amputation although not for ulceration.
Ulcer Evaluation

Description of the ulcer characteristics on presentation is critical for the mapping of its progress during treatment. While some characteristics are more important than others, they all have a prognostic value during management. The presumed etiology of the ulcer needs to be determined (i.e., chemical vs. mechanical) as well as ascertaining whether the lesion is neuropathic, ischemic, or neuroischemic in character. The evaluation should include the size and depth of the ulcer, as well as a description of the margins, base, and geographic location on the extremity or foot. All but the most superficial ulcers should be examined with a blunt, sterile probe. The description should note whether or not the sterile probe detects sinus tract formation, undermining of the ulcer margins, or extension of the ulcer into tendon sheaths, bone, or joints. A positive probe to bone finding has a high predictive value for osteomyelitis. The existence of odor or exudate and the character of each should be noted. Cultures may be necessary when signs of inflammation are present. Current recommendations for culture and sensitivity include thorough surgical preparation of the wound site with curettage of the wound base for specimen or with aspiration of abscess material.

In 1992, Ayello developed a mnemonic—A-S-S-E-S-S-M-E-N-T—for pressure ulcer assessment and documentation. The mnemonic has been adapted for use with any type of wound to provide a thorough look at the parameters that complete and enhance a wound assessment. It provides a support structure, in chart form, for
clinical decision-making regarding ongoing assessment and reassessment. The mnemonic can be used in any practice setting and according to the guidelines set by the practitioner's facility.

A: Anatomic location of wound, Age
S: Size, Shape and Stage
S: Sinus tract, tunneling, undermining, fistulas
E: Exudate
S: Sepsis
S: Surrounding skin
M: Maceration
E: Edges, Epithelization
N: Necrotic Tissue
T: Tissue Bed

**Leg Ulcer Measurement Tool (LUMT)**

Assessing the effectiveness of ulcer therapies requires a measurement tool that will describe the current condition of the wound and detect any improvement or deterioration in wound status over time. Many of the recently developed wound assessment tools were designed specifically to evaluate pressure ulcers. Some of these tools include the Pressure Sore Status Tool (PSST), the Pressure Ulcer Scale for Healing (PUSH Tool), the Sussman Wound Healing Tool (SWHT), the Sessing Scale, the Wound Healing Scale (WHS), and the Photographic Wound Assessment
Many of these tools have been found to provide reproducible evaluations of pressure ulcers; however, only the Sessing Scale and PWAT have been shown to detect changes in pressure ulcer status over time. Tools utilized specifically to assess pressure ulcer status do not necessarily provide accurate evaluation of other common types of chronic ulcers, such as diabetic foot ulcers and venous leg ulcers. Assessment tools that describe the severity of diabetic foot ulcers have been developed, and a staging system for wound bed preparation applicable to venous ulcers has been proposed. Although these classification systems for lower extremity ulcers may be useful in predicting patient outcomes, such as amputation or complete wound closure, they were neither designed nor validated to detect improvement or deterioration in wound status over time.

In practice, many clinicians use pressure ulcer assessment tools designed to measure wounds that are characteristically and morphologically different from other ulcers. Clinicians who measure wound size and use it as the indicator of change in wound status have similar issues. Therefore, wound care clinicians need evaluative tools designed specifically to assess leg ulcer status and change over time so that they can accurately evaluate the effectiveness of their interventions.

The Leg Ulcer Measurement Tool (LUMT) which is being used in this study is the first instrument developed specifically to evaluate leg ulcer appearance. Therefore, there are no criteria against which to evaluate the total LUMT for concurrent criteria validity. The LUMT is easy to use: It takes about 3 minutes to complete after training.
Therefore, this tool would be appropriate for use in research and in clinical practice, and it would provide a full and complete description of wound appearance. The clinician-rated section of the LUMT is reliable when used by different raters or by the same rater, both experienced and inexperienced. Increased clinical training in the use of the LUMT is required to improve reliability.

Classification of Ulcers

Appropriate classification of the foot wound is predicated upon its thorough assessment, should facilitate its treatment, and be generally predictive of expected outcomes. Several systems of ulcer classification are currently in use in an attempt to meaningfully describe these lesions and to communicate severity. Perhaps the easiest system is to simply classify the lesions as neuropathic, ischemic, or neuroischemic with descriptors of wound size, depth, and infection. Regardless of which system is ultimately used, the clinician must be able to easily categorize the wound and, once classified, the ensuing treatment should be directed by the underlying severity of pathology.

Although no single system has been universally adopted, the classification system most often used was described and popularized by Wagner. Since this system fails to consider the important roles of infection, ischemia and other comorbid factors, subsequent authors have modified the classification systems by including descriptors for these considerations. In the Wagner classification system (Table 3), foot
lesions are divided into six grades based on the depth of the wound and the extent of tissue necrosis:

Table 3. Wagner Classification System

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<th>Grading</th>
<th>Features</th>
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<tr>
<td>0</td>
<td>Pre-ulcer. No open lesion. May have deformities, erythematous areas of pressure or hyperkeratosis.</td>
</tr>
<tr>
<td>1</td>
<td>Superficial ulcer. Disruption of skin without penetration of subcutaneous fat layer.</td>
</tr>
<tr>
<td>2</td>
<td>Full thickness ulcer. Penetrates through fat to tendon or joint capsule without deep abscess or osteomyelitis.</td>
</tr>
<tr>
<td>3</td>
<td>Deep ulcer with abscess, osteomyelitis or joint sepsis. It includes deep plantar space infections, abscesses, necrotizing fascitis and tendon sheath infections.</td>
</tr>
<tr>
<td>4</td>
<td>Gangrene of a geographical portion of the foot such as toes, forefoot or heel.</td>
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<tr>
<td>5</td>
<td>Gangrene or necrosis of large portion of the foot requiring major limb amputation.</td>
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Failure of the Wagner classification to specifically address infection and ischemia within each grade \(^{29}\) has been recognized and hybrid schemes have been developed to account for these important attributes of foot ulcers \(^{38}\).

Another hybrid method for classifying diabetic foot lesions has been popularized by the University of Texas (Table 4) and has been retrospectively validated within that center \(^{77,78}\). This scheme employs four grades of depth with four associated stages based on ischemia, infection, or both. This system is also generally predictive of outcome since increasing grade and stage of wounds are less likely to heal without revascularization or amputation \(^{78}\).
<table>
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<tr>
<td>A</td>
<td>Pre or postulcerative lesion completely epithelialized</td>
<td>Superficial wound, not involving tendon, capsule, or bone</td>
<td>Wound penetrating to tendon or capsule</td>
<td>Wound penetrating to bone or joint</td>
</tr>
<tr>
<td>B</td>
<td>Pre or postulcerative lesion, completely epithelialized with infection</td>
<td>Superficial wound, not involving tendon, capsule, or bone with infection</td>
<td>Wound penetrating to tendon or capsule with infection</td>
<td>Wound penetrating to bone or joint with infection</td>
</tr>
<tr>
<td>C</td>
<td>Pre or postulcerative lesion, completely epithelialized with ischemia</td>
<td>Superficial wound, not involving tendon, capsule, or bone with ischemia</td>
<td>Wound penetrating to tendon or capsule with ischemia</td>
<td>Wound penetrating to bone or joint with ischemia</td>
</tr>
<tr>
<td>D</td>
<td>Pre or postulcerative lesion, completely epithelialized with infection and ischemia</td>
<td>Superficial wound, not involving tendon, capsule, or bone with infection and ischemia</td>
<td>Wound penetrating to tendon or capsule with infection and ischemia</td>
<td>Wound penetrating to bone or joint with infection and ischemia</td>
</tr>
</tbody>
</table>

Debridement

The primary goal in the treatment of diabetic foot ulcers is to obtain wound closure as expeditiously as possible. The resolution of foot ulcers and decreasing the rate of recurrence can lower the probability of lower extremity amputation in the diabetic patient. The essential therapeutic objectives include:

