A small scale quality improvement study trialling the use of a monofilament-fibre (Debrisoft®) debridement lolly on chronic ulcers

KEY WORDS
- Debrisoft® lolly
- Foot ulcers
- Clinical effectiveness
- Patient satisfaction

Objective: A small-scale quality improvement study to determine the clinical effectiveness and patient satisfaction of the long-handled monofilament fibre (Debrisoft®) debriding lolly on foot ulcers that were considered to be slow healing in nature. **Methods:** This was a non-comparative, small-scale quality improvement study conducted on ulcers with slough (non-fibrous) at the ulcer base. The long-handled monofilament fibre (Debrisoft®) debriding lolly was used to treat seven patients during ulcer management, following the Trust's guidance for podiatric ulcer treatment. **Results:** Improvement was noted to the majority of ulcers within the second to third week and visible changes were evident, particularly in healing times and slough reduction. Both user and patient satisfaction were high. **Conclusion:** The long-handled monofilament fibre (Debrisoft®) debriding lolly provides an easy-to-use method of debriding foot ulcers. It allows easy access to difficult areas and enables the healing mechanism to commence. Patients verbally reported positive satisfaction when the long-handled monofilament fibre (Debrisoft®) debriding lolly was used.

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The rise in population and the increase of older people with comorbidities such as diabetes have meant that, according to Public Health England (2019), foot complications and lower limb amputations arising from ulceration are on the increase. However, Paisey et al (2018) and both the 2017 and 2019 Public Health Profiles for the NHS Somerset Clinical Commissioning Group (CCG) report that the rate of diabetes-related lower limb amputation is currently on the decrease in Somerset (NHS Somerset CCG, 2020). Many prominent authors within podiatry and medicine report that foot ulcerations can be caused by mechanical actions, such as friction over a joint or poor footwear. However, there are also non-mechanical causes of foot ulceration such as diabetes, an immune compromise which can affect the lower limb potentially lead to deep bony involvement and infections with possible limb loss (Foster, 2006; Lorimer et al, 2006; National Institute for Health and Care Excellence [NICE], 2019a).

Poor health, comorbidities, pressure, delayed or inappropriate treatment, devitalised tissue or slough can be the cause of biofilm resulting in an arrest of the healing process in any stage. Research has shown that the biofilm or 'slime' can be described as an extracellular matrix that is produced by bacteria which inhibits wound healing (Morozova et al, 2018). Biofilms create a hostile environment which inhibits or destroys the relevant building blocks such as growth factors that are required for the progression of wound healing (Attinger and Wolcott, 2012; Metcalf and Bowler, 2013; Morozova et al, 2018). Evidence also suggests that biofilms create a low-grade and persistent inflammatory response which can impede the formation of both tissue granulation and epithelisation (Lorenzelli et al, 2018).

It is widely recognised that effective wound management consists of an understanding of biofilm management along with wound assessment, management and preparation for effective healing to commence (Leaper et al, 2012; Metcalf and Bowler, 2013; Bowen and Richardson, 2016; Morris, 2017). Included in wound management should be the right dressing at the right time, and the use of anti-microbials if infection is present (Leaper et al, 2012; Metcalf

and Bowler, 2013; Bowen and Richardson, 2016; Morris, 2017). Added to the above and of importance is the management of patients concerns. Topical agents such as silver, iodine and honey are often used to reduce the bacterial load and have been shown to be effective against biofilms. Also, a relatively new enhanced Silver dressing currently shows potential in the management of delayed healing through biofilm on diabetic foot ulcers (Wilson et al, 2018).

The importance of wound bed preparation has been strengthened by the concept of biofilm-based wound care in the removal of the associated devitalised tissues (Schultz et al, 2013; Fletcher et al, 2017). In podiatric ulcer care, the normal mechanism for removal of these biofilms could be sharp debridement if possible. However, although sharp debridement has often been seen as the 'way forward' in 'kick-starting' the healing process, it can be difficult to manage the removal of biofilms particularly in undermining cavities or a deep sinus (Harding et al, 2016). Furthermore, Harding et al (2016) and Chadwick and Findlow (2015) suggested that sharp debridement should be used with extreme caution, particularly in patients with lower limb ischemia. It should, therefore, only be performed by experienced clinicians with specialist training.

The Debrisoft® lolly technology uses millions of monofilament fibres with the tips angled in a particular way to lift and remove superficial slough, debris and biofilm without damaging the fragile base below, thus enabling wound healing commencement (Lorenzelli et al, 2018). The use of this lolly for the treatment of all categories of ulcers with biofilm has been considered a safe method for biofilm debridement when clinically indicated. The lolly may also result in reduced time-to-healing and is recommended by the NICE Medical Technological Team, where trials have demonstrated a considerable improvement in ulcer healing rates, and also by the College of Podiatry (NICE, 2019b; Roes and Morris, 2019).

