



ULTRASONIC WOUND DEBRIDEMENT DEVICE

**HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
015/2014**

DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

Please contact: htamalaysia@moh.gov.my, if you would like further information.

Health Technology Assessment Section (MaHTAS),
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya

Tel: 603 88831246

Fax: 603 8883 1230

Available at the following website: <http://www.moh.gov.my>

Author:

Dr. Syaharatul Patimah Binti Kamarudin
Medical Officer
Senior Assistant Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

Reviewed by:

Datin Dr Rugayah Bakri
Public Health Physician
Deputy Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

Dr. Izzuna Mudla Mohamed Ghazali
Public Health Physician
Senior Principal Assistant Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

External Reviewers:

Dr Harikrishna Ragavan Nair
Head of Wound Care Unit and Internal Medicine Consultant
Department of Medicine
Hospital Kuala Lumpur

Dr Yusniza Mohd Yusof
National Advisor and Rehabilitation Medicine Consultant
Hospital Rehabilitasi Cheras
Kuala Lumpur

DISCLOSURE

The authors of this report have no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

EXECUTIVE SUMMARY

Introduction

Debridement plays an important role in wound management. It helps to reduce the bacterial burden within the wound, controls on going inflammation and malodour, and encourages formation of granulation tissue. The word debridement derives from the French *débridement*, which means to remove a constraint. European Wound Management Association (EMWA) has defined debridement as the act of removing necrotic material, eschar, devitalised tissue, serocrusts, infected tissue, hyperkeratosis, slough, pus, haematomas, foreign bodies, debris, bone fragments or any other type of bioburden from a wound with the objective to promote wound healing.

Low frequency ultrasound is claimed to provide a debridement alternative to, for example, surgical debridement. However, it is more commonly used for therapeutic purposes. Ultrasonic waves are also claimed to lead to destruction of bacteria and disruption of biofilms.

It has been utilised as a wound debridement and cleansing technique for years in the United Kingdom, Russia and Germany. While in Malaysia, the first ultrasonic wound debrider was first launched in August 2012 in collaboration with Malaysian Society of Wound Care Professional (MSWCP) and Malaysian Enterostomy Therapy Nurses Association (METNA).

This technology review was conducted to assess the use of the new technology ultrasonic wound debridement device as a treatment option for wound debridement focusing on using low frequency high intensity contact ultrasound as requested by Head of Department and Rehabilitation Medicine Specialist from Hospital Sungai Buloh.

Objective/aim

The objective of this systematic review was to assess the safety, effectiveness and cost-effectiveness of ultrasonic wound debridement device using low-frequency high intensity contact ultrasound for wound debridement.

Results and conclusions

Based on the above review:

- **Safety**

There was limited evidence retrieved to show that this device was not associated with major complications. However, mild pain was one of the reported adverse events.

- **Effectiveness**

Low frequency high intensity contact ultrasound debridement device or ultrasonic wound debridement device seemed to have potential benefit as an adjunct to standard treatment for chronic wounds such as diabetic foot ulcers, venous ulcers and pressure ulcers. However, there was lack of good quality evidence. Hence, more quality evidence is required.

- **Cost / cost effectiveness**

There was no retrievable evidence on the cost-effectiveness. The cost of the device was estimated to be around [REDACTED].

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE[®] In-process and other Non-indexed citations and Ovid MEDLINE[®] 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - June 2014, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to June 2014, EBM Reviews - Health Technology Assessment – 2nd Quarter 2014, EBM Reviews - Database of Abstracts of Reviews of Effects - 2nd Quarter 2014, EBM Reviews – NHS Economic Evaluation Database 2nd Quarter 2014, Embase – 1988 to 2014 Week 29. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. Limits for human study and English full article were applied. Additional articles were identified from reviewing the references of retrieved articles and contacting manufacturers via email to obtain references in their website. Unpublished articles were attempted to retrieve by contacting corresponding author by email. Last search was conducted on 5 August 2014.

ULTRASONIC WOUND DEBRIDEMENT DEVICE

1. INTRODUCTION

Debridement plays an important role in wound management. It helps to reduce the bacterial burden within the wound, controls on going inflammation and malodour, and encourages formation of granulation tissue.¹ The word debridement derives from the French *débridement*, which means to remove a constraint. European Wound Management Association (EMWA) has defined debridement as the act of removing necrotic material, eschar, devitalised tissue, serocrusts, infected tissue, hyperkeratosis, slough, pus, haematomas, foreign bodies, debris, bone fragments or any other type of bioburden from a wound with the objective to promote wound healing.²

Strohal et al. has summarized the primary targets for debridement which include removal of bioburden i.e slough, necrotic tissues etc., decreasing odour, excess moisture and risk of infection, stimulate wound edges and epithelialisation as well as improving quality of life.²

Various methods of debridement existed today require varying level of expertise and have their advantages and disadvantages in term of time taken, patient acceptability and ease of use. Sharp debridement is very quick, using scalpel and is the current standard for wound debridement. Autolytic debridement is often slow and unpredictable process uses the body's own enzymes and moisture to rehydrate, soften and finally liquefy hard eschar and slough. Enzymatic debridement utilises chemical enzymes, fast acting products that produce slough of necrotic tissue. Mechanical debridement using wet to dry technique. Other techniques of debridement includes laser debridement which appear to be efficient and precise when utilised in tissue ablation, however carry the risk of thermal damage to healthy tissue. Maggot therapy utilises maggot to ingest and break down necrotic tissue. Water debridement utilises a high pressure water jet.³ Meanwhile, debridement using low frequency ultrasound will be covered in this review.