1. Debridement
2. Pressure relief (off-loading)
3. Appropriate wound management
4. Management of infection
5. Management of ischemia
6. Medical management of comorbidities
7. Surgical management

Frequent re-evaluation with response-directed treatment is essential. Once healed, the management consists of decreasing the probability of recurrence. Debridement of necrotic tissue is an integral component in the treatment of chronic wounds since they will not heal in the presence of nonviable tissue and debris. Debridement is the process of removing non-living tissue from pressure ulcers, burns, and other wounds. Adequate debridement must always precede the application of topical wound healing agents, dressings, or wound closure procedures. Classically the types of debridement include: autolytic, enzymatic or chemical, mechanical, and surgical.
What is the purpose of debridement? Debridement speeds the healing of pressure ulcers, burns, and other wounds. Wounds that contain non-living (necrotic) tissue take longer to heal. The necrotic tissue may become colonized with bacteria, producing an unpleasant odor. Though the wound is not necessarily infected, the bacteria can cause inflammation and strain the body's ability to fight infection. Necrotic tissue may also hide pockets of pus. Abscesses can develop into a general infection that may lead to amputation or death.

Not all wounds need debridement. Sometimes it is better to leave a hardened crust of dead tissue, called an eschar, than to remove it and create an open wound, particularly if the crust is stable and the wound is not inflamed. Before performing debridement, the physician will take a medical history with attention to factors that might complicate healing, such as medications being taken and smoking. The physician will also note the cause of the wound and the ways it has been treated. Some ulcers and other wounds occur in places where blood flow is impaired, for example, the foot ulcers that can accompany diabetes mellitus. In such cases, the physician or nurse may decide not to debride the wound because blood flow may be insufficient for proper healing.

In debridement, dead tissue is removed so that the remaining living tissue can adequately heal. Dead tissue exposed to the air will form a hard black crust, called an

30
eschar. Deeper tissue will remain moist and may appear white, or yellow and soft, or flimsy.

Surgical debridement (also known as sharp debridement) uses a scalpel, scissors, or other instrument to cut dead tissue from a wound. It is the quickest and most efficient method of debridement. It is the preferred method if there is rapidly developing inflammation of the body's connective tissues (cellulitis) or a more generalized infection (sepsis) that has entered the bloodstream. The procedure can be performed at a patient's bedside. If the target tissue is deep or close to another organ, however, or if the patient is experiencing extreme pain, the procedure may be done in an operating room.

The surgeon will begin by flushing the area with a saline. Using a forceps to grip the dead tissue, the physician will cut it away bit by bit with a scalpel or scissors. Sometimes it is necessary to leave some dead tissue behind rather than disturb living tissue. The physician may repeat the process again at another session. Excision of necrotic tissue extends as deeply and proximally as necessary until healthy, bleeding soft tissue and bone are encountered. Any callus tissue surrounding the ulcer must also be removed. A diabetic ulcer associated with a deep abscess requires hospital admission and immediate incision and drainage. Joint resection or partial amputation of the foot is needed in the presence of osteomyelitis, joint infection, or gangrene.
Necrotic tissue removed on a regular basis can expedite the rate at which a wound heals and has been shown in a recent study to increase the probability of attaining full secondary closure. Less frequent surgical debridement can impact negatively on the rate of wound healing and secondarily increase the risk of infection. Surgical debridement is repeated as often as needed if new necrotic tissue continues to form. Weekly debridement is commonly required.

In mechanical debridement, a saline-moistened dressing is allowed to dry overnight and adhere to the dead tissue. When the dressing is removed, the dead tissue is pulled away too. This process is one of the oldest methods of debridement. It can be very painful because the dressing can adhere to living as well as nonliving tissue. Because mechanical debridement cannot select between good and bad tissue, it is an unacceptable debridement method for clean wounds where a new layer of healing cells is already developing.

Chemical or enzymatic debridement makes use of certain enzymes and other compounds to dissolve necrotic tissue. It is more selective than mechanical debridement. In fact, the body makes its own enzyme, collagenase, to break down collagen, one of the major building blocks of skin. A pharmaceutical version of collagenase is available and is highly effective as a debridement agent. As with other debridement techniques, the area first is flushed with saline. Any crust of dead tissue is etched in a cross-hatched pattern to allow the enzyme to penetrate. A topical
antibiotic is also applied to prevent introducing infection into the bloodstream. A moist dressing is then placed over the wound.

Autolytic debridement takes advantage of the body's own ability to dissolve dead tissue. The key to the technique is keeping the wound moist, which can be accomplished with a variety of dressings. These dressings help to trap wound fluid that contains growth factors, enzymes, and immune cells that promote wound healing. Autolytic debridement is more selective than any other debridement method, but it also takes the longest to work. It is inappropriate for wounds that have become infected. The only method which has been proven efficacious in clinical trials is surgical debridement.

New research published in the October issue of Clinical Infectious Diseases has found that maggots are useful in treating deep wounds without increasing the risk of further infection. Maggots work because they eat dead tissue (debridement) within the wound, which can promote infection. This treatment seems to help reduce the risk of infection after surgery because the larvae are thought to secrete substances that fight infection. Maggot debridement therapy (MDT) has been around since the 1920s as a treatment for bone and tissue infections, but a new wave of studies demonstrating its safety and benefits have prompted a surge of popularity. MDT uses "sterile" larvae, Phaenica sericata, which are placed on a person's wound twice a week and left there for 48 to 72 hours. The maggots only eat dead tissue, leaving live tissue intact. There is some concern that disinfected larvae may cause or worsen a pre-existing infection.
in a wound. Their study shows that wounds debrided with maggots prior to surgery were less likely to develop an infection after surgery compared with wounds not treated with MDT. "Presurgical MDT effectively prepared the wound bed for surgical closure, without increased risk of post-surgical wound infection," the co-authors conclude in their report. Pain at the wound site was the most common side effect.

For carefully selected patients, MDT facilitates more rapid debridement and wound healing than many other currently available alternatives. Recognizing this, the use of maggot therapy has rapidly increased worldwide.

MDT is a therapeutic modality that is again being selected by patients and their physicians, especially when surgery is not clearly the superior option. A great unrealized benefit of MDT exists in the outpatient community, where the attributes of this effective, simple, inexpensive, and non-physician-dependent treatment should make MDT a better choice than many currently available treatment options.

In a few randomized clinical trials There is evidence to suggest that hydrogel increases the healing rate of diabetic foot ulcers as compared to just using gauze or other standard care in diabetic foot ulcers. Surgical debridement and larval therapy showed no significant benefit in these small trials. Other debridement methods such as enzyme preparations or polysaccharide beads have not been evaluated in RCTs of people with diabetes. More research is needed to evaluate the effects of a range of widely used debridement methods and of debridement per se.
The use of honey as a wound dressing material, an ancient remedy that has been rediscovered, is becoming of increasing interest as more reports of its effectiveness are published. The clinical observations recorded are that infection is rapidly cleared, inflammation, swelling and pain are quickly reduced, odour is reduced, sloughing of necrotic tissue is induced, granulation and epithelialisation are hastened, and healing occurs rapidly with minimal scarring \(^{89,90}\). The antimicrobial properties of honey prevent microbial growth in the moist healing environment created. Unlike other topical antiseptics, honey causes no tissue damage: in animal studies it has been demonstrated histologically that it actually promotes the healing process \(^{89,90}\).

Diabetic foot infections should be managed with a multidisciplinary team approach \(^{88,95,192,194}\). This should include obtaining the appropriate consultations as well as admitting the patient to a hospital setting in emergent cases or when the patient does not respond to a course of outpatient treatment. Hospitalization of limb-threatening infections should be considered mandatory. Diabetic foot infections, whether non-limb-threatening or limb-threatening, need to be monitored very closely \(^{60}\). Equally important, especially in the outpatient management of foot infections, patient compliance and education must be addressed in order to provide the best possible outcome.