STUDY OBJECTIVE

The study objective was to determine the clinical effectiveness of the Debrisoft® lolly on foot ulcers presented to the clinic within the study time frame. The inclusion criteria for the small quality improvement study using the Debrisoft® lolly was for ulcers ranging from minimal to complete slough to ulcer base; all pedal pulses were assessed to demonstrate biphasic or triphasic soundings.

STUDY DESIGN

The study was a non-comparative evaluation, including an appraisal of the Debrisoft® lolly in the management of foot ulcers. The Likert Scale, a five-point scoring system, was used to measure patient satisfaction with the Debrisoft® lolly (Likert, 1932).

ETHICAL ISSUES

No formal ethics approval was required as this was a quality improvement study on clinical practice using the Debrisoft® lolly. This technology is also a CE-marked product and currently on the Trust's wound formulary, but it is currently not on the podiatry wound formulary. However, both formularies will shortly be merged.

The use of the monofilament technology was verbally discussed at each appointment including any risks and benefits that may occur. Each patient was given the option to opt-out of the use of the monofilament technology without detriment to their normal podiatric treatment. Written information regarding the technology was made available for patients. Each patient was then asked for verbal consent for treatment if the monofilament technology was to be used.

PARTICIPANTS

Potential participants were identified by the podiatrist from the high-risk caseload within the department. The inclusion criteria for the small quality improvement study using the Debrisoft® lolly was for ulcers ranging from minimal to complete slough at the ulcer base; all pedal pulses were assessed to demonstrate biphasic or triphasic soundings using a handheld Doppler. Patients had varying degrees of peripheral neuropathy — measured using a 10 g monofilament. *Table 1* shows the baseline demographics for the trial sample. Each patient's medication was checked for any immune suppressant therapies (presenting a higher risk of infection) and anticoagulant therapy — causing a decrease in blood clotting and an increased risk of bleeding. Seven patients between the ages of 35

Table 1. Baseline demographics for the small scale quality improvement project

Patient code	Approximate age	Sex	Ulcer aetiology	Ulcer duration	Comorbidities	Ulcer site: foot
A	35–40	F	Pressure related DFU	26 weeks	T2DM; Hx ulceration	5th plantar metatarsal head
B	75–80	M	DFU	10 weeks	T2DM; Hx ulceration	Digital & inter-digital cellulitis
C	60–65	F	Surgical related DFU	10 weeks	T2DM; depression	Amputation 3x digits – same foot
D	65–70	M	Pressure related DFU	8 weeks	Borderline T2DM	3rd – 4th dorsal metatarsal heads
E	50–55	F	Surgical amputation	23 weeks	Non-diabetic; RhA	Left 2nd apex
F	75–80	M	Surgical	10 weeks	Non-diabetic; Hx ulceration	4 digital amputation site
G	80–85	M	Pressure	5 weeks	Non-diabetic; heart failure	Apical hallux

DFU: Diabetic foot ulcer; T2DM: Type 2 diabetes mellitus; Hx: History; RhA: Rheumatoid arthritis

and 85 years with ulcers of different causality were recruited for the project. Of the seven patients, four had diabetes and one had rheumatoid arthritis. The patients were booked weekly appointments for review and treatment of the ulcer status.

TREATMENT

Following dressing removal, the skin around each ulcer was cleansed with Chlorhexidine Gluconate 0.5% and sterile gauze, any callus surrounding the ulcer was sharp debrided to viable tissue if required, in line with practice guidelines. The Debrisoft® lolly head was dampened with saline then gently squeezed with sterile gauze to remove excess saline; the lolly was then used to debride the ulcer bed of biofilms and loose slough using a circular or sweeping stroke across the ulcer bed. A separate lolly was used for each ulcer; the ulcer was then dressed appropriately and in accordance with the trust policy for podiatry. Each patient was seen weekly. During appointments, the ulcers were assessed and recorded using clinical electronic records. Patients were asked to score their satisfaction in the performance/use of the Debrisoft® lolly using a Likert Scale five-point scale.

Outcomes

- Time to healing
- Patient satisfaction using the five-point Likert Scale.

SINBAD (Site, Ischemia, Neuropathy, Bacterial infection, Area, Depth) was also completed if the ulcer was classed as diabetic as per podiatry Trust policy.

RESULTS

Ulcer duration and healing rates

Improvements, following the use of the Debrisoft® lolly, were noted between the second to third weeks of treating the ulcers. One ulcer initially increased in size but it decreased in size with improved condition after the third week.