Low frequency ultrasound is claimed to provide a debridement alternative to, for example, surgical debridement.² It incorporates a probe to selectively excise nonviable or necrotic tissue and can be used in a variety of setting by trained personnel.⁴ Ultrasonic waves are also claimed to lead to destruction of bacteria and disruption of biofilms.²

Ultrasound Assisted Wound Therapy has been utilised as a wound debridement and cleansing technique for years in the United Kingdom, Russia and Germany. While in Malaysia, the first ultrasonic wound debrider was first launched in August 2012 in collaboration with Malaysian Society of Wound Care Professional (MSWCP) and Malaysian Enterostomy Therapy Nurses Association (METNA) in which Dr. Harikrishna, the Head of Wound Care Unit Hospital Kuala Lumpur described the device as one of the great modalities to be held by nurses since it gives a faster result and portable.⁵

This technology review was conducted to assess the use of the new technology ultrasonic wound debridement device as a treatment option for wound debridement focusing on using low frequency high intensity contact ultrasound following a request by Head of Department and Rehabilitation Medicine Specialist from Hospital Sungai Buloh.

2. OBJECTIVE/AIM

The objective of this systematic review was to assess the safety, effectiveness and cost-effectiveness of ultrasonic wound debridement device using low-frequency high intensity contact ultrasound for wound debridement.

3. TECHNICAL FEATURES

Therapeutic ultrasound delivers energy through mechanical vibrations in the form of sound waves at frequencies above detection by human ear (>20 kHz). Ultrasound is commonly associated with diagnostic imaging which utilised high frequency ultrasound waves and as well used in physical therapy, physical medicine, rehabilitation and sports medicine for many years.⁴

There are mainly two classified effects of ultrasound on tissue: thermal and non-thermal. Both these effects are inseparable but their respective proportions vary with the frequency and intensity of ultrasound. Thermal effects are predominant with high frequency (MHz) and intensity (W/cm^2) ultrasound, which raises tissue temperature and possibly enhances blood flow. Low frequency ultrasound (kHz) has predominantly mechanical (non-thermal) effects, namely cavitation and acoustic streaming, although there are some thermal effects on tissue.¹

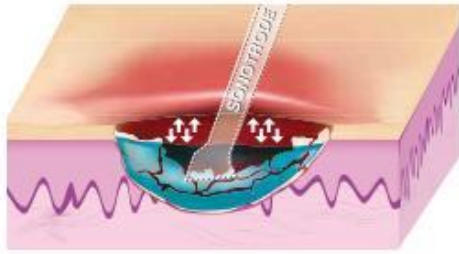
Low frequency ultrasound can be high intensity ($\sim 50W/cm^2$) delivered with direct contact with wound or low intensity ($0.25-0.75W/cm^2$) delivered without direct contact with wound bed; both are used with saline as coupling media between

the ultrasound probe and wound bed. High intensity ultrasound debrides necrotic tissue possibly because of the cavitation effect produced by rapid expansion and implosion of gas bubbles within tissue fluid or coupling media. Whereas low intensity ultrasound may promote wound healing predominantly by acoustic streaming effects such as increased protein synthesis and production of growth factors. In addition, low frequency ultrasound has been reported to have anti-bacterial effects and enhanced fibrinolysis in vitro.¹

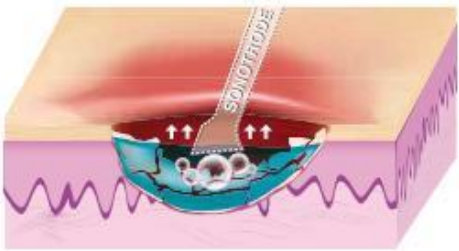
Hence, this technology review focuses on ultrasonic wound debridement devices using low frequency high intensity contact ultrasound.

3.1 Mechanism of action

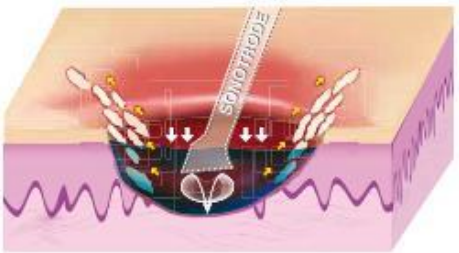
Low frequency ultrasound provides two largely non thermal effects, which are cavitation and acoustic streaming. The cavitation phenomenon may be described as the creation of miniscule gas bubbles in tissue fluid and the expansion and contraction in size of these bubbles in tandem with the variation in the ultrasound field pressure levels. At certain amplitudes of the sound waves, the bubbles implode; this implosion results in the formation of tiny shock waves. Because necrotic tissue has less tensile strength than viable tissue, these locally generated shock waves in turn liquefy the necrotic tissue, other wound debris, and associated biofilm, while not injuring viable tissue. The acoustic streaming initiates a unidirectional movement in fluid in an ultrasound field. This activity stimulates cell activity and enhances clinical outcome.⁴



During UAW, the sonotrode vibrates back and forth 25,000 times a second.



When the sonotrode moves back, vacuum bubbles arise in the irrigation solution (cavitation bubbles).



When the sonotrode moves forward again, the bubbles implode and generate a strong current which removes devitalised tissue and biofilms from the wound ground.

Figure 1: The mechanism of action of ultrasonic wound debridement device

A possible alternative mechanism of action, called frequency resonance, is related to the modification in the structure of proteins and the activation of signal transduction at nuclear level. This can lead to a range of effects at cellular level that impact wound healing, such as leucocyte adhesion, increased angiogenesis and increase of nitric oxide (NO production).²

In [REDACTED] for instance is using low frequency (22.5 kHz) high intensity (~60 W/cm²) ultrasound which has been claimed to be able to disrupt, inactivate and remove bacterial organisms from surfaces and stimulate the body's self-healing ability, resulting in faster healing rates and increased closure rates. The generator converts standard wall voltage to a 22.5 kHz electrical signal which is then transferred, via a cable assembly to the hand piece. The hand piece contains piezoelectric crystals that convert the electrical signal to mechanical vibrations. The titanium alloy probe, attached to the hand piece distal end, amplifies the mechanical vibration and then transfers the acoustic energy into the tissue via direct contact. The resulting cavitation, mechanical and hydrodynamic effects produce tissue disruption, excision, fragmentation and emulsion in the wound bed. The ultrasonic movement of the probe allows the

surgeon to remove tissue in a controlled and precise manner, reducing the bleeding typically associated with surgical debridement.⁶ The varieties of probes that are used are designed to concentrate (sharper tips) or disperse (blunter tips) the vibratory energy resulting either in differing aggressiveness of the dissection or fragmentation of the soft tissues.⁷



Figure 2: An example of ultrasonic wound debridement device



Figure 3: Some examples of the probe

The period of debridement is calculated by the surface area of the wound divided by three, giving a minimum treatment time for antibacterial effect. The clinician may choose to continue treatment over the estimated time to remove all visible unhealthy tissue depending on the patient's tolerance.⁸



Figure 4: Ultrasonic wound debridement in use

search for additional web-based materials and information. Limits for human study and English full article were applied. Additional articles were identified from reviewing the references of retrieved articles and contacting manufacturers via email to obtain references in their website. Unpublished articles were attempted to retrieve by contacting corresponding author by email. Last search was conducted on 5 August 2014. Appendix 1 showed the detailed search strategies.

