

A CASE STUDY SUPPLEMENT

Real-life perspectives on use of Monofilament Fibre Technology™ in practice

Wounds_{UK}

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FOREWORD

Debrisoft is a device available in the form of a Debrisoft pad or Debrisoft Lolly, which uses patented Monofilament Fibre Technology™. These devices are used to remove devitalised tissue and debris from a wound or from the skin to achieve debridement and improved visualisation, thereby facilitating more accurate evaluation of wound status. There is a considerable body of evidence supporting the use of Debrisoft across a variety of aetiologies, including: acute wounds, pressure ulcers, leg ulcers, diabetic foot ulcers and hyperkeratosis. Perhaps the most robust endorsement of Debrisoft is the National Institute for Health and Care Excellence (NICE) medical technology guidance (MTG17) (Meads et al, 2015) (based on 15 multiple-patient case series reports, five of which were peer-reviewed, along with 10 posters). This concluded that there were substantial benefits associated with use of Debrisoft, in terms of:

- Improving the wound condition
- Improving the ability to see the wound bed
- Saving time per treatment and time overall
- Improving patient comfort.

Previous debridement options were often time-consuming, expensive or required additional skill sets, which limited their utility; the challenges clinicians face on a daily basis when cleaning and debriding wounds were not necessarily recognised or addressed. Debrisoft allows every clinician to quickly and effectively clean and debride the wound bed and surrounding skin, as a result of its straightforward mechanism of action. In addition, Debrisoft can be used as part of a biofilm-based wound management pathway to reduce bioburden and prevent reconstitution of the biofilm.

One of the most exciting elements of this innovation is that it can be used by patients, allowing them to participate more readily in their own care. This input is particularly important if a wound is painful, as it gives patients increased control and debridement can take place within levels of pain patients are able to tolerate. Introduction of the new Debrisoft Lolly design has made even hard-to-reach areas more accessible, such as cavities, skin folds and between digits.

This supplement highlights how this technology expedites the debridement and assessment process using case studies from various clinical perspectives and, in doing so, supports clinicians to recognise the role Debrisoft can play across different wound and skin types. These real-life examples illustrate the benefits of Monofilament Fibre Technology™, particularly in the form of the Debrisoft Lolly, to the patient, clinician and organisation, including: improved comfort and healing progression; better wound visualisation; improved access to hard-to-reach areas; and savings in costs and time.

All the clinicians involved in the given case studies were experienced and had attempted — and still continue to use — alternative methods of removing debris, but it is clear that Debrisoft offered benefits for them all. Moreover, the patient experience of wound care delivery is substantially enhanced in each of the case studies and the satisfaction felt by the clinicians as a result of the effectiveness and impact of these devices can be clearly felt.

A wealth of other resources are available that support the use of Debrisoft in practice (www.wounds-uk.com), and its use is also recommended in the All Wales Guidance for Management of Hyperkeratosis of the Lower Limb (Crook et al, 2014); Management of hyperkeratosis of the lower limb: consensus recommendations (2015); NICE clinical guideline 179: Pressure Ulcers; and NICE clinical guideline 19: Diabetic foot problems.

For more evidence to support the use of Debrisoft, please visit: www.debrisoft.co.uk

Jacqui Fletcher, Independent Nurse Consultant

DEBRISOFT: A DEBRIDEMENT DEVICE FOR ALL HEALTHCARE PRACTITIONERS

The importance of debridement

The presence of debris and non-viable tissue in a wound, whether it be necrotic, sloughy or slimy, acts as a barrier to healing, potentially harbouring both aerobic and anaerobic bacteria. Since non-viable tissue produce an abnormal environment that can interfere with healing, wound debridement is an integral step in the process of wound bed preparation, encouraging wound healing and reducing bacterial and biofilm burden (Vowden and Vowden, 2011).

It is generally accepted by most clinicians that debridement is beneficial for wound healing, and numerous techniques are available (i.e. autolytic, biosurgical, sharp, ultrasonic and mechanical [Vowden and Vowden, 2011]), and these methods vary in terms of their characteristics, speed, effectiveness and ease of use (Meads et al, 2015). With biofilms believed to be present in 60% to 70% of wounds (Schultz, 2015), and an estimated UK prevalence of approximately 1.3 million chronic wounds (2012/2013) (Guest, 2015), it is vital that biofilm-based wound management using debridement is part of a nurse's skillset.

It is important that the decision to debride and the method of debridement chosen are suitable for the needs of the patient, based on the amount of tissue to be removed and the location of the wound. Since the aim of debridement is to produce a healthy wound bed, it may often be the first step of the treatment process, but it should always be considered a part of the whole wound management plan (Vowden and Vowden, 2011).

Overview of Debrisoft technology

Debrisoft is an innovative medical device for debridement and cleansing that removes debris quickly and efficiently, stimulates wound healing, protects newly formed tissue and is usually painless, so improving quality of life (Activa Healthcare, an L&R Company, 2016). Importantly, Debrisoft has a unique mode of action that lifts material out of the wound bed or from the surface of the skin, binds it between the Debrisoft fibres, and so removes these barriers to healing (Wounds UK, 2016).