Hyperbaric oxygen therapy (HBO), might be of benefit although this has not been proven conclusively in prospective clinical trials \(^{27}\). Several reviews and retrospective
studies on this modality purport efficacy in difficult wounds where there might be nonreconstructible occlusive vascular disease or limb-threatening infection \(^91,92\). Local, topically applied oxygen has not been proven effective in clinical trials and cannot be advocated for use \(^93\). HBO and other alternative or unproven technologies which are occasionally used in the management of diabetic foot wounds are listed in Table 5 \(^91,92,93,94,95,96\). A variety of other modalities have also been advocated for the chronic wound, although most lack supportive clinical trials. Efficacy for many of these has not clearly been demonstrated and studies supporting their use in diabetic foot ulcers are still needed \(^97\).

Table 5. Alternative technologies for wound management

<table>
<thead>
<tr>
<th>Modality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hyperbaric Oxygen Therapy (HBO)</td>
</tr>
<tr>
<td>2. Vacuum Assisted Closure (VAC)</td>
</tr>
<tr>
<td>3. Heat Therapy</td>
</tr>
<tr>
<td>4. Laser Therapy</td>
</tr>
<tr>
<td>5. Mechanical Constant Tension</td>
</tr>
<tr>
<td>6. Larval/Maggot Therapy (Biodebridement)</td>
</tr>
<tr>
<td>7. Electrical Stimulation</td>
</tr>
</tbody>
</table>

Wound Care

After debridement, the ulcer is covered to protect it from trauma and contaminants. A
moist wound environment will also facilitate healing. Factors that determine the type of dressings to be applied are wound size, depth, location, surface and discharge. Normal saline dressings are commonly used and regarded as standard wound dressings though there is lack of evidence to support its use. Other types of wound care products are as listed below (Table 6).

Topical agents not readily available in Malaysia as yet are: -

(i) Growth factors, (Becaplemin gel, autologous platelets) for use in neuropathic diabetic ulcers but contraindicated in infected and necrotic wounds. (ii) Dermal / skin substitutes, for venous stasis ulcers and diabetic foot ulcers. These are contraindicated in infected necrotic wounds.
Table 6. Wound Care Products

<table>
<thead>
<tr>
<th>Category</th>
<th>Indication</th>
<th>Contra Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dressings</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transparent films — polyurethane film with adhesive layer; semipermeable hydrogels — gel, sheet, gauze; 95% water or glycerin foam — polyurethane foam; open cell, absorbent hydrocolloids — wafer with adhesion carboxy/methylcellulose; pectin gelatin; impermeable to oxygen calcium alginate — pad made of fiber from seaweed gauze pads — sterile cotton</td>
<td>Dry to minimally draining</td>
<td>Infection; significant drainage; over prominence or friction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dry to minimally draining</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate, large exudate clean wound surface</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low to moderate drainage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Undefined</td>
</tr>
<tr>
<td>Calcium alginate — pad made of fiber from seaweed</td>
<td>Heavy exudative wounds</td>
<td></td>
</tr>
<tr>
<td>Gauze pads — Sterile cotton</td>
<td>Low to heavily draining wounds, surgical wounds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low to heavily draining wounds</td>
<td></td>
</tr>
<tr>
<td>Collagen dressings — composite pads with collagen component</td>
<td>Infected or clean wounds to prevent infection</td>
<td>Allergies to components</td>
</tr>
<tr>
<td>Antimicrobial dressings — contain silver or iodine in various preparations</td>
<td>Clean or infected wounds</td>
<td>Undefined</td>
</tr>
<tr>
<td><strong>Topical therapies/agents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saline — amorphous hydrogels; skin cleaners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detergents/antiseptics — povidone-iodine, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topical antibiotics — Silver sulfadiazine, Bacitracin, Mupiricin, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enzymes — collagenase, papain-urea, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth factors — Becaplermin gel (Regranex®); Autologous platelets</td>
<td>Necrotic or escharotic wounds</td>
<td>Healthy or infected wounds</td>
</tr>
<tr>
<td>Dermal/skin substitutes — Apligraf®, Dermagraft® (not available in U.S.)</td>
<td>Venous stasis ulcers; diabetic foot ulcers</td>
<td>Infected wounds, necrotic wounds</td>
</tr>
</tbody>
</table>

Ultrasound Assisted Wound Debridement (UAW)

Recently ultrasound technology has been applied in management of wounds. Podiatrists at Foot & Ankle Clinics of America are taking the lead when it comes to wound care. They’re using Ultrasound Assisted Wound treatment (UAW) for the successful treatment of chronic and slowly healing wounds. UAW is the same technology used for years to remove calcified tumors on the brain. This procedure uses low frequency ultrasound to help foster healing in chronic wounds and wounds that do not heal well or are affected by necrosis and layers often requiring repeated debridement. Within the wound healing community, interest in both diagnostic and therapeutic ultrasound has increased. Ultrasound is defined as a mechanical vibration transmitted at a frequency above the upper limit of human hearing (>20 KHz). High frequency ultrasound (20 to 40 MHz) devices are able to assess the periwound skin, wound bed, and underlying soft tissue components. Therapeutic ultrasound has been employed in sports medicine and physical therapy for years but wound care clinicians are only recently becoming aware of its potential benefits for treating recalcitrant wounds. This alternative to conventional wound debridement improves the wound healing process with less pain for the patient.

Contaminated facial wounds treated by this method resulted in closure with no loss of adjacent facial tissues. Shorter time was required for thorough removal of ingrained dirt and grit compared with other scrubbing procedures and no patients had tattooed
scarring or a neurological deficit. Chronic wounds and wounds that do not heal well and are affected by necrosis often require repeated local surgery for wound debridement in addition to a sufficient therapy for the basic condition. However, these surgeries are extremely painful. Often, local anesthesia or even surgery under anesthetic is required. Furthermore, mechanical debridement cannot always be exactly restricted to the vital border zone; there is always the danger that intact granulation tissue is also removed.

The ultrasonic assisted wound treatment (UAW) with the Sonoca®-180 allows a new kind of treatment as an alternative to mechanical wound debridement. During UAW low-frequency ultrasound is applied together with a wound treatment solution and leads to a destruction of bacteria and necrotic tissue, an improvement of the healing process and a lowering of pain.

With ultrasound-assisted wound treatment, the wound cavitation processes feature a high-efficient deep penetrating bactericidy. Cavitations (micro gas bubbles imploding cyclically) cause destruction of bacteria, viruses and fungi. The ultrasound pulse causes the wound treatment solution to penetrate more deeply into the fissures of the tissue, then mechanical rinsing effects.

Fibrin deposits and bacteria growth are flushed out gently. The central liquid supply through the probe tip (Sonotrode) shaft has been developed for tasks where direct application to a specific area is required.
An acidic wound environment that causes pain characterizes infected chronic wounds. The traits of aseptic wounds change as the bacteria remnants are broken down and the wound environment turns neutral, starting to become permanently free of pain. The neutral wound base tends to heal more quickly.

Low frequency ultrasonic wound treatment is an advanced technology that is an alternative method to surgical and sharp debridement techniques. The potential benefits of this technology include selective tissue debridement with preservation of granulation tissue, exceptional access to tunneling and undermining wounds, microcavitations causing bacterial destruction, improved patient satisfaction due to decreased pain and cost effectiveness related to decreased requirement for invasive surgical procedures. This advanced wound care technology has the potential to revolutionize wound care practice by enhancing clinical outcomes while maintaining cost efficiency. The rates of wound surface area reduction were much faster than those for other studies assessing the effects of pulsed UAW, placebo UAW, or standard care regimens on healing of skin ulcers.