4.2 Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection.

The inclusion and exclusion criteria were:

Inclusion criteria

Population	Patients with wound (chronic wound, diabetic ulcer, pressure ulcer, varicose ulcer)
Interventions	Ultrasonic wound debridement device (low-frequency, high intensity, contact ultrasound) for wound debridement
Comparators	Conventional wound debridement methods / no comparator
Outcomes	i. Safety (adverse events/complications) ii. Effectiveness iii. Economic implication (cost, cost-effectiveness)
Study design	Health Technology Assessment (HTA), Systematic Review, Randomised Controlled Trial (RCT), Non Randomised Controlled Trial, Cohort studies, Case Control studies, Cross sectional studies, case series, case reports
	English full text articles

Exclusion criteria

Study design	Studies conducted in animals and narrative reviews
	Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

5. RESULTS

From the search, 137 articles were retrieved. Only nine studies were relevant. However, only four full text articles were taken as references since they were of high level of evidence (Appendix 3). These articles include a systematic review with meta-analysis, a randomised controlled trial and two pre and post intervention studies. Five case reports were excluded as they have no comparison and have high risk of bias. The evidence was graded according to the US/Canadian Preventive Services Task Force (Appendix 2).

5.1 Safety

Pain and bleeding at the wound site were of concerned adverse events associated with contact ultrasonic debridement device during the procedure. In a RCT by Herberger K et al., 67 patients with chronic leg ulcers of vascular origin were randomised into two groups in which 34 patients were treated with ultrasound assisted wound treatment (UAW) and 33 patients were treated with surgical wound debridement (WD) in Wound Centre of the University Clinics of Hamburg. Pain was assessed before, during and 15 minutes after the procedure measured using a visual analogue scale. Before each treatment, a topical anaesthetic consisting of lidocaine and prilocaine (EMLA cream) was applied occlusively to the wound for 60 minutes. The increase in pain during treatment was not significantly different between the two treatment arms, and lay between 1.1 and 1.7 points for WD and between 1.5 and 1.6 points for UAW.^{10,Level II-2}

Tan J et al. conducted a pre and post intervention study in St Thomas' Hospital, London, United Kingdom involved 19 patients with leg ulceration of at least six months present. Low frequency ultrasound was delivered via a handheld probe. No analgesia was used in the study. Only three of the 19 patients experienced mild negligible pain at the start of the treatment. Two of them complained of pain at the periphery of the ulcer during the treatment and none developed pain that was severe enough to necessitate interruption or abandonment of the treatment prematurely. There was a noticeable reduction in pain in subsequent treatments and by the third treatment pain was no longer reported in any of the patients. Some patients experienced mild venous oozing from the ulcer surface which ceased spontaneously within a few minutes. There were no major complications of treatment.^{11,Level I}

The Food and Drug Administration (USFDA) classified ultrasonic wound debridement device as a class II device and it complies with USFDA Voluntary Standards for safety.¹²⁻¹³ [REDACTED] has CE marking.¹⁴

5.2 Effectiveness

In a systematic review and meta-analysis done by Voigt et al. in 2011, they included eight randomised controlled trials (RCTs) which investigated whether the use of low frequency high intensity contact ultrasound (LFHICU) or low frequency low intensity noncontact ultrasound (LFLINCU) as an adjunctive therapy improves the outcome of complete healing of chronic lower limb wounds. Methodologically, three RCTs included were using LFHICU for intervention therapy. However, two RCTs used for meta-analysis and two other RCTs were reviewed individually as they could not be combined for meta-analysis purposes based on duration of outcome evaluation and lack of specific outcome data.^{15,Level I}

The primary outcome measure was complete wound healing. However, the definition of complete wound healing was unclear. The meta-analysis showed a statistical difference favouring debridement using LFHICU when compared with sharp debridement (RR=0.64; 95% CI=0.46-0.89; P=0.009; I²=0%). At five months, this statistical difference persisted, favouring LFHICU (RR=0.52; 95% CI=0.32-0.85; P=0.008; I²=0%). However, at six months this statistical difference did not persist (RR=0.66; 95% CI=0.36-1.21; P=0.18; I²=15%). The patients included were diabetic foot ulcers with osteomyelitis and venous stasis ulcers.^{15,Level I}

The secondary outcome measure was wound size reduction which included those patients with diabetic foot ulcers and lower extremity ulcers of various aetiologies (venous insufficiency, diabetes, pressure, and arterial insufficiency). Over three months, there was a statistically significant difference in percentage of wound size reduction between LFHICU and sharps debridement, favouring LFHICU (mean difference=25.93%; 95% CI=14.2%-37.66%; P<0.0001; I²=0%).^{15,Level I}

Two of the trials (Li and Singh) could not be combined for meta-analyses purposes due to differences in the duration of outcome evaluation and lack of specific outcome data. In the study reported by Li, the percentage of the wound that had healed over a two week period was significantly higher with LFHICU versus a saline wash (P=0.006). In a trial by Singh A., it was found that the

percentage of the wound that had healed over a two week period was significantly higher with LFHICU versus a sharp debridement ($P=0.001$).^{15,Level I}

Voigt et al. concluded that although the quality of the evidence was in general of lower quality, the evidence does demonstrated a short term clinical beneficial effect of LFHICU used as an adjunctive therapy on the clinical end points of complete healing and reduction in wound area size for patients with venous stasis and diabetic foot ulcers (Wagner 1-3) (see Appendix 4). There may be longer term completing healing effect (at 6 months) of LFHICU in patients with venous stasis ulcer.^{15,Level I}

