

The wound debrider: a new monofilament fibre technology

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The problem of non-healing chronic wounds can be best summarized by the statement that the normal cascade of wound healing has been disrupted. In order to start the process of regular wound healing, the first step must be sufficient debridement (wound bed preparation) essential to overcome the stagnation of the chronic wound (European Wound Management Association (EWMA), 2004; Kammerlander et al, 2005; Ovington and Schultz, 2005). While the process of cleansing facilitates the removal of loose metabolic wastes from the surface of the wound, debridement aims to remove devitalized (necrotic) or contaminated tissue from the wound and the surrounding area until healthy tissue can be seen. The liberation process of newly developed healthy tissues enables granulation and epithelialization from the liberated healthy sources.

Various debridement options are available:

- Mechanical debridement, comprising hand-based rubbing with a woven gauze (e.g. Ulcer Cleansing System™, Welcare Industries SpA, Orvieto, Italy)
- The technique of wet-to-dry dressing
- Absorptive debridement with dextranomer granules or activated charcoal
- Chemical cleansing by means of enzymes or mild, acidic preparations
- Ultrasound or hydro-based technical devices
- Biodebridement with maggots
- Surgical debridement (EWMA, 2004; Shai and Maibach, 2004; Bates-Jones and Apeles, 2007; Rodeheaver and Ratliff, 2007).

A critical look at these options exhibit their potentials but also their limitations. Standard mechanical debridement is performed during every dressing change. For this, woven gauze is first hydrated with a physiological saline solution or antiseptic and then put on the wound. After 5–10 minutes the health professional rubs the swab or gauze over the wound to remove loose foreign material and debris. This procedure is often painful with limited cleansing effectiveness and is not recommended for debridement. This also applies to the pre-moisturized wash wipe (Easyderm®, Welcare Industries SpA, Orvieto, Italy), which additionally harbours ingredients with the potency to induce allergies and sensitization. Moreover, this option is new and, until now, data for efficacy and performance are limited.

As early as 1989, Kammerlander et al (2005) reported a new wet-to-dry dressing change procedure for debridement. Modifications have recently been reported by Wiech (2007). Notwithstanding the fact that this technique is often painful,

Abstract

Debridement is a basic necessity to induce the functional process of tissue repair, especially in chronic wounds. In this pilot study the authors used a new debrider technology with specific monofilament fibres in a unique texture to evaluate its efficacy, safety and tolerability. In eleven patients, exhibiting all types of wound-associated debris (biofilms, slough, necrotic crusts and hyperkeratotic plaques), the debrider, wetted with physiological solution, was wiped without specific force over the wound for about 2–4 minutes. This led to removal of almost all debris leaving healthy granulation tissue intact, including small epithelialized islands of vital tissue. The procedure was without pain and adverse events. Scanning electron microscopic analyses identified the majority of the removed debris tightly packed within the monofilament texture. A surgeon who blindly assessed pictures taken before and after the debridement categorized all except one wound without the need for surgical debridement and ranked all the debridement results with the new debrider as 'very good' (best category). This formulates the basic concept that the new debrider-based technology is easy, fast, highly efficient, well tolerated and cost effective.

Key words: Chronic wound ■ Debridement ■ Monofilament fibres ■ Debridement technology ■ Electron microscopic analyses

it is also not selective in destroying vital tissues. Jones and Fennie (2007) showed that the wet-to-dry dressing change technique for patients with pressure ulcers led to healing in only 8.3% of patients within 6 months. There is now a consensus that wet-to-dry dressing change techniques are a more or less obsolete option for debridement (Niezgoda and Mendez-Eastman, 2006; Ramundo, 2007; Tenenhaus et al, 2007; Weir et al, 2007).

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Absorptive and chemical debridement needs specific material or solutions. Mosher et al (1999) reported on the clinical efficacy of four debridement alternatives (collagenase, fibrinolysin, autolysis and wet-to-dry dressings). This was not a clinical study, but based on a non-experimental estimation algorithm to define the likelihood of achieving a clean wound bed after 2 weeks. Collagenase was the best option with a chance of 70% debridement, yet led to loss of time (at least 2 weeks) and the need for health professionals with special expertise. Technical devices such as ultrasound or high-pressure hydro-based devices and especially conventional surgery provide the opportunity to perform adequate-to-high standard debridements. Their major constraints are limited accessibility because of specific requirements (e.g. infrastructure, specialized physicians and nurses) and the high costs. Also, the force of these procedures often results in the additional removal of small islands of healthy tissue, thereby compromising healing.