NICE released guidance in March 2014 (MTG17) that recommended the use of Debrisoft in the treatment of acute and chronic wounds in the community, acknowledging that Debrisoft is highly effective for chronic sloughy wounds and hyperkeratosis. The guidance suggests that when the Debrisoft pad is used on appropriate wounds there are a number of likely benefits compared with standard debridement methods:

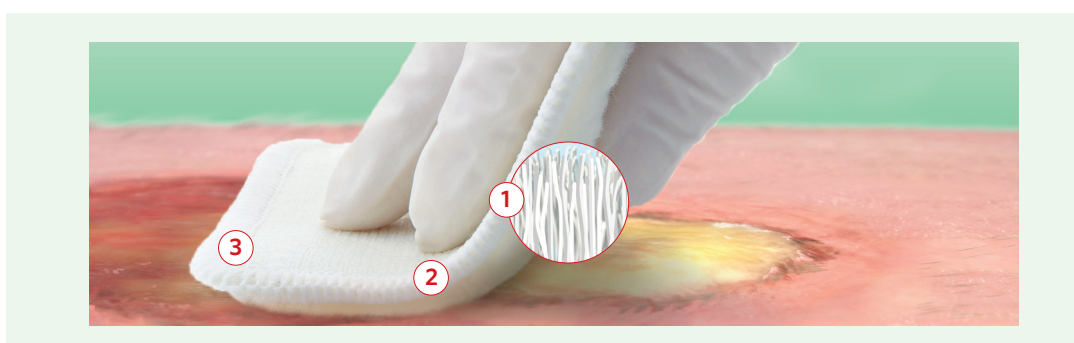
- The wound will be fully debrided more quickly
- Fewer nurse visits will be needed.

The guideline also states that Debrisoft is convenient, easy to use, well tolerated and represents cost savings in comparison with other methods. Indeed, Debrisoft already forms an important part of standard wound management as described in other clinical guideline (NICE clinical guideline 179: Pressure Ulcers; NICE clinical guideline 19: Diabetic foot problems) (Meads et al, 2015).

A recent development in the form of the Debrisoft Lolly, a monofilament fibre debrider for hard-to-reach areas, has extended use of the Debrisoft technology beyond the possibilities of the original debridement pad, while retaining its comparative effectiveness.

THE DEBRISOFT MONOFILAMENT FIBRE TECHNOLOGY™ DEBRIDEMENT PAD

The Debrisoft monofilament debridement pad is a sterile, single-use pad for use on adults and children to remove devitalised tissue, superficial slough and debris, including biofilm, from acute and chronic wounds, and for the removal of hyperkeratosis from the skin. Once the pad has been moistened, the fleecy side is used to gently wipe the surface of the wound in a circular motion. The pad can be used by patients, carers, or non-specialist practitioners, and can be disposed of in household waste (Wounds UK, 2015).

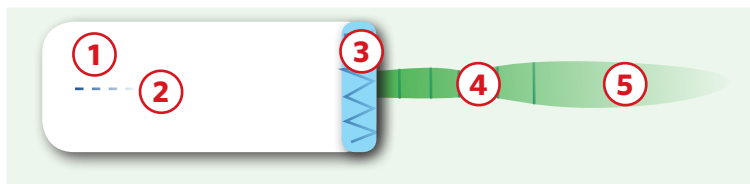


- 1 Monofilament fibres** — Eighteen million polyester fibres. These are a specific length and density that allows them to loosen debris and bacteria, necrotic tissue, hyperkeratotic skin and adherent exudate from the wound and surrounding skin
- 2 Soft and flexible pad** — Allows for non-traumatic debridement and cleansing, usually with no discomfort
- 3 Monofilament fibres are securely fixed with polyacrylate backing** — Material testing has demonstrated that the Debrisoft pad does not shed fibres while in contact with the wound bed.

THE DEBRISOFT LOLLY MONOFILAMENT FIBRE TECHNOLOGY™ DEBRIDEMENT DEVICE

The Debrisoft Lolly utilises the same Monofilament Fibre Technology™ as the Debrisoft pad, which lifts, binds and removes debris while protecting intact tissue. However, the Debrisoft Lolly has been developed for debridement of deep wounds and awkward areas, such as cavities and skin folds. It is easy to use, particularly in hard-to-reach areas that may be difficult to access with Debrisoft pad (Activa Healthcare, an L&R Company, 2016).

The Debrisoft Lolly has a flexible handle enabling application of gentle pressure in both deep and superficial wound types, and its soft fibres make the process painless in most cases, increasing patient acceptance (Morris et al, 2016)



- 1** The Debrisoft Lolly head is made from patented Monofilament Fibre Technology™, designed for effective debridement of deep and superficial wounds, including wounds from invasive surgery and post-operative healing by secondary intention
- 2** Precise and secure seams, ensuring retention of the head
- 3** X-ray detectable thread, providing safety through traceability
- 4** Visible markings to facilitate grip and support wound measurement
- 5** Strong and flexible, polypropylene handle provides safe access to hard-to-reach areas, including cavities, undermining, skin folds and between digits, and allows application of gentle pressure. The handle is safe, ergonomic and comfortable to use.

THE PODIATRIST PERSPECTIVE

Author

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In advanced podiatry, sharp debridement of complex wounds is common practice. The decision to use a mechanical debridement technique such as Debrisoft is based on either the visual presence of a contaminant or the wound's designation as static. The Debrisoft pad and Debrisoft Lolly form part of the debridement formulary for many podiatrists, for use either as a standalone technique or in combination with other debridement methods.

Mechanical debridement is often used in combination with sharp or autolytic debridement, or in place of sharp debridement where there is too much risk involved; for example, when tendon is evident on the wound base, or when the base of the ulcer site is not visible, such as for deep ulcers found on the plantar foot over Charcot deformity in diabetic patients, or in chronic static wounds. Another common rationale for use of Debrisoft is the likely presence of biofilm in the wound and periwound area of chronic ulceration, even without the presence of visual contaminants like slough or callus; for example, for chronic granulation in an ulcer site.

Painful interdigital ulcers — or ulcers that are between the toes — can also be difficult to debride. Prior to the introduction of Debrisoft Lolly, painful interdigital ulcers were usually treated with a combination of autolytic and sharp debridement, as tolerated. Experience has shown that the interdigital treatment of ulcers with Debrisoft Lolly is more tolerable for the patient than sharp debridement, perhaps because of the slight 'tugging' action of sharp debridement, especially in an area where getting good skin tension is difficult. This has been noted particularly where patients are hypersensitive and have chronic foot pain; although the difference is not major, debridement with Debrisoft Lolly can be tolerated in some cases where the patient has requested that sharp debridement is not used.

