

Clinical efficacy of a new monofilament fibre-containing wound debridement product

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- **Objective:** To evaluate the wound debridement efficacy (that is, achievement of 100% granulation tissue on the wound bed) of a new monofilament fibre product (Debrisoft).
- **Method:** This multicentre, prospective, observational evaluation assessed the debridement efficacy, safety, patient comfort and user satisfaction of this new product. Time taken to perform the debridement procedure was also recorded. The new product was wetted with either saline or polihexanide and applied for 2–4 minutes, following which the usual dressing regimen was applied. Clinical outcome was scored by a trained clinician. Additionally, before and after photographs were assessed by one and the same clinician, who was blinded to the treatment given. The debridement outcomes achieved with the test product were compared with results obtained using other methods of debridement, both non-surgical and surgical, taken from an electronic database but using the same scoring systems as here.
- **Results:** Sixty patients with chronic wounds requiring debridement were recruited, of whom 57 were included in the analysis. Debridement was effective in 93.4% (142/152) of the sessions, and the product remained intact in 95.4% (145/152). The average time for each debridement session was 2.51 minutes, markedly less than for the current debridement methods at the evaluation centres. Visible debris and slough were successfully removed with the test product. Patients reported no pain during the procedure in 45% of cases and slight discomfort for a short duration (2.0 minutes on average) in 55% of cases.
- **Conclusion:** The results indicate the potential for this monofilament fibre product to replace several modes of debridement, based on its efficacy, short procedure, ease of use and patient comfort.
- **Conflict of interest:** The evaluation protocol was proposed and supported by Lohmann & Rauscher GmbH, who provided the evaluation products. MS and MA are employees of Lohmann & Rauscher. The other authors declare to have no relevant financial interest in the evaluation. Apart from input to the protocol, the sponsors had no role in the conduct of the study, such as data collection, analysis, or preparation, review, or approval of the manuscript.

monofilament fibre; wound debridement

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An important factor that is reported to delay healing is necrotic, devitalised or sloughy tissue in the wound bed.¹ Devitalised tissue acts as a physical barrier to healing and may impede normal matrix formation, angiogenesis, granulation and epidermal resurfacing.^{2–5} Moreover, the inflammatory response to devitalised tissue may mask or mimic the signs of infection.² Necrotic tissue is a source of nutrients for bacterial cells, which increases the risks of critical colonisation and infection.² Necrotic and devitalised tissues are associated with the overproduction of matrix metalloproteinases,⁶ which also have negative effects on healing.^{3,5,6}

The same principles apply to surgical and acute wounds healing by secondary intention when devitalised tissue is present.⁷ However, in the absence of the aetiological factors and comorbidities associated with chronic wounds, the healing of such wounds is largely uncomplicated.⁷

Debridement — the removal of devitalised tissue — is generally accepted as a necessary precondition for the formation of new tissue.^{1–3,8} It decreases bacterial load⁹ and stimulates and enhances wound healing.^{4,10} Although there is no definitive evidence that debridement plays a crucial role in effective wound closure, the concept is widely accepted as part of systematic wound management.^{1–3,8}

Current options for debridement include surgical, bio-surgical, enzymatic, mechanical and autolytic techniques.^{1–3,8} The choice of method depends on the general goals of patient care and the aetiology and nature of the wound and eschar.^{1–3,8} Other considerations include social and environmental factors, debridement frequency, access to skilled practitioners, complete patient assessment and cost.²

In recent years, the appropriateness and efficacy of different debridement methods has been keenly debated.^{1,2,4} What may be the best debridement method in principle might not be available or feasi-

ble to use in every setting; they all have their drawbacks. For instance, autolytic debridement can be slow or ineffective if biofilm is present;^{10,11} surgical debridement requires the skills of trained specialists and often necessitates anaesthesia, and so will not be possible in many community settings.

An effective method is required that can be handled by all wound care clinicians in all settings. It should be easy to perform, safe and, importantly, comfortable for patients. Debrisoft (Lohmann & Rauscher GmbH, Rengsdorf, DE) was developed to meet these requirements. The product contains monofilament polyester fibres, which are able to gently remove and integrate devitalised tissue (Fig 1).¹²

This multicentre, non-controlled, prospective evaluation aimed to assess the wound debridement efficacy, safety, tolerability and user satisfaction of a novel, monofilament fibre-containing product (Debrisoft) in daily wound debridement routines in a hospital and a community care setting.

