Improving the monofilament-fibre pad to debride wounds

KEY WORDS
- Mechanical debridement
- Product evaluation
- User satisfaction
- Wound care

Objective: In clinical studies, mechanical wound cleansing and debridement using a monofilament fibre product has been shown to be effective, and pain and trauma-free. **Methods:** Two new monofilament fibre devices, both refinements of the existing Debrisoft pad, were created. The first added a pocket grip, and the second increased the size to 13 × 20 cm and retained the pocket grip. They were assessed in two acceptance evaluations. **Results:** The pads were assessed by 65 clinicians, split into two evaluations. The two new products with pocket grip was easy to handle, with a very good grip and hold. They fitted hands well, could be handled safely and were controlled and intuitive. **Conclusions:** The first product with the hand pocket met the design criteria (flexibility and stretchability of the pocket, softness and grip/hold, and easy handling). The larger pad met the design criteria regarding the fit of the pocket, safe and controlled use, and intuitive handling.

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Effective debridement is an essential part in the treatment of complex wounds. It expedites healing and can aid accurate categorisation of pressure ulcers (Leaper et al, 2012; Dowsett et al, 2013).

Historically, mechanical debridement has been associated with the use of wet-to-dry gauze, which removes devitalised tissue in a nondiscriminatory manner, resulting in the risk of significant pain and damage to healthy tissue (Sibbald et al, 2011). Clinical studies have shown mechanical wound cleansing and debridement using a monofilament polyester fibre product to be effective, pain and trauma-free (Bahr et al, 2011; Stephen-Haynes and Callaghan, 2012; Iblasi, 2018; Schultz et al, 2018).

Monofilament debridement products have been further developed to improve usability, patient comfort and user satisfaction. The success of these recent modifications was assessed in two separate acceptance trials.

MATERIALS AND METHODS

The two devices are a development of the existing CE-marked monofilament Debrisoft® debridement pad (Lohmann & Rauscher).

The first new product is 10 × 10 cm, with a pocket grip and a label added to the existing product – the "new" Debrisoft Pad *(Figure 1)*. Indications for use have been extended and the product is now ethylene oxide sterilised. The second product, Debrisoft Pad (13 × 20 cm), had the pocket grip and the pad size increased *(Figure 2)*.

The two new products are used in a similar way to the existing Debrisoft pad — for absorbing exudate, debris and keratotic material during debridement (Bahr et al, 2011; Haemmerle et al, 2011; Strohal et al, 2013; Meads et al, 2015). The existing Debrisoft pad can be used for debridement of acute, complex (i.e. diabetic foot ulcers, arterial and venous ulcers), superficial wounds (i.e burns and scalds), and for deep wounds, such as surgical wounds healing by secondary intention (Haemmerle et al, 2011; Meads et al, 2015).

Design of the acceptance trials

The two newly developed products have been evaluated in two independent acceptance trials with healthcare professionals with experience in wound care.

The first assessment was a multicentre national acceptance trial performed by experienced physicians and nurses (n=31) in Germany using a

Figure 1. New Debrisoft® Pad 10 × 10 cm

Figure 2. Larger Debrisoft® Pad 13 × 20 cm

wound model. Each user was given two identical wound models coated with a viscous film, along with one "old" Debrisoft (existing product) and one "new" Debrisoft Pad (new product with pocket grip). The results of using both products were documented on a questionnaire and with photographs.

Assessment covered the following:

- Handling: improved and easier handling, better grip/better hold with the hand pocket, more control during use, safe handling by the sewn edge of the hand pocket/soft stitched edge on the hand pocket, flexible/elastic hand pocket, comfortable in use
- Efficacy: better use of the total pad surface, higher effectiveness of debridement)
- Fields of applications: more areas of use, e.g. acne, psoriasis and keretoses).

The second trial was a multicentre international acceptance trial by healthcare professionals (n=34) with experience in wound care, based in Germany (n=20) and the UK (n=14). Users compared two versions with pocket grips, the "new" Debrisoft Pad (10 × 10 cm) and the Debrisoft Pad (13 × 20 cm). The results were documented on a questionnaire.