Debrisoft Lolly is an effective option for podiatrists where other debridement methods either are not indicated or are too slow in their effectiveness. It is an excellent adjunct that allows active debridement where treatment may have not been used previously; in one bed-bound patient, for example, his 'hospital' style bed had made accessing the plantar aspect of the foot difficult and dangerous without someone present to assist with lifting the leg, which was not always possible. Instead, Debrisoft Lolly could be used for this patient to allow some debridement to take place.

From the podiatrist's perspective, the Debrisoft pad and Debrisoft Lolly also seem to have a positive impact on the speed of wound healing. In one instance of a patient with diabetic foot ulceration, an 85% decrease in wound size was noted over a 3-week period with the use of Debrisoft Lolly, along with the healing of chronic painful chilblain lesions that had previously been static.

CASE 1

This 80-year-old female had ulcers present on both feet — apices of toes and interdigitally — caused by chilblains, of approximately 12 weeks' duration. This patient had systemic lupus erythematosus, chronic leg pain and neurologic involvement, and was taking prednisolone and methotrexate, in addition to pain management medication.

Debrisoft was chosen for this patient as her wounds were chronic and presence of biofilm was suspected. Previously, sharp debridement had been attempted; however, this was discontinued as the patient found it to be too painful. Initially, the Debrisoft monofilament debridement pad was used, but there was difficulty accessing the interdigital areas effectively without increasing pain levels. Therefore, the Debrisoft Lolly was a logical choice for this patient.

Before debridement

Eight superficial ulcerations, believed to be chilblain lesions, of approximately 1cm² and 0.1cm depth were present, composed of approximately 50% granulation tissue with 50% slough. The

skin around the wounds was intact, but cyanosed and cool to the touch. The patient's pain score was 10 out of 10, measured on a visual analogue scale (VAS) (Burckhardt and Jones, 2003).

During debridement

The wounds were debrided once a week for 3 consecutive weeks with Debrisoft Lolly. Debridement took approximately 2 minutes, although full debridement could not be achieved, as the required application pressure was too painful. During the first treatment, the patient's reported pain level remained the same, but in subsequent weeks her pain reduced, although some pain remained due to the need to open the toes to debride; however, this was reported more bearable with the Debrisoft Lolly compared with sharp debridement.

After debridement

After debridement, the wounds were composed of approximately 60% granulation and 40% slough. Within 7 days, half of the ulcers had healed, leaving just four ulcers remaining, which all healed within 12 weeks.

CASE 2

This 72-year-old male presented with a chronic ulcer of approximately 12 weeks' duration. The ulcer was located to the left plantar forefoot, on the third to fifth metatarsalphalangeal joint (MTJP) area, with lateral involvement of the fifth MTJP area. There had been a previous minor amputation site at the second toe, which had healed, but the ulceration involved some interdigital areas.

The patient had well-controlled type 2 diabetes and stage four chronic kidney disease. He took insulin and metformin, and antiplatelet, lipid and antihypertensive medications. The patient was bedbound with no transferring at all, so there was a degree of difficulty accessing the ulcer site due to the hospital-style bed end.

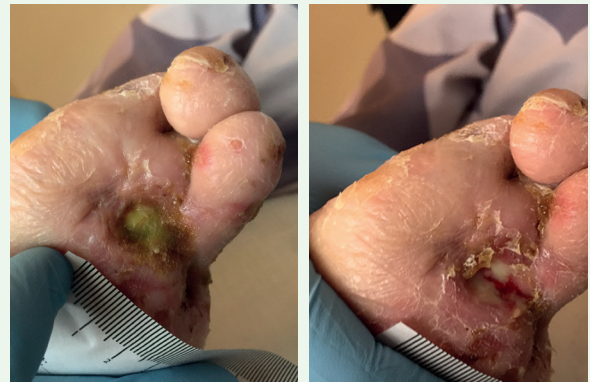
Debridement was required to promote healing in the area. Debrisoft Lolly was chosen due to a small amount of tendon involvement noted at wound bed.

Before debridement

The ulcer was 4.5cm x 1.5cm and 0.5cm deep. The wound bed comprised 40% granulation tissue, 50% slough and 10% tendon, and the surrounding skin was dry. The patient had peripheral sensory neuropathy and therefore had no pain before, during or after treatment.

During debridement

The wound was debrided for 1.5 to 2 minutes for 3 consecutive weeks using the Debrisoft Lolly, which made reaching the foot easier than with the previous method of the monofilament debridement pad. In addition, more of the wound's depth could be accessed with the Debrisoft Lolly compared with the pad. The clinician found no limitations to using the Debrisoft Lolly, reporting it felt similar to using a scalpel, with a grip similar to that required for sharp debridement.



Pre-debridement

Post-debridement

After debridement

The ulcer site changed to 70% granulation and 20% slough, with 10% tendon exposure. After using Debrisoft Lolly, the ulcer size did not change immediately, but within 1 week it had reduced by 0.5cm in both width and length. The amount of granulation tissue increased by 10% and then a further 20% in the following 2 weeks. Within 2 weeks there was substantial improvement in ulcer size (85% reduction). The ulcer healed within 10 weeks. In subsequent weeks, Debrisoft Lolly was used in combination with sharp debridement.

In relation to diabetic foot ulcers, Debrisoft Lolly works well for deeper ulcerations where sharp debridement may not be indicated or as an adjunct to its treatment.

The patient's pain reduced after debridement (to 9 out of 10) and, as the ulcers healed, she would allow more inspection of the interdigital areas, although her reported pain levels remained fairly constant.

Debrisoft Lolly seemed to help promote and speed up wound healing; without it, the process may well have been more protracted and the patient's pain may have not reduced as quickly. The clinician was more than satisfied with use of Debrisoft Lolly.