The usage of low frequency ultrasound equipment in significant damage of soft tissue and bone structures treatment has been shown to be a highly effective which speeds up preoperative wound preparation, reduce the amount of post operative complication and improve the outcome of microsurgical treatment in general.
RESEARCH METHODOLOGY

OBJECTIVE

To compare the efficacy and assess the outcome of ultrasonic assisted wound debridement as compared with sharp manual debridement in diabetic patients with foot ulcers.

IMPORTANCE

In the literature, no comparison exists so far between ultrasound and conventional treatments on the acceleration of wound healing. In this study, we investigated and compared the effects of ultrasound and conventional sharp debridement on the wound healing process through a randomized controlled trial.

STUDY DESIGN

This is a randomized prospective trial comparing two methods of wound debridement in diabetic foot ulcers. The methods were ultrasound assisted wound debridement (UAW) compared with sharp debridement of wounds which is considered as the gold standard. It was commenced on the 26th December 2004 and ended on 24th September 2005.
INCLUSION CRITERIA

Patients with diabetic foot ulcers admitted to the orthopaedic wards in UMMC for management of their wounds were included. Only patients with diabetic ulcers grade 0, 1 or 2 (ulcers without gangrene or OM based on Wagner's classification) were included in this study. Patients were referred by the respective trauma teams in the wards for the wound debridement. Patients were all known cases of DM (either IDDM or NIDDM) and had been followed up at any health centre and were being treated either with oral hypoglycaemic agents or subcutaneous insulin previously. Glycaemic control during their stay in ward were managed by administration of subcutaneous insulin as per ward protocol and according to their dextrostix readings. The patients must have had sensate feet based on the Modified Neuropathic Disability Score (NDS), (Attachment 1) and at least one of the foot pulses must have been palpable (either the dorsalis pedis or the posterior tibial artery).

EXCLUSION CRITERIA

Patients with diabetic foot ulcers of grade 3 or 4 based on Wagner's Classification and patients whose ulcers that were covered with a hard scab were not included in the study. Patients with peripheral neuropathy based on the modified NDS those who did
not have at least one of the foot pulses palpable (either the dorsalis pedis artery or the posterior tibialis artery) were also excluded.

PATIENTS AND METHODS

Once a patient is referred for management of his diabetic wound, the first thing that was done is to determine whether the foot fell into the inclusion criteria above or not. The ulcer was assessed and x rays were examined to determine there was no OM. If they fall into Wagner's Type 0, 1 or 2, then the neuropathy status was assessed. If there was no neuropathy, they were then selected to either be debrided with the ultrasonic method (UAW) or using sharp debridement by simple randomization (drawing lots). The patients were given an explanation regarding the procedure and a verbal consent was obtained to manage the wound.

The debridements were done every other day. The first assessment of the wound was on the first day of debridement and the ulcers were assessed again at day fourteen. The last debridement was done at day thirteen. Therefore the total number of times the wounds were debrided was seven. The wound solution used was Normal Saline 0.9%. The debridements were done by the researcher only and the method is standardized. Ultrasonic debridement was done using an oblique probe at an intensity of 50% at a rate of ½ minute for every square cm of wound. Post debridement, the probe was soaked in Cidex solution and the probe was sent for autoclaving at the end.
of the two week study period for a patient before being used for other patients. This was due to the fact that at the time of the study, only two probes was available.

Sharp debridement was done using a size 10 sterile blade and dissecting scissors at approximately at the same rate as the above method. The debridement was done layer by layer (superficial to deeper layers) and the wounds were flushed with a 0.9% normal saline solution.

Post debridement, the wounds were covered with 2 layers of absorbent gauze followed by one layer of gamzee and lightly bandaged. On the days when debridements were not done, the wounds are exposed, dressed with normal saline and similar dressing applied onto them. The duration of study for each patient is 2 weeks (14 days) starting from the first day of debridement. No anaesthesia was used in any of the patients.

The leg ulcer measurement tool (LUMT) was used to assess the wounds on the 1st day of debridement and at the 14th day. Assessment was done by 2 independent observers (two house officers from the orthopaedic wards) who were blinded. These assessors did not know the method of debridement that was being employed on the wounds. They were trained regarding the method of assessment using the LUMT. They were trained on the parameters that were being used in the LUMT and how to determine them (Attachment 2).
The parameters assessed in the clinician rated domain section were exudate type and amount, size, depth, undermining, necrotic tissue type and amount, granulation tissue type and amount, edge assessment, periumler skin viability status, leg edema type and location of the edema and assessment of bio burden. The parameters assessed in the patient rated domain section were pain amount, pain frequency and quality of life as it relates to the leg ulcer.

Each parameter had to be scored with a minimum point of zero and a maximum of four. The lower the score, the better the healing process. The maximum score in the clinician rated domain section is 56 and the minimum is 0. The maximum score in the patient rated domain section is 12 and the minimum is 0. A high score indicates a poorly healing ulcer whereas the lower scores indicates a well healing ulcer (Attachment 3). Besides the LUMT, the actual size of the ulcers were also measured using the Smith & Nephew flexi grid op site (Figure 1).

Pain was measured using a visual analog scale by the researcher immediately after the procedure is done during the first and last debridement. To determine whether the patient has neuropathy or not, the Modified Neuropathy Disability Score was used. The modified NDS had been used in several large studies and can also be used in the community by a trained nonspecialist (Fig. 1). It had been shown to be the best predictor of foot ulceration and the best neuropathic end point in a large prospective community study. The maximum NDS is 10, with a score of 6 or more being predictive of foot ulcer risk.
Figure 1. Measurement of the actual size of the ulcer using the flexi-grid op site
## MODIFIED NEUROPATHY DISABILITY SCORE

<table>
<thead>
<tr>
<th>Test</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibration Perception</td>
<td>Normal 0</td>
<td></td>
</tr>
<tr>
<td>128 Hz Tuning Fork</td>
<td>Abnormal 1</td>
<td></td>
</tr>
<tr>
<td>Temperature Perception</td>
<td>Normal 0</td>
<td></td>
</tr>
<tr>
<td>Use Tuning Fork</td>
<td>Abnormal 1</td>
<td></td>
</tr>
<tr>
<td>Pin Prick</td>
<td>Normal 0</td>
<td></td>
</tr>
<tr>
<td>Apply pin just enough to deform skin</td>
<td>Abnormal 1</td>
<td></td>
</tr>
<tr>
<td>Can distinguish sharp/not sharp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achilles Reflex</td>
<td>Normal/Present 0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Present with reinforcement 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Absent/Reduced/Uncertain 2</td>
<td></td>
</tr>
<tr>
<td>NDS Total Out Of 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuropathy / No Neuropathy</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Source: AJM Boulton, RA Malik, JC Arezzo, JM Sosenko. Diabetic Somatic Neuropathies, Diabetes Care, Vol 27, No 6, June 2004
Attachment 2. Instructions on Assessment of Ulcers in LUMT

**Section A: CLINICIAN-RATED DOMAINS** Assessments are to be done predebridement but after cleansing the wound. Evaluators should note the exudate type and amount on removal of dressings. Whenever possible, the time since the last dressing change should be consistent from one assessment to the next.

A1. Exudate type—Reminder. Some wound care products may change the appearance of the exudate, eg, silver sulfadiazine or hydrogels.

Definitions:
1. Serosanguineous—thin, watery, pale red to pink
2. Serous—thin, watery, clear, pale yellowish
3. Seropurulent—thin, opaque
4. Purulent—thick, opaque, yellow to green with foul odor (as distinct from body or foot odor)

A2. Exudate amount—Reminder. Consider time since last dressing change.

0 None—ulcer healed or wound tissue dry (if wound dressings changes are not regular)
1 Slight—wound bed moist with dressing dry
2 Small—wound bed moist with some drainage on dressing
3 Moderate—obvious fluid in wound bed and >50% of dressing soaked
4 Copious—overwhelming the dressing system

A3. Size—Measure length as the largest diameter, width is perpendicular to length. Avoid diagonal. Calculate wound area as length by width. Write this in space provided and select appropriate response category.