In a RCT by Herberger K et al., 67 patients with chronic leg ulcers of vascular origin were randomised into two groups in which 34 patients were treated with ultrasound assisted wound treatment (UAW) and 33 patients were treated with surgical wound debridement (WD) in Wound Centre of the University Clinics of Hamburg. The objective was to determine and compare the efficacy, tolerability and benefit of both wound treatment methods.^{10,Level II-2}

The improvement of the wound status was highly significant ($p<0.001$) in both groups in reduction of amount of necrosis and fibrin coatings and an increase in granulation tissue. However, in epithelisation there was no significant change in both groups ($p=0.267$).^{10,Level II-2}

Patients considered both procedures to be equally effective and tolerable. For UAW, the Patient Benefit Index (wound version) was >1 in 88% of patients, the mean score being 2.2 ± 1.0 (evaluation without last observation carried forward (LOCF)). For WD, the score was >1 in 85.1% of patients. The mean score was 2.1 ± 1.1 . The differences between the two treatment arms were not significant. The patients perceived particularly strong benefits in the items 'to have confidence in therapy' with a mean benefit score of 3.2 (both groups), 'to have a clean wound' with 3.4 (both groups) and 'to receive low-pain treatment' with 3.0 (UAW) and 3.2 (WD). The patients reported comparatively small benefits for the item 'to be able to lead a normal working life' in both treatment arms, given their mean age 74.5 years (UAW) and 70.5 years (WD).^{10,Level II-2}

The efficacy was assessed good by patients and practitioners, the mean scores being 4.2 and 4.3 respectively. There were no differences between the means for the assessment of the efficacy of UAW and WD. Tolerability was assessed by the practitioner as slightly better for UAW (2.2 versus 2.1). Overall, both procedures were assessed as being equally well tolerated.^{10,Level II-2}

The global quality of life score increased for all patients over the course of the treatment (p=0.001). The improvement in quality of life did not differ significantly between the two groups.^{10,Level II-2}

In a pilot study, Tan J et al. evaluated the use of low frequency ultrasound device to debride chronic leg ulcers as an adjunct to compression bandages therapy in 19 patients. The leg ulcers were present for more than six months and had failed to respond to standard compression regimens. Each patient underwent a minimum of five treatments averaging 9.7 minutes of treatment per session per ulcer at an interval of two to three weeks. Over half of patients (55%) showed no visible changes in the ulcer area (ulcers remained static) during the treatment period and their ulcers remained static. Seven patients (39%) achieved complete ulcer healing (mean initial ulcer size= $4.72 \pm SD 1.872 \text{cm}^2$) in the subsequent mean follow up period of 16 weeks (range 12-24 weeks). These consisted of one patient with rheumatoid ulcer, two patients with sickle cell ulcers and four patients with chronic venous ulcers. All healed patients showed a response within the first five sessions of treatments compared with the 'non responders' and remained successfully healed for more than six months.^{11,Level II-3}

At the end of the 16 week follow up period, one additional patient with an unhealed ulcer continued to show a steady reduction in ulcer size and eventually healed 21 weeks into the follow up period. An interesting observation from the study was that if no improvement of healing had occurred after the fifth treatment, no additional benefit was gained by continuing treatment.^{11,Level II-3}

Seven of the 18 patients also reported a significant reduction in wound odour. There was no alteration in skin temperature experienced around the ulcer during or following treatment. The authors concluded that the beneficial effects observed may not be related to the ultrasound effects, but as a result of an increased effort to improve the general condition by simple wound cleaning.^{11,Level II-3}

Low frequency ultrasonic debridement (LFUD) has had an early favourable experience in Brigham and Women's Hospital, Boston. Breuing KH et al did a study in 17 patients with acute and chronic wounds of varying aetiologies with a total of 107 procedures done using low frequency ultrasonic debridement (LFUD). The follow up period was three to eight months with the frequency of debridement ranged from twice weekly to every third week, depending on the type and condition of the wound. The average number of treatment per wound ranged from six (small pressure ulcers) to 15 (venous stasis ulcers). Adjunct

wound therapy used were moist saline dressing, alginate and Panafil. Nine of the wounds (53%) healed primarily or with the aid of a skin graft. Six additional patients (35%) experienced wound size reduction of at least 50%. The remaining two patients (12%), one with sickle cells anaemia and one with a venous stasis ulcer had reductions in wound area of 20% to 30%. Among all 17 wounds followed, pressure ulcers, arterial insufficiency and non-healing surgical wounds responded better than venous stasis and diabetic foot ulcers. None of the patients required initiation of antibiotic treatment after starting LFUD.^{16,Level II-3}

There was no evidence retrieved to claim for its antimicrobial effect and bacterial biofilm disruption.

5.3 Cost/Cost-Effectiveness

There was no retrievable evidence on cost effectiveness of the device. Nonetheless, Butcher G and Pinnuck L estimated that overall cost per treatment including staff time, related consumables and dressings is about [REDACTED] either performed in the ward or in an outpatient setting in the Australian health service. Ongoing costs are minimal as the hand pieces can be sterilised and reused and ultrasound assisted wound debridement related consumables (tubing, saline, drapes, protective equipment and topical anaesthetic products) only add about [REDACTED] to the cost of wound treatment.¹⁷

Head of Department and Rehabilitation Medicine specialist from Hospital Sg Buloh and Head of Wound Care Unit from Hospital Kuala Lumpur stated that the device costs around [REDACTED]

5.4 Limitations

This technology review has several limitations. The selection of studies was done by a reviewer and only English full text articles were included in this report.

6. CONCLUSIONS

Based on the above review:

6.1 Safety

There was limited evidence retrieved to show that this device was not associated with major complications. However, mild pain was one of the reported mild adverse events.

6.2 Effectiveness

Low frequency high intensity contact ultrasound debridement device or ultrasonic wound debridement device seemed to have potential benefit as an adjunct to standard treatment for chronic wounds such as diabetic foot ulcers, venous ulcers and pressure ulcers. However, there was lack of good quality evidence. Hence, more quality evidence is required.