Pre-debridement

Post-debridement

THE COMMUNITY NURSING PERSPECTIVE

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A 12-patient clinical evaluation in one community area using a pre-determined evaluation was undertaken within a UK Health and Care NHS Trust. The purpose of this clinical evaluation was to determine the suitability of the new Debrisoft Lolly in debriding various wound types. The Debrisoft Lolly was used to debride the wounds of eight female and four male patients with an age range of 42 years to 84 years (Table 1). The wound aetiologies of these patients varied, including seven patients with pressure ulcers in different locations; one patient with a surgical stump wound; one patient with a haematoma; one with a skin tear; one with a leg ulcer; and one patient with an infected foot and toes. All the wounds examined in this clinical evaluation were chronic and presented with slough that needed debriding.

Evaluation inclusion criteria required that the patient be over 18 years of age with the capacity to consent to the clinical evaluation, be willing to participate in the evaluations, and have a wound requiring debridement. The following cases studies explore use of Debrisoft Lolly for four of these patients in more detail, including images of the patients' wounds before and after use.

The results of this evaluation indicate that the Debrisoft Lolly is effective at debriding small and hard-to-reach wounds, with improvements seen in all patients studied. It was found that the Debrisoft Lolly had less control than the monofilament debridement pad across large areas, such as for the patient with leg ulceration, but still worked effectively to debride the wound.

Table 1: Summary of 12 patients included in the clinical evaluation for Debrisoft Lolly

Client	Age	Gender	Diagnosis	Rationale for use of Debrisoft Lolly for debridement	Outcome
1	72	Female	Leg ulcer	Allowed access under plaques of hyperkeratosis	The Debrisoft Lolly worked, but with less control across such a large area than with the Debrisoft pad
2	72	Female	Infected toes and foot	Allowed access between toes and foot creases	Allowed access to small areas not accessible with the pad
3	42	Male	Pressure ulcer (hip)	Allowed access under slough	Under guidance, the patient was able to use the Debrisoft Lolly himself
4	73	Male	Pressure ulcer (toes)	Allowed access to a small wound	Small piece of bone came out of the wound; the patient's feet are now healed
5	74	Female	Skin tear	Allowed access to corners of the wound (devitalised tissue at the wound edges)	Lifted the devitalised tissue; the wound is now healing
6	70	Female	Pressure ulcer	Allowed access under necrotic tissue	Necrotic tissue was debrided; the wound is now healed
7	84	Female	Pressure ulcer (sacrum)	Allowed access under the edge of the wound	The wound is healing well
8	76	Male	Pressure ulcer (shoulder)	Allowed access under necrotic tissue	Necrotic tissue was debrided, which facilitated pressure ulcer categorisation
9	76	Female	Haematoma	Allowed access under edges of the haematoma	Clot was removed and the wound bed looks much better; new granulation tissue can be seen
10	62	Male	Pressure ulcer (foot)	Allowed access under the hard necrotic top of wound	A large majority of the necrotic tissue was removed
11	72	Female	Pressure ulcer (heel)	Allowed access under slough of wound bed	The slough was difficult to remove in this instance (wet/stringy type); the Debrisoft pad lifts this more easily
12	81	Female	Dehisced surgical stump wound	Allowed access to small wound area and under sutures embedded in slough	Allowed proper access to the wound bed and removal of the sutures; the wound is now healing well

CASE STUDY 1

This 76-year-old female previously had a cerebrovascular accident and is now reliant on a wheelchair. She caught her lower leg on her wheelchair in January 2016, causing a haematoma. Before debridement, the surrounding skin was necrotic. The blood clot was removed using Debrisoft Lolly, which allowed visibility of the wound bed; this also reduced the risk of infection to the patient and supported the healing process.

The reason for using the Debrisoft Lolly was to allow debridement under the edges of the haematoma, which is a difficult area to access with the Debrisoft pad. The nurse used three of the Debrisoft Lolly to debride this extensive area. The shape and design of the Debrisoft Lolly made it very easy to debride the haematoma to remove the blood clot. It was reported that the Debrisoft Lolly made the debridement process quicker compared with the previous experience of the clinician and this helped expedite the healing process.

The patient stated that the use of the Debrisoft Lolly made her wound feel more comfortable. The patient also reported that she felt no pain during debridement of the wound. After debridement, the wound bed was visible as the blood clots were removed, and new granulation tissue could be seen, indicating healing.



Before treatment



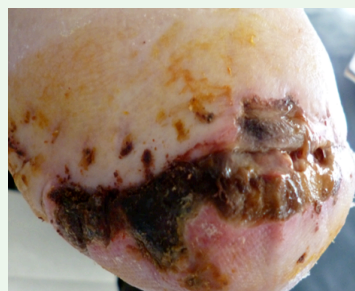
After one treatment

CASE STUDY 2

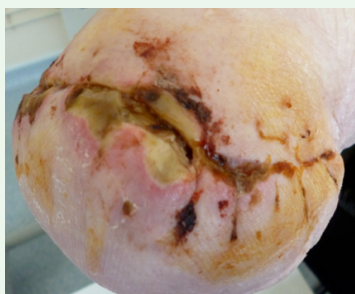
This 81-year-old female had a leg amputation due to arterial disease in 2015. The wound dehisced and became covered in devitalised tissue. Before debridement, slough was present in the wound and the surrounding skin was red and inflamed.

Debrisoft Lolly allowed debridement in the small wound area. The wound was difficult to debride as the slough was deeply embedded into the suture line; using the Debrisoft Lolly allowed the nurse to get under these sutures. The nurse used two of the Debrisoft Lolly, with a treatment time of 15 minutes.

It was reported that the Debrisoft Lolly was very useful in removing the slough out of the small wound cavities. Nurses could assess the wound bed properly and remove the sutures to allow the wound to continue healing. After debridement, the wound bed could be seen more clearly, with less slough present. A week later, the leg wound continued to improve; thus, the Debrisoft Lolly was not required again.