Materials and method

Materials

Debrisoft (the test product) is made of monofilament polyester fibres (18 million fibres per 10x10cm). Its wound-contact side is soft and fleecy,

and is designed to mechanically remove slough and devitalised cells when wetted like a cloth and wiped gently over the wound bed. However, unlike a cloth, this debridement tool integrates devitalised tissue and debris within its structure.¹² The test product is mechanically strong and does not disintegrate when used for debridement.¹² Its fibres are chemically inert, stable and absorb fluids.¹²

The wetting solution used in the current evaluation was either sterile saline or polihexanide, depending on whether or not wounds were considered to be at risk of infection, a distinction that was made in accordance with local best practice. Polihexanide was used when clinicians observed slough and/or necrotic tissue on inspection.

Following debridement sessions, a wound dressing was applied. Dressing selection was at the discretion of the clinician, who chose between an alginate, a Hydrofiber and a foam dressing, again in accordance with the standard dressing regimen at the evaluation centres.

Method

During a 6-month period in 2010, patients were enrolled from 11 wound healing centres: five German (three outpatient clinics and two community

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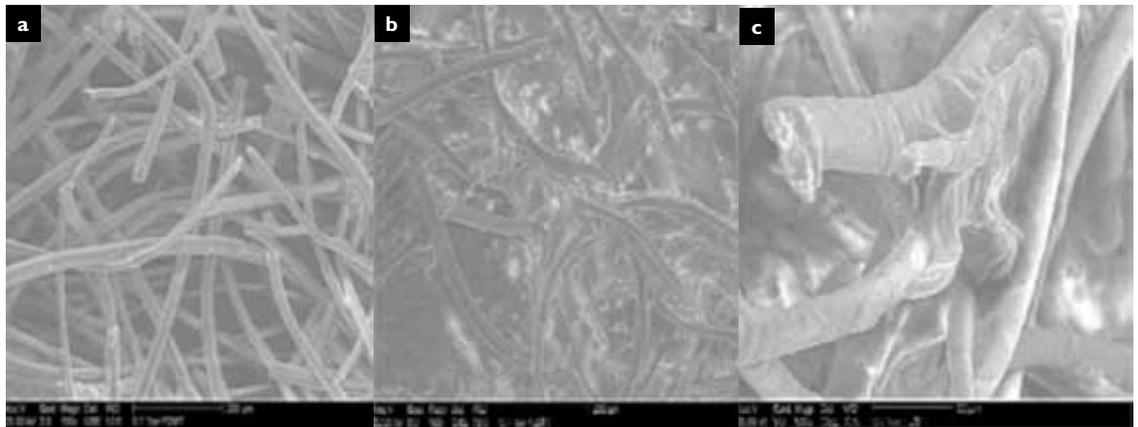


Fig 1. Electron microscope image of Debrisoft fibres: before treatment (a); after the session had been completed (b); after the session has been completed, showing incorporation of debris into the fibres (c)

clinics), four Italian (two outpatient clinics and two long-term care facilities) and two Austrian centres (outpatient clinics). All clinicians were instructed on how to use the product.

We aimed to include all wounds in need of debridement. Specific inclusion criteria were:

- Wounds coated with slough and/or yellow fibrinous tissue
- Wounds with both serous crusts and healthy tissue
- Wounds with hyperkeratotic debris and/or dried exudate on the periwound skin
- Wounds suspected of containing biofilm. At the centres included in this evaluation, clinicians are trained to recognise extracellular polymeric substance (EPS), a slimy, mucus-like substance that is associated with biofilm.¹¹

Exclusion criteria were:

- Symptoms and signs of systemic and/or spreading wound infection (including erythema and fever)⁷
- Severe pain (level 7 or higher on a 0–10 visual analogue scale, VAS) or hyperaesthesia in the wound area (as we reasoned it would be difficult to distinguish if pain was caused by the test product or was already present)
- Patients aged under 18 or over 85
- Allergy to any of the evaluation materials
- Patients who were pregnant or lactating.

The wetted test product was applied at the dressing change, which was done at 4-day intervals, for up to a total of three debridement sessions per wound during a 12-day (± 1 day) evaluation period. Clinicians took standardised digital photographs before and after debridement and timed the procedure with a stopwatch. If the patient reported a pain score >5 the procedure involving use of the test product was stopped and considered to have failed.

Ethical approval was not necessary as the evaluation used a CE-certified product for its intended use. All patients gave written and informed consent.