A4. Depth—layers. Pick the most appropriate descriptor.

A5. Undermining—Place moistened rayon-tipped sterile applicator or wound probe under the edge of the wound. Advance it gently as far as it will go. Place gloved thumb on the applicator against the wound edge to mark the extent of undermining on the applicator. Holding the thumb in place, remove the applicator and measure the distance along the applicator in centimeters. Indicate the area of greatest undermining according to the face of a clock, with 12 o’clock at the top of the patient.

A6. Necrotic tissue type—Reminder. The wound should be thoroughly cleansed before evaluating.

Pick the predominant type of necrotic tissue, eg, if most of the wound bed is attached fibrin with small amount of black eschar, choose attached fibrin as tissue type.

A7. Necrotic tissue amount of predominant type selected in A6.

The sum of the percentages in A7 and A9 may be less than but should not exceed 100%.

A8. Granulation tissue type—Choose predominant type of granulation tissue.

A9. Granulation tissue amount—The sum of the percentages in A7 and A9 may be less than but should not exceed 100%.) The percentage of granulation tissue refers only to the nonapthelialized (open) portion of the wound. The advancing border of epithelium is not considered part of the wound surface.

A10. Edges—Definition: Indistinct borders—where you would not be able to trace the wound edge.

1. More than half of advancing borders may be indistinct because most of wound is epithelializing.

   Advancing wound edge is

2. Less than half of the wound edge is advancing (the process of epithelialization appears smooth and shiny).

3. Attached, no advancing border—unable to probe. Looks like

4. Unattached wound edge is

   Undetermined wound edge is

A11. Periocular skin viability—Select the following items that are present; count the number selected; then use this total to determine appropriate response category.

Definitions:
- Callos—thick, dry epidermis
- Scaling dermatitis—scaling, red skin which may be peeling
- Maceration—wet, white, opaque skin
- Induration—feels firmer than surrounding skin when pressed
- Erythema—skin redness (bright red)
A12. Leg edema type- Indicate the worst edema type located anywhere on the leg. Definition: lipodermatosclerosis- waxy, white, firm tissue.

A13. Leg edema location- Indicate the most proximal location of any type of edema. Clinical example: Pitting edema ankles with non pitting edema to mid calf: For A10, leg edema type =2 > pitting =, A11, leg edema location =3 > mid calf =.

A14. Assessment of bioburden
1 Lightly colonized : small amount of serous type exudates.
2. Heavily colonized : large amount of sero purulent drainage with foul odour and no other cardinal signs of inflammation
3. Localized infection : large amount of seropurulent drainage with foul odour and either induration, erythema, warmth, or pain.
4. Systemic infection : advancing cellulites or osteomyelitis.

Section B PATIENT – (PROXY) RATED DOMAINS. Read the questions “as they are” to the patient. It is important to qualify that the questions refer to the last 24 hours. If the patient is unable to understand the question due to cognition or language deficit, section B should not be completed or it may be completed by a proxy only if the proxy knows the patient well and has been with the patient for most of the last 24 hours. The same person should provide proxy information for each assessment: do not complete section B by proxy if the person providing proxy information is not the same.

B1. Pain amount as it relates to the leg ulcer in the last 24 hours. Determine the rating based on a numerical rating scale ranging from 0-10, then place response in appropriate category.

B2. Pain frequency as it relates to the leg ulcer in the last 24 hours. How often patient experienced pain in the last 24 hours.

B3. Quality of life as it relates to the leg ulcer in the last 24 hours.

Attachment 3 : Leg Ulcer Measurement Tool (LUMT)

<table>
<thead>
<tr>
<th>(A) CLINICIAN RATED DOMAINS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A1. EXUDATE TYPE</strong></td>
<td></td>
</tr>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 SEROSANGUINEOUS</td>
<td></td>
</tr>
<tr>
<td>2 SEROUS</td>
<td></td>
</tr>
<tr>
<td>3 SEROPURULENT</td>
<td></td>
</tr>
<tr>
<td>4 PURULENT</td>
<td></td>
</tr>
<tr>
<td><strong>A2. EXUDATE AMOUNT</strong></td>
<td></td>
</tr>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 SCANT</td>
<td></td>
</tr>
<tr>
<td>2 SMALL</td>
<td></td>
</tr>
<tr>
<td>3 MODERATE</td>
<td></td>
</tr>
<tr>
<td>4 COPIOUS</td>
<td></td>
</tr>
<tr>
<td><strong>A3. SIZE</strong></td>
<td></td>
</tr>
<tr>
<td>0 HEALED</td>
<td></td>
</tr>
<tr>
<td>1 &lt; 2.5 CM 2</td>
<td></td>
</tr>
<tr>
<td>2 2.5 - 5.0 CM 2</td>
<td></td>
</tr>
<tr>
<td>3 5.1 - 10.0 CM 2</td>
<td></td>
</tr>
<tr>
<td>4 10.1 CM 2 OR &gt;</td>
<td></td>
</tr>
<tr>
<td><strong>A4. DEPTH</strong></td>
<td></td>
</tr>
<tr>
<td>TISSUE LAYERS</td>
<td></td>
</tr>
<tr>
<td>0 HEALED</td>
<td></td>
</tr>
<tr>
<td>1 PARTIAL THICKNESS SKIN LOSS</td>
<td></td>
</tr>
<tr>
<td>2 FULL THICKNESS</td>
<td></td>
</tr>
<tr>
<td>3 TENDON/JOINT CAPSULE VISIBLE</td>
<td></td>
</tr>
<tr>
<td>4 PROBES TO BONE</td>
<td></td>
</tr>
<tr>
<td><strong>A5. UNDERMINING</strong></td>
<td></td>
</tr>
<tr>
<td>0 0CM</td>
<td></td>
</tr>
<tr>
<td>1 &gt;0-0.4 CM</td>
<td></td>
</tr>
<tr>
<td>2 &gt;0.4-0.9 CM</td>
<td></td>
</tr>
<tr>
<td>3 &gt;0.9-1.4CM</td>
<td></td>
</tr>
<tr>
<td>4 &gt; 1.5CM</td>
<td></td>
</tr>
<tr>
<td><strong>A6. NECROTIC TISSUE TYPE</strong></td>
<td></td>
</tr>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 LOOSE WHITE TO YELLOW SLOUGH</td>
<td></td>
</tr>
<tr>
<td>2 ATTACHED WHITE TO YELLOW SLOUGH/FIBRIN</td>
<td></td>
</tr>
<tr>
<td>3 SOFT GREY TO BLACK ESCHAR</td>
<td></td>
</tr>
<tr>
<td>4 HARD DRY BLACK ESCHAR</td>
<td></td>
</tr>
<tr>
<td><strong>A7. NECROTIC TISSUE AMOUNT</strong></td>
<td></td>
</tr>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 1-25% WOUND BED</td>
<td></td>
</tr>
<tr>
<td>2 26-50%</td>
<td></td>
</tr>
<tr>
<td>3 51-75%</td>
<td></td>
</tr>
<tr>
<td>4 76-100%</td>
<td></td>
</tr>
<tr>
<td><strong>A8. GRANULATION TISSUE TYPE</strong></td>
<td></td>
</tr>
<tr>
<td>0 HEALED</td>
<td></td>
</tr>
<tr>
<td>1 BRIGHT BEEFY RED</td>
<td></td>
</tr>
<tr>
<td>2 DUSKY PINK</td>
<td></td>
</tr>
<tr>
<td>3 PALE</td>
<td></td>
</tr>
<tr>
<td>4 ABSENT</td>
<td></td>
</tr>
<tr>
<td><strong>A9. GRANULATION TISSUE AMOUNT</strong></td>
<td></td>
</tr>
<tr>
<td>0 HEALED</td>
<td></td>
</tr>
<tr>
<td>1 76-100% WOUND BED</td>
<td></td>
</tr>
<tr>
<td>2 51-75%</td>
<td></td>
</tr>
<tr>
<td>3 26-50%</td>
<td></td>
</tr>
<tr>
<td>4 1-25%</td>
<td></td>
</tr>
</tbody>
</table>
### A10. EDGES