A precise look at the standard hand-based debridement process with a gauze between dressing changes shows that this procedure, though seemingly exhibiting some cost and handling benefits, mainly suffers from an inadequate level of efficacy and often tolerability (especially pain). Taking this into account, there was a clear need to further improve the existing technology for a faster, easier and especially more efficient debridement process. With this in mind, a hand-based debrider has been developed, consisting of a new monofilament fibre technology of a highly specific texture with the potency to actively loosen and further bind debris just by gently wiping the wound surface. After a series of technical and product property tests, this prospective, blindly assessed pilot study was designed and performed to generate the primary proof of concept. Within this pilot study, practicability and handling, clinical

(i.e. debridement) efficacy, safety and tolerability have been evaluated. To better understand the new technology and its mode of action, scanning electron microscopic analyses were performed on the debrider after the debridement process and viewed against the unused product.

Materials and methods

The debrider with monofilament fibres

Based on the clinical goals, a new type of artificial monofilament fibre technology, with specifically woven fibres, was developed. Material tests then proved the mechanical strength of the debrider in not shedding any fibres while in contact with the surface. The fibres themselves are chemically inert, create less linting, do not absorb any fluid during use and remain stable. This new, specially woven debrider (Debrisoft®, Lohmann and Rauscher, Rengsdorf, Germany) was used in the present study for the debridement of all wound types.

Patients and methods

A total of eleven patients (patients characteristics are listed in *Table 1*) from two different hospitals suffering from chronic wounds of all medical aetiologies located at the lower extremities were included in the pilot study. The primary inclusion criterion was defined as the need for debridement, regardless of the nature of the wounds. The patients exhibited three typical clinical pictures: locally infected wounds with biofilms and high exudate including slough (three patients); wounds with serotic, partly necrotic crusts (three patients); and wounds with serotic, partly necrotic crusts and considerable hyperkeratotic debris as well as dry, plaque-like anhydrous exudate over the whole lower extremity (five patients).

The primary objective questioned the clinical efficacy of debridement in the form of a health professional's global assessment and a blind efficacy ranking by a surgeon. Secondary objectives looked at potential pain during the procedure according to the patient's statement, as well as the safety and tolerability of the product and procedure. Tolerability and safety were delineated by patient feedback immediately after the use of the debrider and by a general assessment by the health professional. Initially the debrider was hydrated with a physiological saline solution and then used by wiping the wound as well as the whole lower extremity for about 2–4 minutes, notably without excess pressure. The primary endpoint was defined as clinical result after one use of the debrider.

Blinded assessment of the method by a surgeon

At the end of the study the authors performed a blinded assessment of the debrider-based debridement procedure by a surgeon who was not involved in any other part of the study. Having seen the pictures of nine patients taken before and after the procedure, he was asked the following:

- To define the quality of the new debridement technique in comparison with all existing non-surgical debridement modalities (ranking from 1–5; 1 = very good, 2 = good, 3 = acceptable, 4 = poor, 5 = very poor)

Table 1. Characteristics of the patients included in the new debridement technology pilot study

Patient	Gender	Year of birth	Diagnosis	Comorbidities
1	Female	1922	Mixed ulcer	Methicillin-resistant Staphylococcus aureus colonized
2	Male	1945	Venous ulcer	Cellulitis
3	Male	1940	Mixed ulcer	NYHA III
4	Male	1958	Mixed ulcer	Diabetes, pulmonary hypertension, chronic obstructive pulmonary disease
5	Female	1922	Venous ulcer	Cellulitis
6	Male	1950	Venous ulcer	Dermatitis, diabetes
7	Female	1924	Arterial ulcer	NYHA III with post-myocardial infarction
8	Female	1931	Venous ulcer	Cellulitis
9	Male	1931	Diabetic ulcer	Diabetes, NYHA II
10	Female	1928	Mixed ulcer	Dermatitis, NYHA III, renal insufficiency
11	Male	1941	Mixed ulcer	None

NYHA=New York Heart Association class

- Whether there is an indication for surgical debridement (yes/no)
- If yes, to define the quality of the new debridement technique in comparison with surgical debridement (ranking from 1–5; 1 = much better than surgery, 2 = better than surgery, 3 = equal to surgery, 4 = less good than surgery, 5 = worse than surgery).