Before treatment



After one treatment

CASE STUDY 3

This 72-year-old male is a known smoker with no history of diabetes, with a pressure ulcer that had occurred when he stubbed his second toe on his bed. This patient had very dry skin on his legs and feet, and has had a big toe amputation. He is no longer able to mobilise so is hoisted in order to move, and rated his pain as 5 out of 10. Before debridement, the surrounding skin was very dry and necrotic with a hard nail in the middle of his toe.

Only one Debrisoft Lolly was needed to debride this wound, as it covered a small area. The wound was cleaned for 5 minutes. The Debrisoft Lolly was an appropriate size to access between the patient's toes; it was reported as bendy when accessing the wound, which allowed good control but did require good dexterity for use.

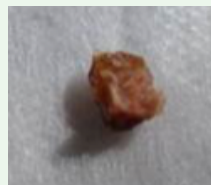
After debridement the wound improved, with granulation and slough present; the surrounding skin remained dry. During use of the Debrisoft Lolly, a small piece of bone became dislodged from the foot; after this, the wound continued to improve quickly. A week after debridement, during a phone conversation with the patient, it was discovered that the wound was healing very well and further use of Debrisoft Lolly was not necessary.



Before treatment



After one treatment



Bone dislodged from the wound

CASE STUDY 4

This 70-year-old female was mobile and used a Zimmer frame for short distances, until she suffered a fall to her knees. Following the fall, she became less mobile and developed a knee wound. The nursing home reported this as a pressure ulcer but, upon examination, it appeared more like a carpet friction burn. Before debridement, the wound bed was necrotic with a little slough, and the surrounding skin was red and inflamed. The necrotic tissue made it difficult to determine the depth of the wound and the eschar was making the knee stiff and so painful for the patient to walk, decreasing her mobility. The wound needed debridement to enable healing.

This patient had a tremor due to Parkinson's disease so sharp debridement was unsuitable, but the Debrisoft Lolly was able to slide under the eschar, which had started to lift, and peel it from the wound. The nurse used two of the Debrisoft Lolly for debridement and cleaned the wound for 20 minutes. However, whilst the necrotic tissue had been removed, slough was still present and it was difficult to determine how deep this knee wound was.

A week later, slough and granulation were present in the wound. As the remaining slough was not lifting, further debridement with the Debrisoft Lolly was not continued; however, Debrisoft had greatly reduced levels of slough by this point. Nurses described the Debrisoft Lolly as being a very cost-effective method of debridement in terms of time, as well as improving the patient's quality of life.



Before treatment



After one treatment



After two treatments

THE USER PERSPECTIVE

A recent multicentre, international study evaluated experiences of using Debrisoft Lolly in practice, for the debridement of hard-to-reach locations, wound cavities and for surgically invasive use, focusing on usability, user satisfaction and performance of Debrisoft Lolly. One-hundred-and-seventy patients with chronic, acute or surgically invasive wounds were treated. There were no exclusion criteria for use of Debrisoft Lolly in terms of type, dimensions or location of wounds, or regarding patients' underlying disease (Morris et al, 2016).

Twenty-three clinicians who were familiar with Debrisoft Lolly were included in the study, completing a questionnaire of 33 questions based on use of the product with between one and ten individuals. The questions covered: comparison with the standard method; device performance (i.e. time required for debridement, effectiveness of wound debridement); usability (i.e. unpacking, dimensions); type of wounds treated and location; patient satisfaction; tolerability and safety (i.e. negative or positive signs in the wound or surrounding areas, pain experienced by patients); special suitability; willingness to use the device; and design and intended use. An overview of results is given below.

Comparison with standard therapy

Debrisoft Lolly was compared with standard therapy in four categories: debridement ease, duration of procedure, pain and efficacy of debridement. Debrisoft Lolly was clearly superior to the most commonly used method (surgical, mechanical or autolytic) for the debridement ease, duration and pain categories. In the debridement efficacy category, Debrisoft Lolly was considered to be marginally better than the standard therapy.

Device performance

The time required for debridement with Debrisoft Lolly was reported to be better than good by most users; indeed, when analysed by location, depth and wound location, mean procedure time was almost always lower than with the standard method, with the exception of just one thorax wound and one pressure ulcer.

Of particular interest were savings in time for surgical and post-surgical wounds, of 8 minutes and 11 minutes, respectively. A second, efficacy-specific evaluation was undertaken under the umbrella of 'Device performance'; in this case, most users reported the debridement effectiveness of the device as satisfactory or better than the most commonly used therapy. The absorption capabilities of Debrisoft Lolly were also reported to be good by most users.

Usability

Of the total users, 87% considered the usability of the Debrisoft Lolly to be good or very good, 68% of users reported the size of the device was good or better than standard therapy, and 91% assessed the length of the handle to be good or better. The current dimensions of the device satisfied the needs of the users across a range of wound sizes.

Wound types and locations

A broad spectrum of wounds was represented in the patient population for this study. The indications treated most often were arterial-venous (leg) ulcers and diabetic foot syndrome, but many other wounds were also mentioned, including pressure ulcers, surgical and post-surgical wounds, abscess cavities, and pyoderma gangrenosum. Wound locations were widely spread, including deep, superficial, cavity and pocket wounds. The device was considered satisfactory or better than the standard method in terms of application in hard-to-reach areas, and was appropriate for surgically invasive procedures in various different locations.

Patient satisfaction

Patients reported that debridement with Debrisoft Lolly was more comfortable than with other methods, while 95% of users reported patient comfort to be good or very good.

Tolerability and safety

The tolerability of the device was analysed within four parameters, with users answering 'yes' or 'no': positive signs of wound healing (40% replied 'yes'), negative signs (100% replied 'no'), intolerability signs (96% replied 'no'), and whether any damage was done to the new tissue during debridement (100% replied 'no'). Patients considered Debrisoft Lolly to be safe and tolerable, which is confirmed by the fact that no incidents were registered to MDD93/42/EWG during the study.