Primary outcome

- **Debridement efficacy** This was evaluated by comparing wound bed condition before and after debridement at day 0 (session 1), day 4 (± 1 day) (ses-

sion 2) and day 8 (± 1 day) (session 3). Clinicians were all trained on how to use both the test product and the scoring tool, which recorded: time needed for the debridement procedure (<2 minutes, 2–4 minutes, 5–7 minutes, >7 minutes); removal of visible debris/necrosis/slough from the wound bed (yes/no); was debris/necrosis/slough absorbed by test product (yes/no). The standardised digital photographs were assessed by a trained, independent clinician, who was blinded to treatment and the treatment centres.

Before and after each debridement session, clinicians classified the condition of the wound bed as one of three categories (A, B or C):

- **Class A** The wound bed is covered with slough and some black necrotic plaques, and the peri-wound skin is covered with scales, dried exudate and hyperkeratotic tissue
- **Class B** The wound bed is covered with slough (no black necrotic tissue) and there are some scales and dried exudate on the peri-wound skin
- **Class C** The peri-wound skin is clean, with $<20\%$ slough present in the wound bed.

The same scoring tool was used to assess the digital photographs.

Clinicians were asked to rate the test product against the other debridement methods used at the evaluation centres in terms of time required to debride, its ease of use and its efficacy.

Secondary outcomes

- **Safety** This was evaluated by noting adverse events in terms of the Medical Device Directive (MDD) (Council Directive 93/42/EEC) and according to national legislation (MPG/D, ÖMG/A) definitions. In addition, the structural integrity of the test product was scored — following debridement — by the clinician who performed the procedure and by photographic assessment by a trained clinician, who was blinded to the centre where the treatment was given. Both clinicians used the following tool: material intact after debridement? (yes/no); change in shape/structure/shedding of fibres/other? (yes/no).
- **Tolerability** This was assessed by both clinicians

and patients. Following each debridement session, patients completed a questionnaire that assessed: discomfort (yes/no); pressure (yes/no); burning sensation (yes/no); pain (VAS); bleeding (yes/no); irritation of the periwound skin (yes/no); swelling (yes/no); redness (yes/no) and adverse reactions (yes/no). Clinicians also assessed tolerability, using a tool that scored comfort during the procedure, pain during the procedure and periwound skin irritation on a 5-point Likert scale (where 1=completely agree, 5=completely disagree).

• **User satisfaction** Following each debridement session, the clinician that had used the test product completed a questionnaire. The product's convenience and efficacy were compared with the other available debridement options, such as surgical and autolytic techniques, using a 6-point scale (excellent/very good/good/poor/very poor/inadequate). At the end of the evaluation period, the user's overall degree of satisfaction with the test product was also evaluated, using the same 6-point scoring system as above. In addition, the practitioners were asked: 'will you use the test product again after this evaluation?' and 'will you inform your colleagues about this product?'. These questions were scored

using a separate 6-point scoring system: most certainly/certainly/probably/don't know/probably not/certainly not).

Statistical analysis

An analysis of variance (ANOVA) was used to compare the different modes of debridement. Confidence intervals were set at 95% and results were considered significant where $p \leq 0.05$. All cases that were withdrawn were regarded as unsuccessful in terms of treatment and all variables. Other data are descriptive.

Results

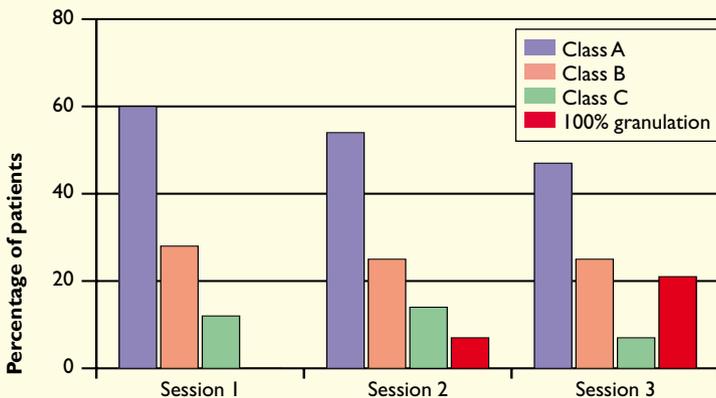
Sixty patients with acute and chronic wounds were enrolled across the 11 centres. Fifty-seven patients were included in the analysis, of whom 54 had one wound and three had two wounds. Three patients were lost to follow-up and did not complete the evaluation period. A total of 164 visits were documented by the 57 clinicians (20 physicians and 37 nurses) and a total of 152 test-product procedures were performed. Saline was used as a wetting agent in 30% ($n=17$) of cases and polihexanide in 70% ($n=40$).