Scanning electron microscopic analyses

Analyses using the scanning electron microscope in the environmental mode made it possible to analyse non-metallic probes without coating. Small pieces (1 cm²) of the unused and used debrider were cut out and brought into the vacuum chamber. Analyses comprised multiple series of pictures with a magnification ranging from 50–2500x.

Results

Clinical testing of the new debrider in different wound bed situations

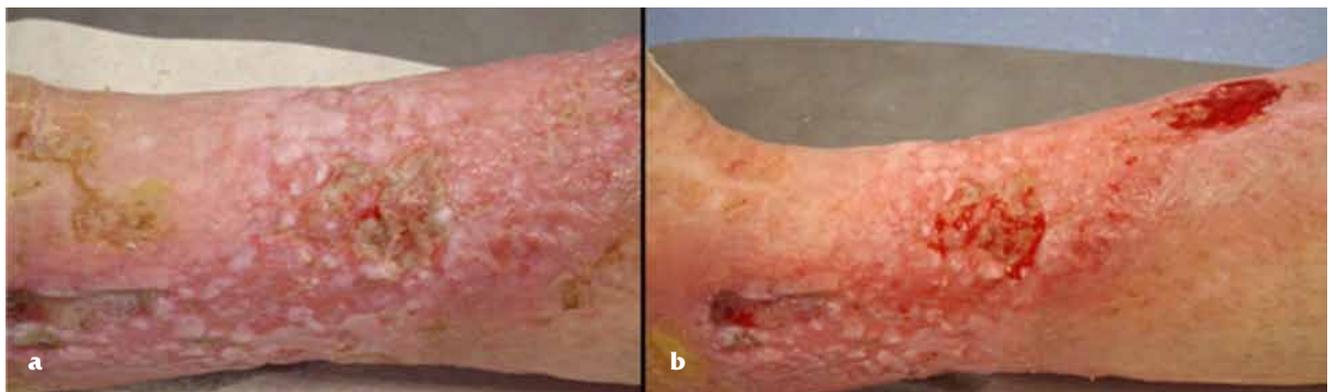
Exudating, seropurulent wounds

In exudating, seropurulent wounds with highly viscous yellow slough indicative of local infection in the form of a bacterial biofilm (Figure 1a), the debrider was able to remove most of these coatings and led to vital tissue (Figure 1b) after only a single use. Most of the material removed by the debridement became attached to the debrider.

Figure 1. (a) Exudating, seropurulent wound with highly viscous yellow slough indicative of local infection and a bacterial biofilm (patient 1); (b) The debrider removes the vast majority of these coatings and leads to vital tissue.



Figure 2. (a) Dry wound specifically suffering from serocrusts between the new vital granulation and epithelialization tissue (patient 2); (b) The debrider selectively removes the crusts without affecting the new healthy tissue.



Dry wounds with serocrusts

In dry wounds specifically suffering from serocrusts between the new vital granulation and epithelialization tissue (Figure 2a), the debrider was able to specifically remove the crusts without affecting the new healthy tissue (Figure 2b). Notably, even the smallest islands of healthy tissue were not disturbed by the debridement process.

Wounds with necrotic layers, hyperkeratotic debris and crusts of dried exudate

In these situations the debrider not only removed the necrotic layers after a single use, but also revealed skin of the lower extremity free from all the waste, showing an almost normal epidermis (Figures 3a,b). Consistent with the two situations mentioned above, small islands of granulation and epithelialization tissue were spared from the debridement process.

General assessment of the debridement

The healthcare professional's global assessment revealed that the use of the debrider was easy, fast and efficient. Without any pre-debridement pain medication, neither locally nor systemically, patients did not report any adverse symptoms during the debridement process, in particular pain. By using both a gauze and the debrider on one patient (patient 7), the result shows the overall higher efficiency of the

debrider (Figure 4a,b,c). In addition, a synergistic look at the procedure shows that for each wound situation in different patients the new debridement technique leads to similar, i.e. standardized, results.