6.3 Cost/Cost Effectiveness

There was no retrievable evidence on the cost-effectiveness. The cost of the device was estimated to be around [REDACTED].

8. REFERENCES

1. Madhok BM, Vowden K, Vowden P. New Techniques for Wound Debridement. *International Wound Journal*. 2013;10:247-251
2. Strohal R, Apelqvist J, Dissemond J et al. EMWA Document: Debridement. *J Wound Care*. 2013;22(Supp.1):S1-S52.
3. Lee I, Low Frequency Ultrasound Debridement. Prioritising Summary. Horizon Scanning Technology. Health Policy Advisory Committee on Technology. 2007. Available at <http://www.horizonscanning.gov.au>
4. Conlan W, Weir D. Ultrasound Assisted Wound Therapy: An Exceptional Adjunct to Wound Bed Preparation. *Today's Wound Clinic*. 2008;2(3)
5. The 1st Ultrasound Wound Debrider. Available at <http://www.mswcp.org/events/the-1st-ultrasound-wound-debrider>. Accessed on 18 July 2014.
6. Misonix, Ultrasound Surgical Debridement. Available at www.misonix.com. Accessed on 18 July 2014.
7. Alvarez OM, DeGroat K, Markowitz L et al. Effective and Long-Lasting Debridement of Venous Ulcers with Low Frequency, High Intensity Contact Ultrasound. *Wound Supplement–Spring* 2013. Available at <http://pubs.royle.com/article/Effective+And+LongLasting+Debridement+Of+Venous+Ulcers+With+Low+Frequency,+High+Intensity+Contact+Ultrasound/1380183/0/article.html> Accessed on 25 July 2014
8. Shannon MK, Williams A, Bloomer M. Low-frequency Ultrasound Debridement (Sonoca-185) in Acute Wound Management: A Case Study. *Wound Practice and Research*. 2012;20(4):200-205
9. Vowden K, Vowden P. Debridement Made Easy. *Wounds UK*. Nov 2011;7(4):1-4.
10. Herberger K, Franzke N, Blome C et al. Efficacy, Tolerability and Patient Benefit of Ultrasound-Assisted Wound Treatment versus Surgical Debridement: A Randomised Clinical Study, *Dermatology*, April 2011;222:244-249

11. Tan J, Abisi S, Smith A et al. A Painless Method of Ultrasonically Assisted Debridement of Chronic Leg Ulcers: A Pilot Study. *Eur J Vasc Endovasc Surg.* 2007;33:234-238
12. Exhibit E 510(k) Summary. Misonix SonicOne Plus Ultrasonic Wound Care System and Accessories. USFDA. Available at www.accessdata.fda.gov/cdrh_docs/pdf12/k123980.pdf. Accessed on 5 August 2014
13. 510(k) Summary (K131096). USFDA. Available at www.accessdata.fda.gov/cdrh_docs/pdf13/k131096.pdf. Accessed on 5 August 2014
14. Available at kapsnovi.com/en/media/djcatalog/Brochure_Sonoca_180.pdf. Accessed on 18 July 2014.
15. Voigt J, Wendelken M, Driver V et al. Low-Frequency Ultrasound (20-40 kHz) as an Adjunctive Therapy for Chronic Wound Healing: A Systematic Review of the Literature and Meta-Analysis of Eight Randomized Controlled Trials, *The International Wound Journal of Lower Extremity Wounds*, 2011;10:190-199
16. Breuing KH, Bayer L, Neuwalder J et al. Early Experience Using Low-Frequency Ultrasound in Chronic Wounds. *Annals of Plastic Surgery.* August 2005; 55(2):183-187
17. Butcher G & Pinnuck L. Wound Bed Preparation: Ultrasonic-Assisted Debridement. *British Journal of Nursing (Tissue Viability Supplement)* 2013;22(6):S36-S43

9. APPENDIX

9.1 Appendix 1

LITERATURE SEARCH STRATEGY

**Ovid MEDLINE® In-process & other Non-Indexed citations and
OvidMEDLINE® 1946 to present**

Search Strategy:

1. Wound.tw.
2. Chronic wound\$.tw.
3. Wound infection/
4. (wound adj1 infection\$).tw.
5. Pressure ulcer/
6. (pressure adj1 sore\$).tw.
7. (bed adj1 sore\$).tw.
8. bedsore\$.tw.
9. (pressure adj1 ulcer\$).tw.
10. (decubitus adj ulcer\$).tw.
11. Leg ulcer/
12. (leg adj1 ulcer\$).tw.
13. Pyoderma gangrenosum/
14. Pyoderma gangrenosum.tw.
15. Diabetic foot/
16. ((foot or feet) adj1 diabetic).tw.
17. Foot ulcer diabetic.tw.
18. Diabetic foot ulcer\$.tw.
19. Diabetic ulcer\$.tw.
20. Foot ulcer/
21. (foot adj1 ulcer\$).tw.
22. (plantar adj1 ulcer\$).tw.
23. Varicose ulcer/
24. Venous stasis ulcer\$.tw.
25. Ulcer\$ venous stasis.tw.
26. Stasis ulcer\$ venous.tw.
27. (venous adj1 ulcer\$).tw.
28. (stasis adj1 ulcer\$).tw.
29. (varicose adj1 ulcer\$).tw.