After five weeks of treatment using the debriding lolly where possible, three ulcers had healed (B, E, G) and the remainder had decreased in size. The clinician noted that ulcer healing had quickened by using the monofilament lolly. No patient required antibiotic treatment. No patient withdrew from the study. All ulcers eventually healed.

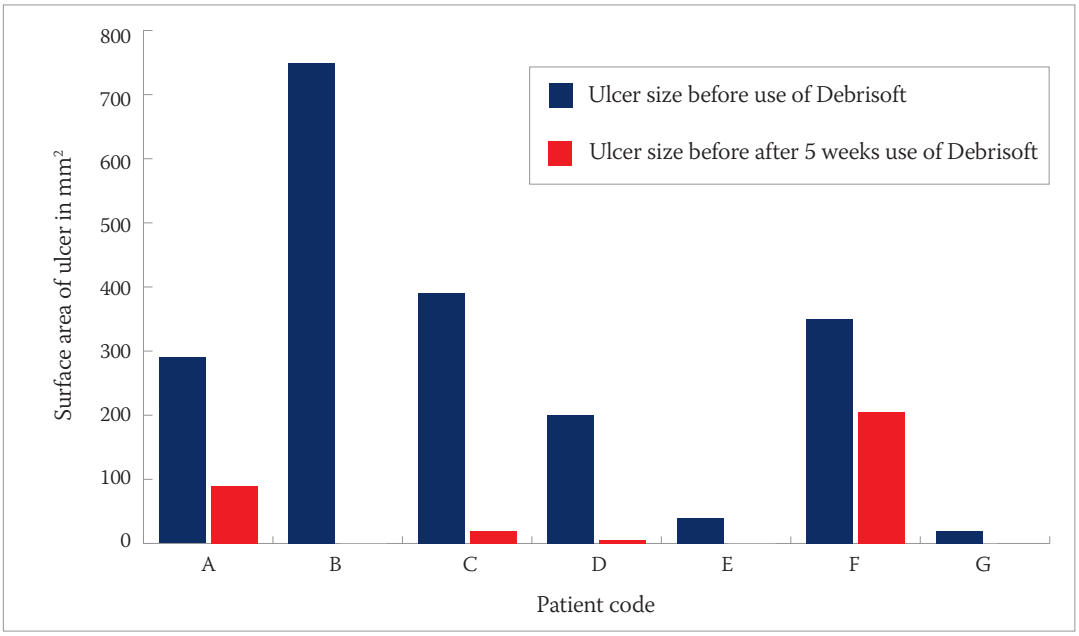

Figure 1. Outcome of healing times regarding the ulcers before and at 5 weeks using the Debrisoft® lolly

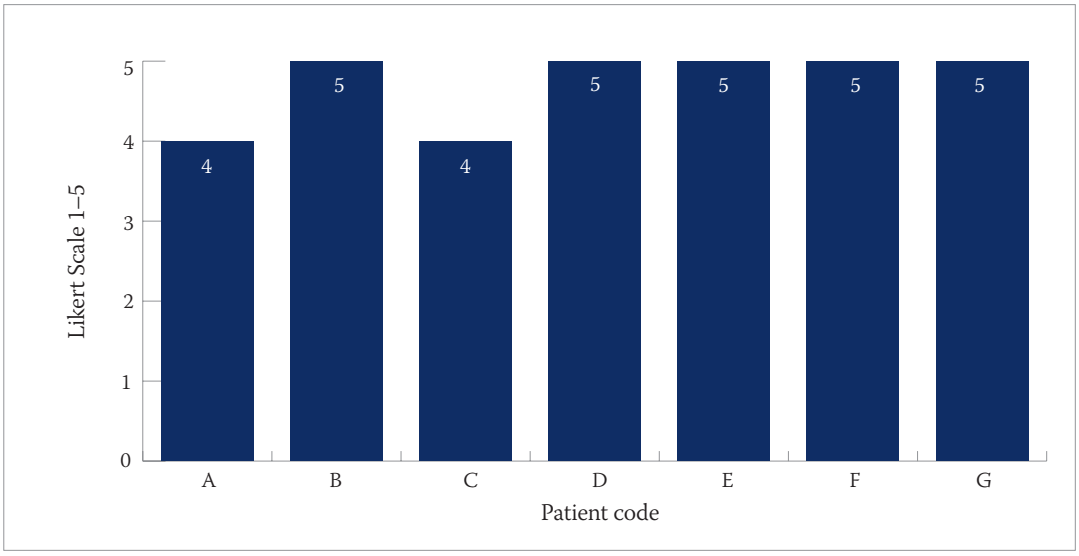

Figure 1. Patient satisfaction regarding the use of the Debrisoft® lolly when using the Likert five-point scale

Patient satisfaction

All patients verbally reported being satisfied with the performance of the Debrisoft® lolly. Five patients reported the highest satisfaction level 5. Two patients scored 4, one of whom had reported minimal discomfort during the second clinical appointment but decided to carry on with treatment with no further discomfort afterwards. The other patient gave no reason for the score.