Special suitability

Due to its size and dimensions, Debrisoft Lolly was considered appropriate for middle-sized and superficial wounds, and wounds with cavities and pockets.

Willingness to use

Of the users included in this study, 95% were willing to use the device.

CONCLUSION

Users consider Debrisoft Lolly to be successful at facilitating the debridement process across a number of chronic wound aetiologies, including invasive surgical wounds. The Debrisoft Lolly satisfied the expectations of the users and was rated as very good, good, or satisfactory across all of the tested criteria. Moreover, the material used on the head of the Debrisoft Lolly and the handle's flexibility were found to be appropriate to avoid excessive pressure being applied to the wound. In particular, the Debrisoft Lolly was found to offer wide applicability across wound types, reduced time to debridement, good debridement effectiveness and absorption capacity, and importantly, could be used effectively in hard-to-reach areas.

REFERENCE: Morris C, Browning A, Schmitz M, de Lange S, Martin A (2016) New monofilament-fibre debrider for debridement of difficult locations wound cavities, and surgically-invasive use - experience in practice. Poster presented at European Wound Management Association, Bremen, Germany

THE BIOFILM PERSPECTIVE

Biofilm: a common problem requiring an effective solution

There is a body of evidence that now strongly supports the notion that wound biofilm plays a critical role in delaying wound healing (Metcalf et al, 2014). Since biofilm is reported to be a major factor contributing to multiple chronic inflammatory disease, it is likely that almost all chronic wounds have biofilm communities on at least part of the wound bed (Phillips et al, 2010). In 2015, Guest reported the existence of 1.3m chronic wounds. In a recent survey at a national wound care conference, 71% of the audience believed 60% to 100% of such chronic wounds contained a biofilm (Fletcher et al, 2016). Moreover, Schultz (2015) confirmed what Metcalf et al reported, that this biofilm delays healing.

Thus, chronic wounds require biofilm-based wound management to enable healing. Due to such a large proportion of chronic wounds containing biofilm, it is necessary that all general nurses who manage wounds have the tools and knowledge required to address the problem of biofilm. Indeed, biofilm-based wound management is an essential first step in the proactive management of chronic wounds.

Debrisoft can be used as part of a biofilm-based wound management pathway (see opposite and below) to reduce bioburden and prevent reconstitution of the biofilm, as described by Phillips et al (2010).

BOX 1: SUSPECTED BIOFILM IN A CHRONIC WOUND – ARE ANY OF THE FOLLOWING PRESENT?

- Absence of healing progression, even though all obvious comorbidities and wound management issues have been addressed
- Visible slimy, gel-like and shiny material on the surface of the wound bed, which detaches easily and atraumatically from the wound bed
- Reforming of slough quickly, despite debridement
- An increase in the production of exudate
- Poor quality granulation tissue — possibly fragile and/or hypergranulation
- Signs of local infection (as biofilm is a precursor to infection), e.g. heat, redness, swelling, pain, odour
- Persistent or recurring infection
- Slow, or no, response to antiseptic dressings such as silver, iodine or PHMB
- Positive healing response following implementation of the Debrisoft biofilm-based wound management 2-week pathway.

BOX 2: FOLLOWING THE 2-WEEK PATHWAY, REASSESS THE BIOFILM STATUS IN THE CHRONIC WOUND – ARE ANY OF THE FOLLOWING PRESENT?

- Healing progression
- Reduction in the production of exudate and slough
- Improved quality of granulation tissue
- No signs of local infection (heat, redness, swelling, pain, odour).

*Box 1 and Box 2 have been developed using the following publications: Phillips et al, 2010 and Metcalf et al, 2014

Debrisoft®

Biofilm-based wound management pathway

Reduce the biofilm burden + Prevent reconstitution of the biofilm
= Biofilm-based woundcare

↓	Wound assessment	<ul style="list-style-type: none"> • Suspected biofilm in the chronic wound • See Box 1 opposite 	
↓	NB: For Venous Leg Ulcers (ABPI 0.8–1.3) – Apply appropriate compression if indicated following a full holistic assessment, incorporating a vascular assessment		
↓	Week 1		
↓	Dressing change 1	<ul style="list-style-type: none"> • Debrisoft® the wound (This will reduce the biofilm burden) and • Apply a suitable topical antimicrobial* (e.g. Suprasorb® X+PHMB) (This will help prevent reconstitution of the biofilm) 	↖
↓	Dressing change 2	<ul style="list-style-type: none"> • Debrisoft® the wound and • Apply a suitable topical antimicrobial* (e.g. Suprasorb® X+PHMB) 	↑
↓	Dressing change 3	<ul style="list-style-type: none"> • Debrisoft® the wound and • Apply a suitable topical antimicrobial* (e.g. Suprasorb® X+PHMB) 	↑
↓	Please repeat if more dressing changes are required		
↓	Week 2		
↓	Dressing change 1	<ul style="list-style-type: none"> • Debrisoft® the wound and • Apply a suitable topical antimicrobial* (e.g. Suprasorb® X+PHMB) 	↑
↓	Dressing change 2	<ul style="list-style-type: none"> • Debrisoft® the wound and • Apply a suitable topical antimicrobial* (e.g. Suprasorb® X+PHMB) 	↑
↓	Please repeat if more dressing changes are required		
↓	Wound re-assessment	<ul style="list-style-type: none"> • Re-assess the biofilm status in the chronic wound • See Boxes 1 & 2 and consider the following: 	↑
↓	Healing progression? NO	<ul style="list-style-type: none"> • Consider repeating with another topical antimicrobial* (e.g. Suprasorb® A+Ag) • Consider repeating with a 3rd topical antimicrobial* • If no progression after 3rd antimicrobial – consider specialist referral 	↑
↓	Healing progression? YES	<ul style="list-style-type: none"> • Consider reducing the use of Debrisoft® and • Consider stopping the topical antimicrobial 	↗

* Or use the antimicrobials listed on your local WC formulary

THE LYMPHOEDEMA PERSPECTIVE

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Hyperkeratosis



Papillomatosis

Lymphoedema is a lifelong condition that affects millions of people globally. At any one time in the UK, it is estimated that at least 240,000 people may be living with varying degrees of lymphoedema, which can be managed but not cured (Hardy et al, 2015). Lymphoedema is the accumulation of fluid in the tissues resulting from lymphatic failure, which, as the disease progresses, can bring about an increase in oedema and skin changes such as hyperkeratosis, papillomatosis (left), and fibrosis with a positive stemmer's sign (i.e. the inability to pinch a fold of skin at the base of the second toe) (Woods, 2007).