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Fig 2. Changes reported in the condition of the wound bed (n=57)



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Debridement efficacy

A significant shift in wound bed condition was found after three debridement sessions with the test product (Fig 2). After one session, 60% of wounds (n=34) were identified as class A, 28% (n=16) as class B and 12% (n=7) class C. After three sessions, 47% (n=27) were class A, 25% (n=14) class B, 7% (n=4) class C and 21% (n=12) had re-epithelialised.

Clinicians reported that the test product removed debris, slough, dried exudate and crusts efficiently, without damaging the fragile periwound skin. Photographic analysis confirmed this.

The mean duration of debridement with the test product was 2.68 minutes at session 1, 2.50 minutes at session 2 and 2.31 minutes at session 3. The overall mean duration was 2.51 minutes per procedure.

These results were compared with retrospective data from the same centres at which the evaluation was performed. Local best practice at these centres involves the routine collection of electronic data regarding treatment duration, so researchers were able to search an electronic database and compare the time taken for debridement with the test product versus other methods that have previously been used. These methods included surgical debridement, ultrasound, sharp spoon debridement, autolytic debridement with hydrogel and mechanical debridement with wet gauze.

Debridement with the centres’ best practice method (as decided by local clinicians) — autolytic debridement with hydrogel — took significantly longer (p<0.05) than with the test product. This also was the case when comparing the test product with both mechanical wet gauze debridement (p<0.05) and surgical debridement (p<0.05) (Table 1).

Clinicians reported that, when using the test product, visible debris and slough were removed from the wound in 93.4% (142/152) of procedures.

Table 1. Duration of the debridement procedure for different modalities

Type of debridement	Mean duration (minutes)
Test product	2.51 (±0.57; 1.8–3.1)
Autolytic with hydrogel*	7 (±2.08; 8.6–6.4)
Mechanical with wet gauze	5 (±1.60; 6.2–4.5)
Surgical	9 (±2.64; 10.5–7.4)

*Centres’ best practice method: Results are given as SD and range

Safety

The test product was observed to remain intact in 95.4% (145/152) of debridement sessions. Its shape changed slightly in 3.3% (5/152) of sessions, and in 1.3% (2/152) of cases a small number of fibres were loosened. Change in shape was not found to influence debridement efficacy, and remnant fibres were easily washed away with rinsing solution (either saline or polihexanide), as instructed.

No serious adverse events (SAE) or adverse events (AE) were reported during the evaluation. Furthermore, no incidents were reported within the definition of the MDD Directive 93/42/EEC. The product was found to be safe, bearing no risk for patients.

Tolerability

During the debridement procedure 45% (n=26) of patients reported that they experienced no pain, 50.4% (n=29) reported slight discomfort of short duration (mean: 2 minutes) and 4.6% (n=2) reported moderate pain of short duration (mean: 2.4 minutes). When patients were asked about irritation, allergies and pain after the procedure, 98.2% (n=56) reported that they experienced no side effects. No adverse events were reported.

User satisfaction

The convenience and ease of use of the test product was rated ‘very good’ by its users, with a mean score of 2.29 (±0.57) on a 6-point scale (1=excellent, 2=very good, 3=good, 4=poor, 5=very poor, 6=inadequate) (Fig 3). A similar result was found when retrospectively comparing the test product with mechanical debridement with wet gauze, which had a mean score of 2.49 (± 0.67). This comparison was possible due to the routine collection of large amounts of electronic data at the evaluation centres, which routinely used the same 6-point scoring tool.

Test product users rated its debridement efficacy as ‘very good’, giving a mean score of 1.98 (±0.68). Autolytic debridement with hydrogel (local best practice) scored 2.54 (±0.72) (very good/good) and the mean efficacy score for all the debridement options available at the evaluation centres (with the exception of the test product) was 2.62 (±0.47) (good).

At the evaluation end, the test product achieved a mean overall user satisfaction score of 2.73 (\pm 0.59) (good).