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 HEALED</td>
<td></td>
</tr>
<tr>
<td>1 &gt; 50% ADV BORDER OF EPI/</td>
<td></td>
</tr>
<tr>
<td>INDISTINCT BORDERS</td>
<td></td>
</tr>
<tr>
<td>2 &lt; 50% ADV BORDER OF EPI</td>
<td></td>
</tr>
<tr>
<td>3 ATTACHED, NO ADV BORDER</td>
<td></td>
</tr>
<tr>
<td>4 UNATTACHED/ UNDERMINED</td>
<td></td>
</tr>
</tbody>
</table>

### A11. PERIULCER SKIN VIABILITY

<table>
<thead>
<tr>
<th>Condition</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO OF FAC AFFECTED</td>
<td></td>
</tr>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 ONE ONLY</td>
<td></td>
</tr>
<tr>
<td>2 TWO/THREE</td>
<td></td>
</tr>
<tr>
<td>3 FOUR/FIVE</td>
<td></td>
</tr>
<tr>
<td>4 SIX/&gt;</td>
<td></td>
</tr>
</tbody>
</table>

### A12. LEG EDEMA TYPE

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 NON PITTING/ FIRMNESS</td>
<td></td>
</tr>
<tr>
<td>2 PITTING</td>
<td></td>
</tr>
<tr>
<td>3 FIBROSIS/ LIPODERMATOSCLEROSIS</td>
<td></td>
</tr>
<tr>
<td>4 INDURATED</td>
<td></td>
</tr>
</tbody>
</table>

### A13. LEG EDEMA LOCATION

<table>
<thead>
<tr>
<th>Location</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 NONE</td>
<td></td>
</tr>
<tr>
<td>1 LOCALIZED PERI ULCER</td>
<td></td>
</tr>
<tr>
<td>2 FOOT, INCLUDING ANKLE</td>
<td></td>
</tr>
<tr>
<td>3 TO MID CALF</td>
<td></td>
</tr>
<tr>
<td>4 TO KNEE</td>
<td></td>
</tr>
</tbody>
</table>

### A14. ASSESSMENT OF BIOBURDEN

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 HEALED</td>
<td></td>
</tr>
<tr>
<td>1 LIGHTLY COLONIZED</td>
<td></td>
</tr>
<tr>
<td>2 HEAVILY COLONIZED</td>
<td></td>
</tr>
<tr>
<td>3 LOCALIZED INFECTION</td>
<td></td>
</tr>
<tr>
<td>4 SYSTEMIC INFECTION</td>
<td></td>
</tr>
</tbody>
</table>

### TOTAL CLINICIAN RATED DOMAINS
(B) PATIENT RATED DOMAINS

| B1. PAIN AMOUNT | 1 >0 - 2  
|                | 2 >2 - 4  
|                | 3 >4 - 7  
|                | 4 >7      |
| B2. PAIN FREQUENCY | O NONE  
|                   | 1 OCCASIONAL  
|                   | 2 POSITION DEPENDANT  
|                   | 3 CONSTANT  
|                   | 4 DISTURBS SLEEP  |
| B3. QUALITY OF LIFE | 0 DELIGHTED  
|                     | 1 SATISFIED  
|                     | 2 MIXED  
|                     | 3 DISSATISFIED  
|                     | 4 TERRIBLE  |

TOTAL PATIENT RATED DOMAINS

TOTAL LUMT SCORE
INSTRUMENTS USED

Sonoca UAW is a wound debridement and treatment instrument that utilizes low-frequency pulsed ultrasound directed to the wound surface and surrounding tissues via an ultrasound probe. Wound irrigation fluid (0.9% Normal Saline) is directed through an opening in the probe's tip to administer the fluid directly to the wound surface to serve as a coupling medium, coolant, wound lavage or flush, and topically treat the wound base. The instrument used was the UAW device Sonoca-180, manufactured by Soring Incorporated, Germany (Figure 2 & 5). The hand pieces (Figure 3) are connected to the ultrasonic generator via a cable and the normal saline solution is channeled into the probe using a simple intravenous drip set. There are three different types of tips in the probes. The type used in this study is the sloped probe (Figure 4 No. 2).

Technical data of the equipment (Sonaca 180) is as follows:

| Mains voltage : 230 V +/-20%, 50 Hz +/-5% |
| Switchable to 115V, 60 HZ |
| Power Consumption: 250VA |
| Frequency 24KHz |
| Dimension of device : 310x150x380 mm |
| Dimensions of trolley: 540x860x580mm |
Figure 2. The Sonaca-180 Ultrasonic Debrider
Figure 3. Hand pieces with detachable cable for easy and quick exchange

Figure 4. The different types of tip in the hand pieces.
Figure 5. The Sonaca-180 Ultrasound Generator
Figure 6. Debridement using the sloped probe
CHAPTER 3 : RESULTS

There were 60 foot ulcers managed either with Ultrasound Assisted Wound Debridement (UAW) or sharp debridement. The total number of patients involved were 59. One patient had bilateral foot ulcers. 33 ulcers were treated using the UAW method whereas 27 were treated using the sharp debridement method. We used a Mann-Whitney U-test for statistical analysis of all the parameters.

3.1 DEMOGRAPHIC DATA

Age and Intervention

The age ranges from 34 to 92 years old with a mean age of 56.87 years (SD 11.06)

Figure 7. Age distribution of study population
The Mann-Whitney test was used to test the difference in the age in both the UAW group and the sharp debridement group. There was no difference in both groups (p>0.05)

![Figure 8: Ulcers in Various Age Group In UAW And Sharp Debridement](image)
Sex and Intervention

33 ulcers were in male patients whereas 27 were in female patients.

Table 7: Sex Distribution According To Intervention

<table>
<thead>
<tr>
<th>Sex</th>
<th>Intervention</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UAW</td>
<td>Sharp Debridement</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>13</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Figure 9: Male And Female Patients In UAW And Sharp Debridement Groups
Race and Intervention

25 of the ulcers were in Malay patients, 11 in Chinese, 23 in Indians and 1 in a patient of other race.

Table 8: Racial Distribution According to Intervention

<table>
<thead>
<tr>
<th>Race</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UAW</td>
</tr>
<tr>
<td>Malay</td>
<td>12</td>
</tr>
<tr>
<td>Chinese</td>
<td>5</td>
</tr>
<tr>
<td>Indian</td>
<td>16</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 10: Patients of Different Races In UAW And Sharp Debridement Intervention
Type of Diabetes and Intervention

55 of the ulcers were in patients with NIDDM and 5 were in patients with IDDM.

Table 9: Type of Diabetes According To Intervention

<table>
<thead>
<tr>
<th>DM</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UAW</td>
</tr>
<tr>
<td>IDDM</td>
<td>5</td>
</tr>
<tr>
<td>NIDDM</td>
<td>28</td>
</tr>
</tbody>
</table>

Figure 11: Types of Diabetes Mellitus in UAW and Sharp Debridement Groups
Site of the ulcers and intervention

The site of ulcers were recorded as in the dorsum, plantar, heel of the foot. If more than one site is involved, it was recorded as others.

Table 10: Site of Ulcers According to Intervention

<table>
<thead>
<tr>
<th>Site</th>
<th>Intervention</th>
<th>UAW</th>
<th>Sharp Debridement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsum</td>
<td>9</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Plantar</td>
<td>10</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Heel</td>
<td>9</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>5</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>33</strong></td>
<td><strong>27</strong></td>
<td></td>
</tr>
</tbody>
</table>

Figure 12: Site Of Ulcers In UAW and Sharp Debridement Groups
Location of the ulcers and intervention

Location of ulcers were recorded as either in involving the forefoot, midfoot or hindfoot. If more than one area is involved, it is documented as others.