30. (varicose adj1 ulcer\$.tw.
31. Arterial ulcer\$.tw.
32. Recalcitrant wound\$.tw.
33. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
34. Ultrasound wound debridement.tw.
35. Ultrasonic wound debridement.tw.
36. Ultrasonic debridement.tw.
37. Ultrasound debridement.tw.
38. Contact low frequency ultrasonic wound debridement.tw.
39. Contact low frequency ultrasound wound debridement.tw.
40. Contact ultrasonic wound debridement.tw.
41. Contact ultrasound wound debridement.tw.
42. Contact ultrasonic debridement.tw.
43. Contact ultrasound debridement.tw.
44. Low frequency ultrasound.tw.
45. Low frequency contact ultrasound.tw.
46. Ultrasonic wound debridement therapy.tw.
47. Low frequency high intensity contact ultrasound.tw.
48. High intensity low frequency contact ultrasound.tw.
49. Contact low frequency ultrasound debridement.tw.
50. Low frequency ultrasound debridement.tw.
51. Contact low frequency ultrasound.tw.
52. Low frequency high intensity ultrasound wound debridement.tw.
53. High intensity low frequency ultrasound wound debridement.tw.
54. 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53
55. Hydrostatic wound debridement.tw.
56. Hydrostatic debridement.tw.
57. (hydrosurg\$ adj system).tw.
58. Hydrosurg\$ debridement.tw.
59. Versajet.tw.
60. Waterjet hydrosurgery system.tw.
61. High power parallel waterjet.tw.
62. High pressure waterjet debridement.tw.
63. 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63
64. 54 or 63
65. 33 or 64
66. Limit 65 to (English language and humans)

OTHER DATABASES	
------------------------	--

EBM Reviews – Database of Abstracts of Review of Effects	Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews – Cochrane Database of Systematic Reviews	
EBM Reviews – Health Technology Assessment	
EBM Reviews – NHS Economic Evaluation Database	
INAHTA	Ultrasonic wound debridement
U.S. FDA	
NIHR Centre for Reviews and Dissemination – CRD Database	
EuroScan International Network	
Australia and New Zealand Horizon Scanning Network	
Health Policy Advisory Committee on Technology (HealthPACT)	
Google Scholar	

hydrosurgery system[Title/Abstract] OR High power parallel
waterjet[Title/Abstract] OR High pressure waterjet debridement[Title/Abstract])

9.2 Appendix 2

DESIGNATION OF LEVELS OF EVIDENCE

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris S2001)

9.3 Appendix 3

Evidence Table: Ultrasonic Wound Debridement Device

Question: Is ultrasonic wound debridement device safe, effective and cost-effective for wound debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
1. Voigt J <i>et al.</i> Low-Frequency Ultrasound (20-40 kHz) as an Adjunctive Therapy for Chronic Wound Healing: A Systematic Review of the Literature and Meta-Analysis of Eight Randomized Controlled Trials, The International Journal of Lower Extremity Wounds, 2011;10:190-199	<p>Systematic review & Meta-Analysis</p> <p>The objective was to determine whether low frequency ultrasound used as adjunctive therapy improves the outcomes of complete healing and the reduction of size of chronic lower limb wounds.</p> <p>Search methods: PubMed, Cochrane/CENTRAL, technical assessment, relevant wound-related journals and clinical guidelines were searched along with contacting manufacturers</p>	I	<p>8 RCTs included</p> <p>Low frequency low intensity contact ultrasound (LFLINCU) : -5 RCTs included -Ennis 2005, Kavros 2007, Peschen 1997, Weichenthal 1997 and Park 2001</p> <p>Low frequency high intensity contact ultrasound (LFHICU) : -methodologically 3 RCTs included -i.e. Li 2009, Wendelken 2009 and Tehrani 2011 -however, 4 RCTs included in the review, Singh A. 2006.</p> <p>-only RCTs evaluating the effect of low-frequency ultrasound as an adjunct to therapy (both contact and noncontact) vs other forms of adjunctive</p>	<p>Low-frequency (20-30 kHz), low intensity (0.1-0.5W/cm²), noncontact ultrasound (LFLINCU): - Peschen 1997 and Weichenthal 1997, using water (saline) as a medium</p> <p>• LFLINCU plus standard of care vs. sham LFLINCU plus standard of care in patients with chronic venous insufficiency over a period of 2-3</p>	<p>Sharp debridement, sham or standard of care</p> <p><i>(sham=the vibratory sound was turned on but no ultrasound energy emanated from the device)</i></p>		<p><u>Primary outcome: complete wound healing</u></p> <p>LFHICU: (vs sharp debridement) -3 months – there was statistical difference (RR=0.64; 95% CI=0.46-0.89; P=.009; I²=0%)-favouring LFHICU. These patients included diabetic foot ulcers with osteomyelitis and venous stasis ulcers</p> <p>-5 months – statistical difference persisted (RR=0.52; 95% CI=0.32-0.85; P=.008; I²=0%)-favouring LFHICU</p> <p>-6 months – no statistical difference (RR=0.66; 95% CI=0.36-1.21; P=.18; I²=15%)</p> <p>LFLINCU: (vs sham) -3 months – statistically significance difference (RR=0.74; 95% CI=0.58-0.95; P=.02; I²=0%). These patients included those with diabetic foot ulcers and chronic venous ulcers.</p> <p><u>Secondary outcome: wound area reduction</u></p>	

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	<p>and authors of relevant randomized controlled trials were completed.</p> <p>Data collection and analysis: -2 review authors screened the titles and abstracts of all studies identified in the search strategy -2 review authors assessed screened studies for inclusion -any disagreement was resolved by discussion or adjudicated by a third party</p> <p>Meta-analysis and heterogeneity checks were performed on studies with similar outcomes (complete healing and percent wound area reduction) over similar time period. Single</p>		<p>therapy or control (eg, sharps debridement, sham) were included.</p> <p>-RCTs using the same patient as the treatment and as control were also considered, if randomisation of the treatment was performed</p> <p>-Patients with chronic lower limb wounds of the following aetiology were evaluated:</p> <ul style="list-style-type: none"> ▪ venous insufficiency ▪ diabetes (type1 or 2) ▪ pressure/immob ile patient ▪ arterial occlusive disease ▪ neuropathic insufficiency <p>-</p>	<p>months - Ennis 2005, Kavros 2007 and Park 2001, using saline</p> <p>mist as a medium</p> <ul style="list-style-type: none"> • LFLINCU plus standard of care vs. standard of care, examined over a period of 5 weeks to 3 months <p>Or</p> <p>Low-frequency (20-30 kHz), high intensity (50-60W/cm2), contact ultrasound (LFHICU): -all 3 trials (Li 2009, Wendelken 2009 and Tehrani 2011)</p>			<p>LFHICU: (vs sharp debridement) -3 months – statistically significant difference, favouring LFHICU (mean difference=25.93%; 95% CI=14.2% to 37.66%; P<.0001; I²=0%). These patients included those with diabetic foot ulcers and lower extremity ulcers of various aetiologies (venous insufficiency, diabetes, pressure and arterial insufficiency)</p> <p>-several trials could not be combined for meta analysis based on duration of outcome evaluation and lack of specific outcome data:</p> <p>1. Li,2009 – LFHICU vs washing with isotonic normal saline in burn patients. The percent of the wound that had healed over 2 weeks period was significantly higher (P=.006)</p> <p>2. Singh A. – LFHICU vs sharp debridement in patients with diabetic foot ulcer. The percentage of wound that had healed over 2 week period was significantly higher (P=.001)</p> <p>LFLINCU: (vs sham) - 2 months - statistically significant difference (mean difference=25.97%; 95% CI=11.09% to 40.86%; P=.0006; I²=0%). These patients were treated for chronic venous ulcers.</p>	