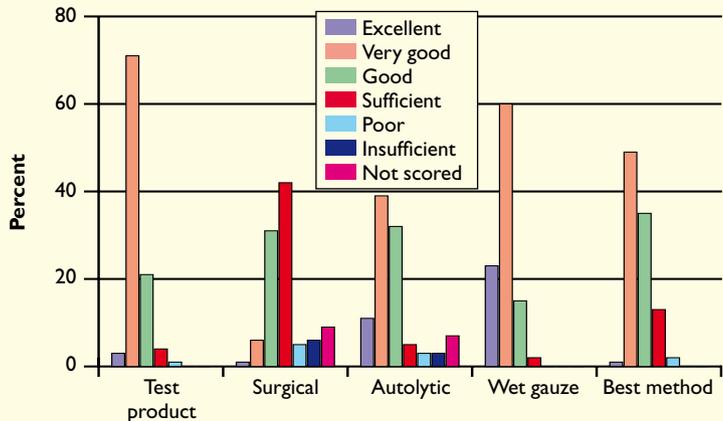
Discussion

The present evaluation shows that effective and fast debridement can be achieved in less than 3 minutes when applying the test product to various wound types. With an average duration of 2.51 minutes per session, this method is significantly less time-consuming than the best debridement practice offered at the centres that participated (autolytic debridement with hydrogel), as well as both mechanical (wet gauze) and surgical (scalpel or a sharp spoon) debridement techniques.

In addition, the average time to complete debridement — where the wound bed is covered with 100% granulation tissue, with no slough or necrosis — is about 20 days with enzymes or moist wound healing dressings, such as hydrogel.^{2-5,8} The test product was shown to be faster, with 77% (n=44) achieving complete debridement by 12 days.

The test product is wetted before use with saline or a wound rinsing solution such as polihexanide. Local guidelines at the participating centres advo-

Fig 3. The test product versus other methods for debridement



cate the use of an antimicrobial solution where wounds are considered to be at risk of infection. However, in terms of impact on debridement efficacy, it seems unlikely that the choice of wetting solution will have much effect as the duration of

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Fig 4. Condition of the wound bed before treatment (a); after one debridement session (b); appearance of the monofilament product of the debridement session had been completed (c)



Fig 5. Condition of the wound before treatment (a); after one debridement session (b)

contact is so brief (less than 3 minutes). The ‘wet-to-dry phase’ — a wound debridement practice previously described by Kammerlander et al.,² which involves leaving antimicrobial solutions in contact with the wound bed — has shown that to be effective, this contact should last from 20 minutes to an hour. Hence, we do not consider the rinsing solution used in this evaluation to be a significant confounding factor.

One of the most important features of any new debridement product is its clinical efficacy. In addition to this, safe performance, good patient tolerability and high user acceptance are all necessary characteristics for a debridement tool.

This evaluation shows that the test product possesses all of these qualities. When rating its debridement efficacy, users scored it as ‘very good’. It was shown to be very safe, with no reported adverse events, and it was very well tolerated — most patients experienced either no discomfort or only slight discomfort during the procedure, and more than 97% experienced no discomfort directly after the procedure. Clinical examples are given in Figs 4 and 5.

While other debridement methods may be preferred for deep wounds (the manufacturer’s instructions recommend the test product be used for debriding superficial wounds and periwound skin), our results indicate that the test product has the potential to replace several modes of debridement, such as surgical and autolytic debridement, due to its efficacy, short duration, ease of use and high level of patient comfort.

Limitations

As case series are descriptions of practice and do not have comparators or control groups, cause and effect relationships cannot be inferred, so we are unable to do so here. Although it is generally accepted that fast and effective debridement of devitalised tissue supports wound healing, it is beyond the scope of this evaluation to draw any conclusions regarding any possible impact of the test product on wound healing. This aspect of its use will be addressed in future studies that are currently planned.

Conclusion

This evaluation demonstrates that Debrisoft has good debridement properties, removing debris and slough from the wound bed fast and effectively. The product was easy to use when compared with other methods of debridement, and it can be easily and safely used by non-specialist nurses in both hospital and community settings. The product showed good tolerability and a high level of user satisfaction. Considering its efficacy, ease of use, short duration of use and good patient comfort, the product has the potential to replace some other debridement modalities that are currently used in some settings.

The results of this evaluation demonstrate that this product is an efficient and time-saving device for debridement and wound bed preparation in different types of wounds. It was shown to be safe and well tolerated by patients, and was rated ‘very good’ or ‘good’ in terms of ease of use, convenience and overall user satisfaction. ■