Healthcare professionals did not need specific instruction to successfully perform the debridement. After the debridement no adverse events or adverse reactions of the treated wounds could be detected; the procedure was safe and well tolerated by the patients. After the debridement, the structure of the debrider was unchanged and, in the case of slough, the debrider harboured almost all the removed material (Figure 5a), and in the case of crusts, large parts of the removed material.

Blinded assessment of the new debridement technique by a surgeon

At the end of the study, a surgeon highly experienced in the field of wound care blindly assessed the quality of the new debridement technique by analysing the pictures taken before and after debridement. From the pictures taken before the debridement he defined all wounds (except one) as having no indication for surgical debridement. Looking at the pictures taken after the debridement procedure, he ranked the debridement results of all wounds with no indication for surgical debridement into the best category (1 = very good). The debridement result of the wound formerly defined as requiring surgical debridement was evaluated as equally effective to surgery.

Scanning electron microscopic study

The 150x magnification of the unused debrider delineates the specifically woven network of round, i.e. blunt, artificial fibres of a new form and texture (Figure 5b). The same magnification of a used debrider shows only the remaining top of the fibres in a loose connection, as the major parts are obscured by the removed material attached into the texture of the debrider (Figure 5c), or fibres are fixed together, like adhesive tapes, by the removed material (Figure 6a,b). These pictures show the high activity and effectiveness of the overall new fibre technology, not only by pulling debris and necrotic material into the debrider but also by holding it within the texture.

Discussion

There is full consensus in the literature that debridement of chronic wounds up to the level of healthy tissue represents the first necessary step to induce the healing process (EWMA, 2004; Kammerlander et al, 2005; Ovington and Schultz, 2005; Bates-Jones and Apeles, 2007; Rodeheaver and Ratliff, 2007). In this prospective, blindly assessed pilot study the authors demonstrated that a new, specifically woven debrider painlessly debrides chronic wounds in a fast way, with high clinical efficacy, comparable outcomes and no adverse events. In line with the ranking results given by health professionals who used the debrider, the surgeon ranking the wound debridement in a blinded manner marked the result of the new debrider technology as 'very good' (best category). Additionally, in the case of

Figure 3. (a) Small plaque of necrotic material together with hyperkeratotic debris and crusts of dried exudates over large parts of the lower extremity (patient 3); (b) The debrider not only removes the necrotic layer, but also releases the skin of the lower extremity from all the metabolic waste, showing an almost normal epidermis



Figure 4. (a) Wound bed with hyperkeratotic debris and crusts of dried exudate (patient 7); (b) Direct comparison of using a gauze on the wound and (c) the debrider



a patient's wound classified for a clinical need for surgical debridement, the result of the new debridement technology was seen as equal to the requested surgical procedure.

In treating chronic wounds, the major objective is to lead the wound back to an acute status where a number of biochemical interactions and cascades fulfil the process of healing, such as coagulation, angiogenesis, remodelling of the wound, granulation and epithelialization (Ramundo, 2007). In this context, it is important to mention that the debridement with the new debrider also liberates small islands of vital granulation and epithelialization tissues by leaving them intact. After the process of debridement these small islands of healthy tissue are areas from which epithelial cells can migrate. From what is known about the process of wound healing, this is an additional positive factor to overcome stagnation in the chronic wound (Ramundo, 2007).

Finally, seven of the patients had lower extremities that were coated with thick, hyperkeratotic, scaly debris together with plaque similar to dried exudate crusts in the peri-wound area. After use of the debrider the authors were able to restore the normal but irritated skin of the lower extremity completely. To the best of the authors' knowledge the removal of such hyperkeratotic, scaly debris as well as dried plaques without any damage to the underlying irritated normal tissues cannot be achieved with any of the present debriding modalities. By using topical medication

or emollients following the new debridement technique it should be possible to further enhance the restoration of the healthy skin surrounding the ulcers.

Technical solutions such as hydro- or ultrasound-based treatments including surgical debridement are able to perform adequate or high-standard debridement. However, the force of these techniques usually also removes small parts of healthy tissue together with the necrotic material. Additionally, the problem of accessibility (especially in non-surgical units) and the costs for the infrastructure as well as the specialized physician often limits the fast access and broad use of these treatment options.