Patients with chronic oedema arising from poorly managed chronic venous insufficiency (CVI) may go on to develop secondary lymphoedema (Fife et al, 2009; Bianchi, 2013). In particular, a link between obesity, CVI and secondary lymphoedema has been found in relation to leg oedema (Fife et al, 2009). In a prevalence study conducted in Derby city by Moffatt and Pennington (2012), with an estimated population of 246,900 (mid-2010), the number of people with chronic oedema in the 65-to-74-year-old age group was 10.31 per 1000 population compared with 28.57 in those aged over 85 years. As a nation with increasing levels of obesity and longevity of life, lymphoedema is likely to be a continuing problem.

Patients with lymphoedema are known to be at risk of cellulitis (Al-Niaimi et al, 2009), which is frequently caused by the bacterium *Staphylococcus aureus* and *Streptococcus* (Wingfield, 2012), and most commonly affects the lower legs. Patients with lymphoedema should follow a pathway for cellulitis, taking an extended course of antibiotics: initially for a minimum period of 2 weeks and continuing if still symptomatic. Prophylactic antibiotics are recommended if patients have had two or more episodes of cellulitis in a year (BLS, 2015).

It is important to ensure the barrier function of the skin is maintained in patients with lymphoedema. As such, good skin care is one of the cornerstones of treatment; for example, the removal of hyperkeratosis and meticulous cleansing of papillomatosis (Moffat, 2006), including cleansing between skin folds and toes. Patients with lymphoedema should also exercise, and receive compression therapy and lymphatic drainage, which can be either manual (therapist-led) or simple (patient-led). Support should be given to the patient at an early stage to encourage self-care, enabling long-term management of the condition (Hardy et al, 2015).

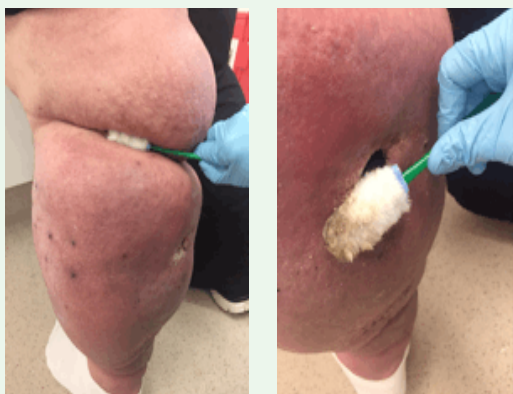
CASE STUDY

This 42-year-old woman has a long-standing history of lymphoedema and associated complaints. She was referred to the tissue viability service by the local community nursing team, as they were unable to deal with the complex management of her lower limb. She has no significant past medical history with only mild asthma and hypertension. However, she is morbidly obese, with her last known weight 168kg and a current BMI of 50. She had previously received lymphoedema management under the local hospice service but found it difficult to comply with treatment plans, resulting in episodes of rebound swelling and tissue breakdown. At times, she has expressed difficulty coping with the psychological aspects of living with secondary lymphoedema and often became tearful during appointments, particularly regarding setbacks in treatment. She has been offered community-based psychological support to develop coping strategies, although historically she has not engaged with health improvement initiatives, such as weight management programmes and exercise classes.

Before debridement

On first assessment with the tissue viability service, this patient presented with grossly oedematous lower limbs, three wounds to her left leg, deepened skin folds, papillomatosis and excoriation from poorly managed lymphoedema. The lymphoedema was controlled with an intensive chronic-oedema-bandaging regime using Actico® Inelastic bandages, and she was fitted with made-to-measure flat knit hosiery and a Velcro wrap device.

One month into the maintenance phase of lymphoedema management, the patient began to experience difficulties with continued daily wear of compression maintenance garments, her limb condition deteriorated, and a wound spontaneously developed to the posterior aspect of the mid-calf.



Using Debrisoft Lolly on this patient

The area of tissue that had broken down was heavily fibrosed, which had caused a large cavity wound; on return to clinic, a wound measuring 2.3cm x 2.5cm x 3cm was present. There was no granulation tissue visible in the cavity and the wound was sloughy and dark in colour.

The Debrisoft Lolly was chosen to debride the wound, as it would allow mechanical debridement to be applied directly to the wound bed, provide periwound skin care and ensure thorough cleansing in the deepened skin folds of the limb. However, this patient often experienced anxiety regarding changes in care plan, and was apprehensive about the use of the Debrisoft Lolly inside the wound cavity; this anxiety was combatted with unconditional positive reinforcement.

During debridement

The Debrisoft Lolly was used twice in a week, and when reviewed a week later, islands of granulation were apparent at the wound base and small areas of granulation tissue were present at the wound edges, with improvement of the periwound area. The continued use of one or two of the Debrisoft Lolly to debride the cavity at each dressing change led to an increase of granulation tissue over a 4-week period. The wound size had previously remained the same and the patient had been unable to tolerate continuous compression, but at 4 weeks, only 40% slough remained and 60% granulation tissue was present. Initially, pain scores during debridement were reported at between 4 and 6 out of 10 on a VAS scale (Burckhardt and Jones, 2003). Following use of the Debrisoft Lolly, pain reduced immediately to 1 out of 10 and no lasting pain or discomfort was reported.