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	study results were reported via the statistical methods used in the study.			<p>using LFHICU plus saline wash as the medium -Wendelken 2009 and Tehrani 2011:LFHICU</p> <p>vs. sharp debridement over 6 months, mainly venous stasis ulcer ad diabetic foot ulcers</p>			<p>-1 study reported separately as the end point was the percentage of patients who exhibited a >50% reduction in wound size over 3 months period, mainly evaluate diabetic ulcer. Demonstrated a statistically significant difference, favouring LFLINCU (63% of patients exhibited >50% reduction in wound size over 3 months vs sham at 29%; P<.001)</p> <p>-4th trial, Park, 2011, LFILNCU plus standard care vs standard care only, evaluate wound percentage area reduction over a 5 week period in non-healing diabetic foot ulcers, had a significant reduction (n=4, P<.05)</p> <p>Authors' conclusion: -although the quality of the evidence is in general of lower quality of both types of ultrasound, the evidence does demonstrate a short term clinically beneficial effect of LFLINCU and LFHICU used adjunctive therapy on the clinical end points of complete healing and reduction in wound area size for patients with venous stasis and diabetic foot ulcers (Wagner 1-3) -there may be longer term completing healing effect (at 6 months) of LFHICU in patients with venous stasis ulcer</p>	

Evidence Table: Ultrasonic Wound Debridement Device

Question: Is ultrasonic wound debridement device safe, effective and cost-effective for wound debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
2. Herberger K <i>et al.</i> Efficacy, Tolerability and Patient Benefit of Ultrasound-Assisted Wound Treatment versus Surgical Debridement: A Randomized Clinical Study, Dermatology, April 2011;222:244-249	<p>Study type: Randomized-controlled trial, partly blinded in Hamburg, Germany</p> <p>Method: Monocentric prospective study assessing patient-reported outcomes and clinical efficacy of ultrasound-assisted wound treatment (UAW) compared to surgical wound debridement (WD). Patients were divided into 2 groups. The observation and treatment period covered 4-12 days. During this period, 3 procedures (V1, V2, V3) were performed at</p>	II-2	<p>67 patients (n=67) from Wound Centre of the University Clinics of Hamburg</p> <p>Inclusion: -Age ≥ 18 years -chronic leg ulcers of vascular origin-including venous, arterial and mixed ulcers</p> <p>Exclusion: -blood coagulation disorders -medicinal anticoagulation with vitamin K antagonists, -wound infections requiring treatment, -thrombophlebitis -wounds of malignant origin.</p> <p>Patients were divided into 2 groups, 34 (n=34) were treated with UAW and 33 (n=33) with WD.</p> <p>Mean age was 74.5 years (UAW) and 70.5 years (WD)</p>	<p>Ultrasound-assisted wound treatment (UAW)</p> <p>Performed with a Sonoca®-180 (Söring, Germany)</p>	<p>Surgical wound debridement (WD)</p> <p>Performed with Stiefel® ring curettes (7mm diameter, Stiefel Germany)</p>		<p>The primary target variables</p> <ul style="list-style-type: none"> Pain during procedure – the increase in pain during treatment was not significantly different between the two groups and lay between 1.1 and 1.7 points for WB and between 1.5 and 1.6 points for UAW Wound status – the improvement was highly significant with the exception of epithelialization. led to a significant reduction in the fibrin coatings and an increase in granulation and epithelialisation. Patient-defined benefit – the differences between UAW and WD were not significant (in UAW, Patient Benefit Index (wound version) was >1 in 88% patients, the mean score being 2.2 ± 1.0. While in WD, the score was >1 in 85.1% of patients with mean score of 2.1 ± 1.1). <p>The secondary criteria</p> <ul style="list-style-type: none"> Efficacy – good (assessed by patients and practitioners, mean scores 4.2 and 4.3 	2. Herberger K <i>et al.</i> Efficacy, Tolerability and Patient Benefit of Ultrasound-Assisted Wound Treatment versus Surgical Debridement: A Randomized Clinical Study, Dermatology, April 2011;222:244-249

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	<p>intervals of at least 2 days with either UAW or WD. (1 treatment every visit.) Topical local anaesthetic were given prior treatment. Values of $p \leq 0.05$ (two-sided) were considered significant.</p> <p>Objective: To determine and compare the efficacy, tolerability and benefit of UAW and WD treatment methods.</p>						<p>respectively). No differences between the means for UAW and WD.</p> <ul style="list-style-type: none"> • Tolerability – slightly better for • UAW (assessed by practitioner, 2.2 vs. 2.1). overall, both procedures equally well tolerated. • Quality of life – the global quality of life score increased for all patients over the course of the treatment ($p=0.001$) <p>Authors' conclusion: -compared to the gold standard (i.e wound debridement) UAW displays the same high efficacy, comparable patient benefit and improved quality of life -both procedures are equally suitable for highly beneficial guideline-based treatment of chronic wounds.</p>	