The new debrider is used like a woven gauze or other scrubbing devices, and is flexible when combined with saline solutions of different concentration, antiseptics or other wound-cleansing solutions (Rodeheaver and Ratliff, 2007; Weir et al, 2007). Yet its specific nature makes the debrider not only as safe as the standard gauze but also a highly effective and tolerable debridement tool, notably without any biological or physicochemical additives (Bertone et al, 2008; Cassino et al, 2009). As the debrider and the standard woven gauze are used for the same procedure, i.e. to rub the wound surface without excessive pressure, the reason for the extensive difference in their efficacy, painlessness and time saving is of interest. Scanning electron microscopic analyses of the used debrider with its monofilament fibre texture revealed that the debrider is packed with the removed

Figure 5. (a) The debris that has been removed by the debridement of an exudating, seropurulent wound with highly viscous yellow slough is attached to the surface of the debrider; (b) Scanning electron microscope analyses (150x magnification) of the unused debrider delineates a woven network of round, artificial fibres in a specific texture and a loose connection; (c) The 150x magnification of a used debrider shows the attached debris to the fibres of the debrider.

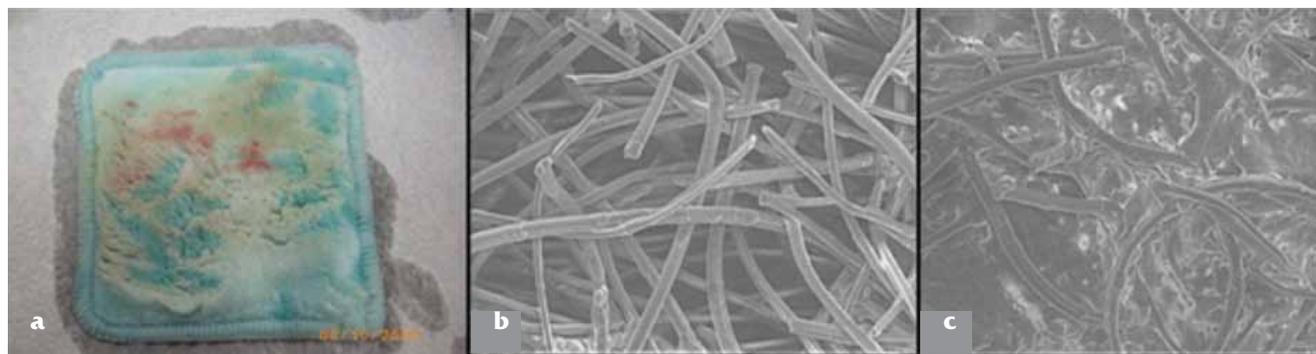
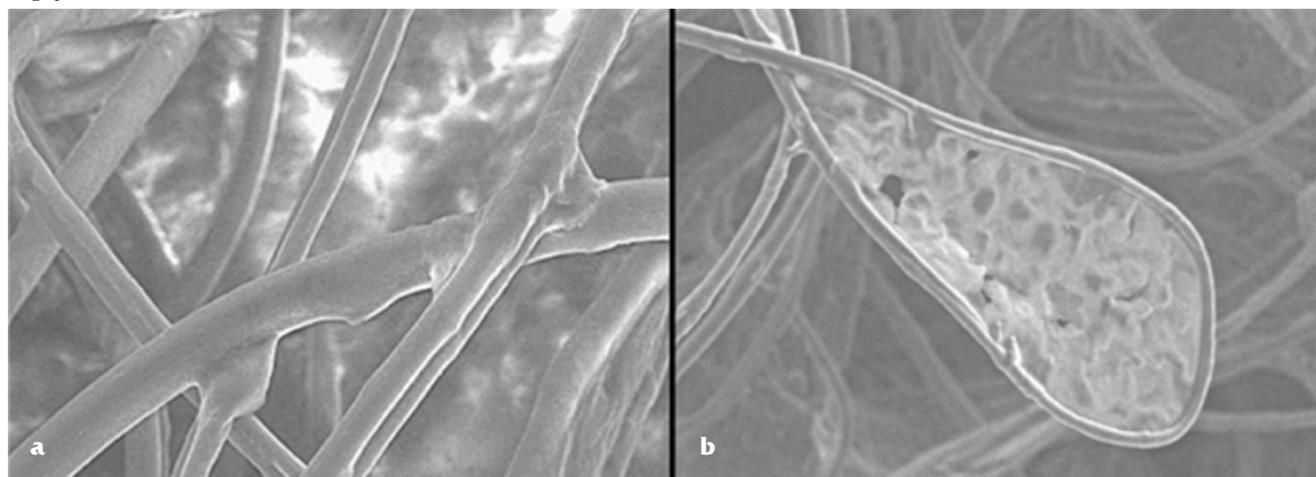