The Debrisoft Lolly was the perfect size to mechanically debride the wound bed of the cavity without causing discomfort or pain. Until Debrisoft Lolly was used, the wound was simply irrigated with cleaning fluid and packed with alginate dressings to aid autolytic debridement. The ability to insert the Debrisoft Lolly into the wound and make contact with the wound bed in the cavity aided the debridement process, and ensured wound debris and slough could be removed to encourage healing. Its handle enabled individual areas of tissue that required particular attention to be targeted precisely. The Debrisoft Lolly was also helpful to cleanse in the skin folds on the lower limb to ensure good overall skin care and hygiene.

After debridement

Due to difficulties with long-term concordance with compression, it has been difficult to obtain good outcome data regarding wound healing for this patient. However, use of the Debrisoft Lolly did have a positive effect on her overall wound management plan. Five months after initial presentation, treatment was completed and she was discharged from weekly clinic with a self-care management plan and follow-up reviews. In this case, Debrisoft Lolly allowed the team to establish a skin care regime around areas of skin folds that previously had been substantially more difficult to reach, and to debride the cavity wound much faster and more effectively than traditional methods would have allowed. The contribution of this new technology to the overall care package allowed a swift resolution to be achieved.

CONCLUSION

This case study encapsulates the complex management needs of patients with lymphoedema; for example, rebound from the maintenance phase of treatment as seen with this patient is common in this population.

Service provision for lymphoedema can be sporadic or non-existent; it often falls to tissue viability services or community nursing teams to provide for the complex physical, motivational and psychosocial needs of these patients. Lymphoedema management presents a growing resource issue in the community, since poor management can lead to much frustration on the part of both the patient and nurses. Long-term plans must reflect the need for rapid access to services if problems reoccur or establishment of simple rescue remedies in the home to ensure that hard gotten gains are not lost. As part of a long-term skin care regime, Debrisoft offers one such solution.

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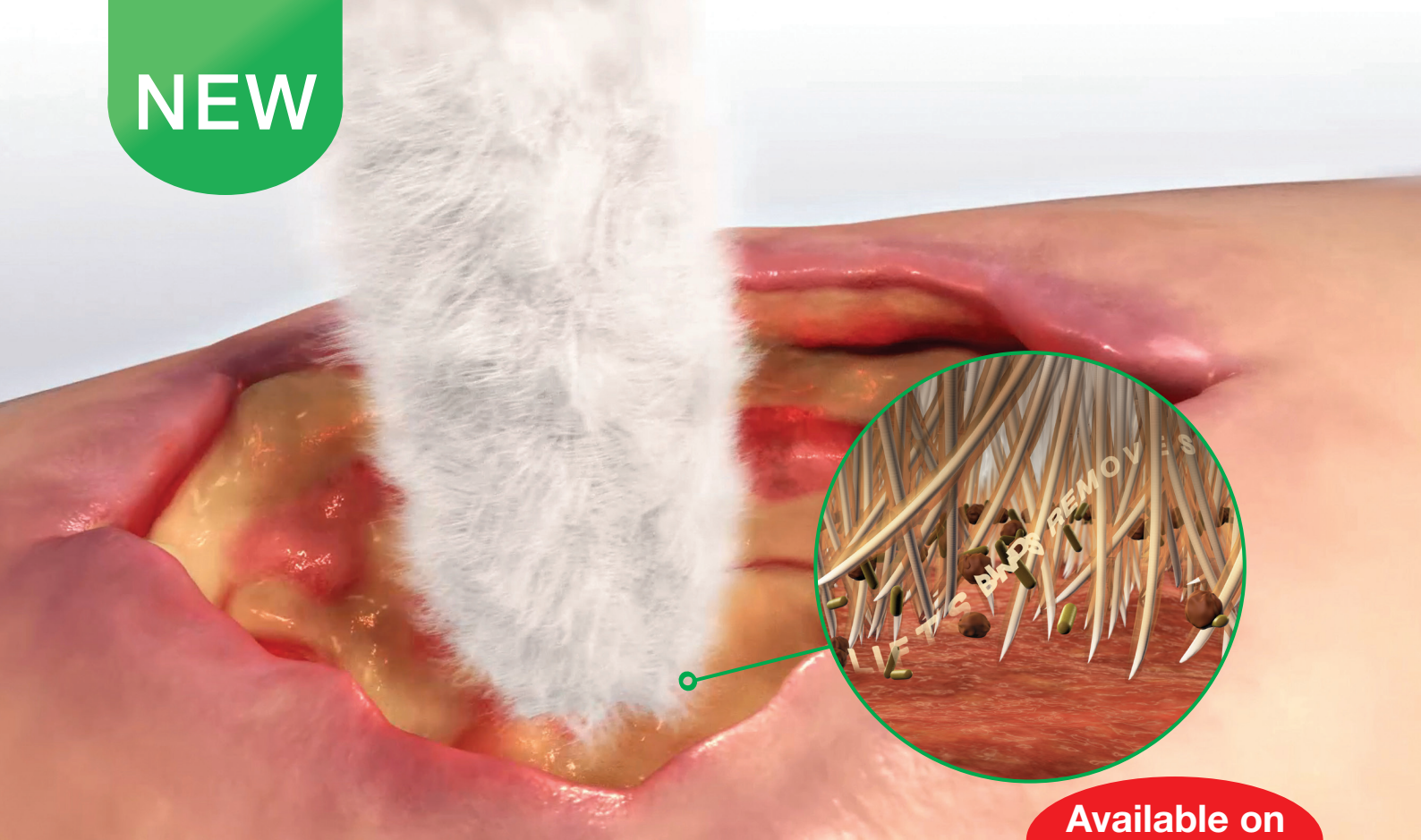
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