Evidence Table: Ultrasonic Wound Debridement Device

Question: Is ultrasonic wound debridement device safe, effective and cost-effective for wound debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
<p>3. Tan J <i>et al.</i> A Painless Method of Ultrasonically Assisted Debridement of Chronic Leg Ulcers: A Pilot Study. <i>European Journal of Vascular and Endovascular Surgery.</i> 2007;33:234-238</p>	<p>Pre and post intervention study in London, UK</p> <p>Objective: to evaluate the use of a non-invasive low frequency ultrasound device to debride chronic leg ulcers as an adjunct to compression bandages therapy</p>	<p>II-3</p>	<p>19 patients with leg ulceration of at least 6 months, and had failed to respond to standard compression regimens (13 venous ulcers, 3 rheumatoid ulcers, 2 sickle cells ulcers)</p> <p>-attended outpatient clinic for chronic leg ulcer</p> <p>-total median age 63 years (18-82 years)</p> <p>-total mean ulcer duration 23.4 months</p> <p>-exclusion criteria: patients with ischemic ulcers</p>	<p>Low frequency ultrasound (25 kHz) using Sonoca-180</p> <p>Each patient received treatment once every 2-3 weeks</p> <p>A total of 95 treatments were performed</p> <p>Each patient received an average of 5.7 sessions averaging 9.7 minutes per session per ulcer</p> <p>No analgesia was used in the study</p>		<p>Minimum 12 weeks</p>	<p>Wound Healing:</p> <p>-over half of patients (55%) showed no visible changes in the ulcer area (ulcers remained static) during the treatment period</p> <p>-39% (7 patients) achieved complete ulcer healing in the subsequent mean follow up period of 16 weeks (range 12-24 weeks). These consisted of one patient with rheumatoid ulcer, 2 patients with sickle cell ulcers and 4 patients with chronic venous ulcers</p> <p>-despite various aetiologies, all healed patients showed a response within the first 5 sessions of treatment compared with the 'non-responders'. These ulcers remained successfully healed for more than 6 months</p> <p>-at the end of 16 weeks follow up period, 1 additional patient with an unhealed ulcer continued to show a steady reduction in ulcer sizes and the ulcer eventually healed 21 weeks into the follow up period.</p> <p>Pain:</p> <p>-only 3 out of 19 patients experienced mild negligible pain at the start of the treatment</p> <p>-2 of these complained of pain at the periphery of the ulcer during the</p>	

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
							<p>treatment and none developed pain that was severe enough to necessitate interruption or abandonment of the treatment prematurely</p> <p>-there was a noticeable reduction in pain on subsequent treatments</p> <p>-by 3rd treatment , pain was no longer reported in any of the patients</p> <p>Wound Odour: 7 out of the 18 patients reported a significant reduction in wound odour</p> <p>Skin temperature: there was no alteration in skin temperature experienced around the ulcer during or following treatment</p> <p>Some patients experienced mild venous oozing from the ulcer surface which ceased spontaneously within a few minutes</p> <p>There were no major complications of treatment.</p> <p>Authors conclusion:</p> <p>-this study demonstrated that over a third of patients with recalcitrant ulcers healed within 5 treatment sessions.</p> <p>-an interesting observation from the study was that if no improvement of healing had occurred after the fifth treatment, no additional benefit was gained by continuing treatment</p> <p>- the beneficial effects observed may</p>	

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
							not be related to the ultrasound effects, but as a result of an increased effort to improve the general condition by simple wound cleaning	

Evidence Table: Ultrasonic Wound Debridement Device

Question: Is ultrasonic wound debridement device safe, effective and cost-effective for wound debridement?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
<p>4. Breuing KH <i>et al.</i> Early Experience Using Low-Frequency Ultrasound in Chronic Wounds. <i>Annals of Plastic Surgery</i>, August 2005(2):183-187</p>	<p>Pre and post intervention and Case series in Boston</p>	<p>II-3</p>	<p>17 patients, 107 debridements procedures</p> <p>Patients with acute and chronic wounds of varying etiology: -venous stasis ulcer (5) -arterial insufficiency-related ulcers (2) -diabetic ulcers (3) -pressure ulcers (3) -sickle cell anemia (1) -nonhealing surgical wounds (4)</p> <p>The age ranged from 44-70 years</p>	<p>Low frequency ultrasonic debridement (LFUD) device</p> <p>Performed with Sonoca®-180 (Söring, Germany)</p> <p>Frequency of debridement ranged from twice weekly to every third week</p> <p>The average no. of treatments per wound ranged from 6 (small pressure ulcers) to 15 (venous stasis ulcers)</p>		<p>3 -8 months</p>	<p>Percentage of healing: -100% healed – total 9 wounds (1 venous stasis ulcer, 3 pressure ulcers, 2 arterial insufficiency ulcer, 3 other nonhealing/surgical) -50-99% healed- total 6 wounds (3 venous stasis ulcers, 2 diabetic ulcers, 1 nonhealing/surgical) -0-49% healed-total 2 wounds (1 venous stasis ulcer, 1 nonhealing /surgical)</p> <p>Authors' Conclusion: -LFUD appears to be an excellent method for wound bed preparation to achieve wound closure in small wounds by secondary intention and prior to skin grafting or flap closure -appealing modalities for relatively painless, bloodless debridement -potential cost saving means if antibiotics and amputations are avoided -in 2 case studies, author has been successfully debride complex wounds and prepare them for skin grafting -since pain can be considered an indication of secondary wound infection, a decrease in narcotic requirement may indicate the infection is improving or being controlled</p>	

9.4 Appendix 4

Wagner's Classification of Diabetic Foot Ulcers

Grading	Features
0	Pre-ulcer. No open lesion. May have deformities, erythematous areas of pressure or hyperkeratosis.
1	Superficial ulcer. Disruption of skin without penetration of subcutaneous fat layer.
2	Full thickness ulcer. Penetrates through fat to tendon or joint capsule without deep abscess or osteomyelitis.
3	Deep ulcer with abscess, osteomyelitis or joint sepsis. It includes deep plantar space infections, abscesses, necrotising fasciitis and tendon sheath infections.
4	Gangrene of geographical portion of the foot such as toes, forefoot or heel.
5	Gangrene or necrosis of large portion of the foot requiring major limb amputation.

Source: Wagner WF (1981) The Dysvascular Foot: A System of Diagnosis and Treatment. J Foot Ankle 2:62-1221.