When analysing the quantitative data from the Likert Scale five-point score system, the total point's value was 33; the ordinal data 4.714; the median 4; the interquartile range 0. It could, therefore, be argued that this evidence demonstrates patient satisfaction levels are high in the use of the Debrisoft® lolly as the score falls above the range of midway of agree/strongly agree (4.714). However, this was only a small sample size. Patients often verbally expressed being satisfied with the use of the Debrisoft® lolly.

DISCUSSION

This study set out to examine the clinical effectiveness of the Debrisoft® lolly on slow-healing ulcers to 'kick start' the healing process by removal of any devitalised tissue such as biofilm or slough

from the ulcers. The results show that all ulcers had either healed or established signs of healing after use of the Debrisoft® lolly as a debridement aid.

The monofilament fibre technology, with every single fibre having a 'hook' on the end, enables the biofilm to be easily removed from the wound or ulcer surface, allowing healing to occur (Roes and Morris, 2019). Therefore, the Debrisoft® technology (pad or lolly) could be seen as a safe and effective means of removing nonviable/devitalised, any infected tissue, dead material from the difficult to access ulcer bed through debridement (Lorenzelli et al, 2018; Roes and Morris, 2019; NICE, 2019a). Failure to remove this tissue could inhibit healing, cause an over-production of exudate. It could also lead to infection and impede an accurate assessment of the area including the ulcer bed potentially leading to amputation (Chadwick et al, 2014; NICE, 2019a; Roes and Morris, 2019). Therefore, regular maintenance through debridement of the ulcer bed is required to halt any biofilm build-up and remove non-viable tissue (Stang, 2013; Harding et al, 2016; Morris, 2017). Furthermore, NICE guideline NG19 stipulates wound/ulcer debridement when required, and NICE MGT17 recommends Debrisoft® technology as an easy and safe method of ulcer debridement (NICE, 2019a; 2019b).

Clinical trials and patient case studies using the Debrisoft® technology have all, so far, demonstrated the value in using this technology for many forms of wounds, ulcers and skin conditions where there is damaged or broken tissue, debris or slough that requires removal using debridement (Chadwick et al, 2014; Young, 2014; Morris, 2017; Lorenzelli et al, 2018; Roes and Morris, 2019). However, the Debrisoft® lolly, is a recent addition to the Debrisoft® technology and only one trial was found to have possibly used the lolly form although it is not mentioned as such (Roes and Morris, 2019). Therefore, no research, trials or case studies focusing solely on podiatric patients and the use of the Debrisoft® lolly could be found. On the other hand, much research has been carried out and found regarding the Debrisoft® pad; however, this pad is infrequently used within the podiatry setting due to size. Nevertheless, this monofilament debriding technology has been recommended for use in ulcer care by NICE as it is recognised as aiding mechanical debridement and is easy to use (NICE, 2019b).

Patients verbally reported being satisfied when the Debrisoft® lolly was used as reported previously. Previous literature shows a variable association between the clinical outcomes of the patient and the patient's experience/satisfaction (Prakash, 2010). Patients, who become more engaged with their care and gain a greater understanding, could be equated with better clinical outcomes (Chen et al, 2019). Nevertheless, patient satisfaction is a complex gauge which is difficult to quantify as to whether it could affect clinical outcomes.

Limitations: There were several limitations to this case study. It is recognised the wounds were of different aetiologies, at different stages of healing and were dressed with different dressing regimes. The small sample size with heterogeneous demographics also presents a limitation. Also, as the ulcers progressed in healing and became smaller, the lolly was too big to use on the ulcer base.

Recommendations: Manufacture of a much smaller/thinner Debrisoft® lolly so as to access smaller cavities as often found on the foot.

CONCLUSION

Regular debridement of the ulcer to control and remove the biofilm build-up where appropriate using the Debrisoft® lolly, could improve ulcer healing rates and provide patient satisfaction but more research is required in this area. Following the trial, the long handle monofilament fibre (Debrisoft®) debriding lolly and pad have since been added to the podiatry wound formulary enabling regular use within wound/ulcer care, and clinicians have been advised to make use of this technology. WUK

DECLARATION OF INTEREST

The author declares that Debrisoft® – Lohmann & Rauscher GMBH & Co. KG provided the long-handled monofilament fibre (Debrisoft®) debriding lolly for the small quality improvement study.

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