Table 11 : Location of Ulcers According to Intervention

<table>
<thead>
<tr>
<th>Location</th>
<th>Intervention</th>
<th>UAW</th>
<th>Sharp Debridement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forefoot</td>
<td>21</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Midfoot</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Hindfoot</td>
<td>9</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>27</td>
<td></td>
</tr>
</tbody>
</table>

Figure 13: Location Of Ulcers In UAW And Sharp Debridement
Side of ulcers and Intervention

Table 12: Side of Ulcer According To Intervention

<table>
<thead>
<tr>
<th>Side</th>
<th>Intervention</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UAW</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Left</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>27</td>
</tr>
</tbody>
</table>

Figure 14: Side of Ulcers In UAW And Sharp Debridement Groups
Although many wound parameters were collected, according to the protocol, only the secondary end points of pain during debridement, wound exudation, size of the ulcers, necrotic tissue amount, granulation tissue amount and their cumulative scores were analyzed statistically.

3.2 STATISTICAL ANALYSIS

The statistical analysis is done based on the difference of the scores in the LUMT of the final debridement and the first debridement. Therefore, the more negative (the smaller) the values, the better the outcome for that particular parameter.

Difference in the amount of exudate

The mean difference in the amount of exudate at day 14 compared to day 1 in the UAW group was -1.55 whereas in the sharp debridement group was 0.37.

Null hypothesis: Mean Exudate difference of UAW = Mean Exudate difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the amount of exudate produced is considered.

This means that wounds debrided with the UAW had significantly less exudate on day 14 compared with wounds debrided sharply.
Difference in the depth of the ulcers

The mean difference in the depth at day 14 compared to day 1 in the UAW group was -1.21 where as in the sharp debridement group was -0.56.

Null hypothesis : Mean Depth difference of UAW Intervention = Mean Depth difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the depth is considered.

This means the UAW group wounds were significantly shallower on day 14.

Difference in the necrotic tissue amount (NTA) of the ulcers

The mean difference in the NTA at day 14 compared to day 1 in the UAW group was -2.27 where as in the sharp debridement group was -1.11.

Null hypothesis : Mean NTA difference of UAW Intervention = Mean NTA difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the NTA is considered.

This means UAW debrided wounds have significantly less necrotic tissue on day 14.
**Difference in the granulation tissue amount (GTA) of the ulcers**

The mean difference in the GTA at day 14 compared to day 1 in the UAW group was -2.15 where as in the sharp debridement group was -1.11.

Null hypothesis: Mean GTA difference of Ultra Sound Intervention = Mean GTA difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the GTA is considered.

Therefore, UAW debrided wounds have significantly more granulation tissue on day 14.

**Difference in the scores of Total Clinician Rated Domains (TCRD) of the ulcers**

The mean difference in the TCRD at day 14 compared to day 1 in the UAW group was -18.85 where as in the sharp debridement group was -8.59.

Null hypothesis: Mean TCRD difference of UAW Intervention = Mean TCRD difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the TCRD is considered.
This shows that the UAW group have significantly better overall clinical outcome at day 14.

**Difference in the scores of Total Patient Rated Domains (TPRD) of the ulcers**

The mean difference in the TPRD at day 14 compared to day 1 in the UAW group was -3.18 where as in the sharp debridement group was -0.96.

Null hypothesis : Mean TPRD difference of UAW Intervention = Mean TPRD difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the TPRD is considered.

This means UAW group have a significantly better outcome in terms of patient perception on day 14

**Difference in the scores of Total Leg Ulcer Measurement Tool ( TLUMT) of the ulcers**

The mean difference in scores of the TLUMT at day 14 compared to day 1 in the UAW group was -22.21 where as in the sharp debridement group was -8.85.

Null hypothesis : Mean TLUMT difference of Ultra Sound Intervention = Mean TLUMT difference of Sharp Debridement Intervention
The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the TLUMT is considered.

Therefore the UAW have a significantly better outcome (clinical and patient rated) when all the above parameters were considered on day 14.

**Difference in the actual size of the ulcers**

Null hypothesis : Mean size difference of Ultra Sound Intervention = Mean size difference of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the size is considered.

The 1 tailed Z test was done to determine which type of intervention proceeded better results.

Null hypothesis : Mean size difference of Ultra Sound Intervention = Mean size difference of Sharp Debridement Intervention

The Z value was -4.002 which falls within the a=0.05 area, therefore the null hypothesis is rejected. Therefore, Mean size difference of Ultra Sound Intervention < (more negative) Mean size difference of Sharp Debridement Intervention. This means the UAW resulted in significantly smaller size wounds at day 14.
Pain During the first debridement (VASBL)

The mean pain score for the UAW debridement group was 4.18 with a range of 1 to 7. In the group that underwent sharp debridement, the mean was 6.56 with a range of 3 to 8.

Null hypothesis : Mean VASBL of Ultra Sound Intervention = Mean VASBL of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of debridement when the VASBL is considered.

Therefore the UAW was significantly less painful during the first debridement.

Pain During the final debridement (VASFU) at day 14

The mean pain score for the UAW debridement group was 1.94 with a range of 0 to 6. In the group that underwent sharp debridement, the mean was 5.44 with a range of 2 to 8.

Null hypothesis : Mean VASFU of Ultra Sound Intervention = Mean VASFU of Sharp Debridement Intervention

The Mann whitney test was used and the p value was 0.001 (<0.05), which means there is a significant difference between the results of the 2 different types of
debridement when the VASFU is considered. Thus UAW was significantly less painful during the last debridement.

Figure 15 - 19 shows that the peaks or most of the score differences in the UAW is located in the negative value area as compared to the sharp debridement group where it is mainly in the centre (0). This gives us a picture regarding the outcome of UAW compared to sharp debridement. This differences have been proven to be statistically significant in the analysis above.

Figure 15 : Difference At Day Fourteen of Intervention In Exudate Amount, Depth, NTA And GTA Scores-UAW
Figure 16: Differences at Day Fourteen of Intervention In Exudate amount, Depth, NTA And GTA - Sharp Debridement Group
Figure 17: TCRD Differences (Day Fourteen Compared to Day One) of UAW And Sharp Debridement Intervention

![Graph showing differences between UAW and Sharp Debridement interventions](image-url)
Figure 18: TPRD Differences Day Fourteen Compared To Day One) of UAW And Sharp Debridement Intervention
Figure 19: TLUMT Differences (Day Fourteen Compared to Day One) of UAW And Sharp Debridement Intervention

- The x-axis represents the difference in the number of ulcers.
- The y-axis represents the number of ulcers.
- The graph compares the UAW and Sharp Debridement interventions.

Legend:
- UAW
- Sharp Debridement
CHAPTER 4 : DISCUSSION

Ulceration, infection, gangrene and lower extremity amputation are complications often encountered in patients with diabetes mellitus. These often result in extensive morbidity, repeated hospitalizations and mortality to the patient. They take a tremendous toll on the physical, mental and financial well-being of the patient as well as potentially removing the patient from a country’s work force and becoming a financial burden on our health care system.