Figure 6. Scanning electron microscopic analyses of the used debrider shows the fibres fixed together by the removed material (a) x350 magnification (b) x150 magnification.



material. Higher magnifications show that the removed material sticks the fibres together like an adhesive band, creating stable bonds between them. Thus, it may be that the 'rub' procedure produces some kind of 'electrostatic field' within the debrider around the fibres, which strongly attracts the debris, metabolic waste and necrotic tissue. This specific texture of the debrider provides an adherence force that holds the removed material into the wipe, a concept just recently shown for other polymer fibres (Aksak et al, 2007). The high potency of monofilament fibre textiles, such as mops, to remove material or even bacteria has also been shown for the disinfection of surfaces. In one study (Rutala et al, 2007) the monofilament fibre system demonstrated superior microbial removal compared with cotton string mops when used with a detergent cleaner. This might be the reason why such a simple procedure of rubbing and washing but performed with new monofilament fibre technology creates superior debridement results.

Further clinical studies are needed to examine the clinical position of the new debrider. However, on the basis of the authors' pilot study, it seems unnecessary to use the debrider during every dressing change, but only use once or twice a week (when needed). Additionally, the fact that the debrider offers a simple, safe and easy-to-access debridement technique enables its broad use not only by specialized physicians but also by all health professionals.

Based on the beneficial efficacy/safety/tolerability profile as well as good economy and rapid treatment, this new modality might be used as a firstline device for all wounds with a necessity to debride. Such a process should then be followed by adequate dressings according to the rules of modern moist wound healing. From what is known, the effectiveness of this debridement procedure should also shorten the overall healing process. The debrider also

appears to be able to clinically handle locally infected wounds by removing the bacteria, seropurulent secretions and the bacterial biofilm. Following these considerations, the use of expensive procedures such as surgical debridement or systemic antibiotic treatments may be reduced. This would not only increase the safety and efficacy profile of what is done in the field of chronic wound healing, but also save substantial costs.

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Conflicts of interest

This work was supported by a personal grant for Robert Strohal. Gilbert Haemmerle was involved as investigator in a multi-centre clinical study funded by Lohmann and Rauscher. Heinz Duelli reports no potential conflict of interest. Martin Abel works as head of the Medical and Regulatory Affairs at Lohmann and Rauscher, Rengsdorf, Germany. Robert Strohal is the principle inventor of the debrider, holding shared patent rights for this new technology. In addition, he works as a free consultant for Lohmann and Rauscher, was involved as principle investigator in a clinical study funded by Lohmann and Rauscher and serves as speaker in the global speakers' bureau of Lohmann and Rauscher.

KEY POINTS

- Debridement is a basic necessity to induce or allow the functional process of tissue repair, especially in chronic wounds
- In this prospective, blindly assessed pilot study the authors used a new debrider technology with specific monofilament fibres in a unique texture to evaluate its efficacy, safety and tolerability
- The new debrider led to the removal of almost all debris, but importantly left healthy granulation tissue including small epithelialized islands of vital tissues intact
- Patients did not feel any adverse symptoms during the debridement process, in particular no pain, and the health professional's global assessment revealed that the use of the debrider was easy, fast and efficient.
- A surgeon blindly assessed all pictures taken before treatment, categorized all except one wound without the need for surgical debridement and ranked all the debridement results with the new debrider as 'very good' and the one wound formerly classified as needing surgical debridement as 'equal to surgical debridement'
- The new debrider with its specific monofilament fibres offers a simple, safe and easy-to-access debridement technique and enables a broad use; it is anticipated that the use of the new debrider could save substantial costs

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