All diabetic foot complications cannot be prevented but it is indeed possible to dramatically reduce their incidence through appropriate management and prevention programs. The multidisciplinary team approach to diabetic foot disorders has been demonstrated as the optimal method to achieve favorable rates of limb salvage in the high risk diabetic patient. Foot care programs emphasizing preventive management can reduce the incidence of foot ulceration through modification of self care practices, appropriate evaluation of risk factors, and the formulation of treatment protocols aimed at early intervention, limb preservation, and the prevention of new lesions. Information concerning the bio-acoustical effects of ultrasound continues to evolve from animal, plant, human, cellular, and epidemiological studies. One of the main mechanisms of action for ultrasound is achieved through the process of cavitation. Cavitation involves the production and vibration of micron-sized bubbles within the coupling medium and fluids within the tissues. As the bubbles collect and condense, they are compressed before moving on to the next area. The movement and
compression of the bubbles can cause changes in the cellular activities of the tissues subjected to ultrasound. Microstreaming (the movement of fluids along the acoustical boundaries as a result of the mechanical pressure wave associated with the ultrasound beam) refers to the development of microscopic cavities created by the formation of micro-bubbles.\textsuperscript{116} The combination of cavitation and microstreaming, which are more likely to occur with kilohertz ultrasound, provides a mechanical energy capable of altering cell membrane activity.\textsuperscript{116}

The micro-cavitations also causes bacterial destruction. In vitro wound models have proven highly effective bactericidal effects. The solution also provides a gentle flushing of the wound, cleansing it of fibrin deposits and bacterial growth while preserving the granulation tissue. This debridement technique is particularly useful in deep, tunneling and undermining wounds. Leukocyte adhesion, growth factor production, collagen production, increased angiogenesis, increased macrophage responsiveness, increased fibrinolysis, and increases in nitric oxide are all examples of ultrasound-induced cellular effects.\textsuperscript{117}

This study was conducted to evaluate the effectiveness of a new, novel technology using non-contact, kilohertz-range ultrasound therapy for the treatment of recalcitrant diabetic foot ulcers.

The ultrasound therapy described in this study employs a device for the cleansing and debridement of wounds with an expanded indication (promotes healing). The current
report is the first randomized human clinical trial describing the clinical effectiveness of this new approach of delivering kilohertz ultrasound therapy directly to the wound bed employing a non-contact delivery model with comparison to the gold standard sharp debridement method. The results of this, randomized trial demonstrate a positive effect on the healing of diabetic foot ulcers using UAW as compared with manual sharp debridement in terms of reduction in amount of exudate, significant reduction in size and depth of the ulcers, reduction in amount of necrotic tissue amount and increase in amount of granulation tissue (Figure 7 and 8).

Besides these individual parameter advantages, the overall clinical ulcer characteristic assessment and also patient perception of the outcome As demonstrated by the significant reduction in the scores of the Total clinician Rated Domains, Total Patient Rated Domains and the Total Leg Ulcer Measurement Tool scores) is significantly better as compared with the conventional sharp debridement.

Another main advantage of using this method is in terms of the significantly less pain experienced by patients during the debridement. This also contributes the better patient satisfaction during debridement and in them looking forward to this treatment as compared to the painful sharp debridement. The procedure it self is not time consuming. If the UAW is done at an average of half a minute for every 1 cm², it will actually take only 5 minutes to complete debridement ao an ulcer a size of 10 cm². There was also no usage of any sharp instrument in these procedure for example a dissecting scissors or a scaple blade. Therefore the risk of any sharp injury to the
health care personal is absent. The set up of the instrument before a debridement is very simple. The required materials are readily available in any ward, clinic or health set up. The only required material is actually a bottle of 0.9% normal saline with one IVI drip set and a basin. There is no need for an assistant. In sharp debridement method, there is additional requirement of dressing sets, sterile instruments, dressing trolley and at times an assistant.

Ulcer severity was controlled by limiting enrollment to patients with ulcers that were either Wagner grade one or two. Prior ultrasound studies either did not include a control group that underwent a debridement procedure or a control instrument or debriding agent.
Figure 7. Wound prior to UAW

Figure 8. Same wound after two weeks of UAW
CHAPTER 5 : CONCLUSION AND RECOMMENDATION

Based on this study, it can be concluded that UAW have statistically significant positive effect on the outcome of ulcer healing in terms of:

1. Amount of exudate produced
2. Reduction in the depth of the ulcer
3. Amount of necrotic tissue present
4. Amount of granulation tissue
5. Overall clinical assessment of the ulcer and overall patient perception of the ulcer based on the 17 parameters in the LUMT
6. Reduction of size of ulcers
7. Pain experienced by the patient during debridement

In this study ultrasound assisted wound debridement has been shown to be a useful adjunct to standard of care for the treatment of diabetic foot ulcers. Despite the small sample size, statistically significant differences were observed. The results of this study suggest the need for further research, including assessing the impact of debridement depth as well as the potential antimicrobial action of this ultrasound device. Better methods of quantifying the debridement process must be evaluated in order to accurately compare study results.
UAW is an advanced technology that provides an alternative method to or augmentation of surgical sharp debridement techniques. Ultrasonic debridement is a valuable tool in the armamentarium of the advanced wound care practitioner. The use of low-frequency ultrasound delivered directly to the wound bed is a wound debridement and cleansing technique that has many advantages. The results are as immediate as sharp or surgical debridement, can be preformed in a variety of settings by trained personnel including in the out patient set up, does not typically require anaesthesia, is selective for nonviable or necrotic tissue, and is bactericidal at the surface and penetrates into surrounding tissues. In addition to separating dead tissue from the wound bed, ultrasound has other positive wound healing properties. The benefits of this technology also includes selective tissue debridement with preservation of granulation tissue, exceptional access to tunneling and undermining wounds, microcavitations causing bacterial destruction, improved patient satisfaction due to decreased pain and cost effectiveness related to decreased requirement for invasive surgical procedures. The technique of ultrasonic debridement and the device utilized for ultrasonic assisted wound treatment are not currently well known in wound care disciplines but is rapidly gaining acceptance as an alternative method to surgical and sharp debridement techniques. This advanced wound care technology has the potential to revolutionize wound care practice by enhancing clinical outcomes while maintaining cost efficiency.

It is also important to realize that the success of the debridement in these patients with foot ulcers would not be considered excellent if the patient is not satisfied with it. In
this part of the world, frequently the patient has no knowledge about what and how
the wounds are being managed despite the explanation given. Rather they judge the
success from their experience with only the size of the wound, pain experienced
during the procedure and pain during other times.

This study shows that the UAW also had significant advantage over the sharp
debridement method in terms of patient satisfaction. Therefore this procedure will be
beneficial in management of ulcers in the hospital and it can be applied for both the in
patient population and the out patient population. The use of this technique eliminates
the long waiting period often experienced by patients before they are called to the
operation theatre for the scheduled debridement. It also eliminates the use of
anaesthesia during the procedure as it is relatively painless. The other important
aspect is that this technique can be used to manage patients on an out patient basis.
Therefore the patients need not stay and occupy beds in the wards for surgical
debridement of their ulcers. They just need to come to the wound care clinic for the
UAW on a regular basis just as they are coming for dressing. The technique can be
taught to a wound care personal with ease.
CHAPTER 6: LIMITATION OF THIS STUDY

Attempts have been made to control all possible variables that might influence the outcome measured. However, as the wound healing is a complicated process, there are still many more variables that were either known or unknown affecting the entire process, which can be uncontrollable.

Although the neuropathic status was standardized, the vascular status was not analysed in detail. Only the distal pulses (Dorsalis pedis and posterior tibialis) were assessed. All the patients in the study had at least one palpable pulse but no further assessment in terms of the ABSI, ultrasound doppler of angiogram was done to further assess the status of the vessels. Therefore it cannot be concluded how much the vascularity in the limb is affecting the healing of the ulcer.

The other parameter that was not analyzed was the infective process that was going on in the ulcer. This is because the swab or tissue cultures are sent to the microbiology lab routinely but the organism counts are not done as a routine. Therefore a quantitative assessment of the bio burden is not available before commencement of treatment and at the end of the treatment for comparison. Just assessing the positivity of the culture results qualitatively before and at the end of the treatment would not make any impact.
It is also known that wounds continue to evolve for periods of weeks to months until it either heals completely or it fails to heal and ends with gangrene, fulminant infection and amputation. The outcome would be better assessed if the study period for each ulcer could be longer than two weeks and more episodes of debridement could be done.
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