Some questions had yes/no options, while others involved scales:

- For a yes or no answer, if more than 50% answered "yes", the product characteristic or claim was considered to be valid
- For a five-point scale, where 1 is the most positive and 5 the least, the tested product characteristic or claim was considered as passed if the mean value was <3.0
- For a six-point scale (1 the most positive answer and 6 the least), if the mean value was <3.5, the product characteristic or claim was considered to be valid
- For a 10-point scale (agreement = 1, no agreement = 10), the product characteristic or claim was considered to be valid if the mean value was <5.5.

The different parameters were evaluated by an exploratory-descriptive statistical analysis, according to data distribution.

RESULTS

There were 31 clinicians in the first acceptance trial of the "new" Debrisoft (10 × 10 cm with pocket grip). The flexibility of the hand pocket was rated as flexible (mean 1.77; on a six-point scale where 1=very flexible and 6=very inflexible). The stretchability of the hand pocket was "spot on" (mean 1.00; five point-scale: 1=spot-on, 5=much too tight). The stitched edge on the hand pocket was rated as "soft" (mean 1.65; six-point scale: 1=very soft and 6=very hard).

When compared with the existing monofilament debridement pad ("old" Debrisoft), the new product was considered to lie better in the hand (new product mean 1.32 [very good], existing product mean 2.45 [good]) and to have a better grip during the cleansing of the wound model (new product mean = 1.32 [very good], existing product mean = 2.52 [satisfactory]), measured on the six-point scale (very good=1, good=2, satisfactory=3, sufficient=4, deficient= 5, insufficient=6) *(Figure 3)*.

The handling of the product during the cleansing of the wound model was very easy for the new pad (mean 1.26) and easy for the existing product (mean 2.03), rated on a six-point scale *(Figure 4)*.

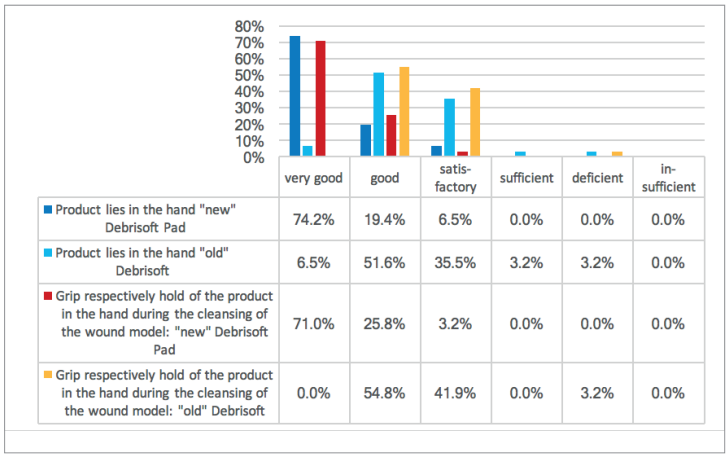
In the direct comparison of overall handling, the new monofilament device was rated to have better handling (n=26, 83.9%). Four users scored the existing pad as having better handling (12.9%) and one user (3.2%) said that there was no difference. When asked about other conditions on which to use the monofilament product, healthcare professionals agreed it would be useful for acne (n=26, psoriasis (n=26) and keratosis (n=29) *(Figure 5)*.

The second acceptance trial was performed by 34 healthcare professionals who compared the 10 × 10 cm "new" Debrisoft with the larger 13 × 20 cm Debrisoft Pad.

The clinicians' mean measured hand size was 18.26 cm (SD 1.18) long and 8.30 cm (SD 0.75) wide (length × width = 151.96 cm² (SD 20.93)). The pocket grip fitted the hand very well for both the 10 × 10 cm product (mean 3.31) and the 13 × 20 cm product (mean=2.31), as measured on a 10-point scale *(Figure 6)*. When asked if the grip enabled the product to be used in a safe and controlled manner this was rated as very good (10 × 10 cm product mean=3.21, 13 × 20 cm product mean=2.53) on a 10-point scale *(Figure 6)*. Neither width, length nor the overall size of the hand had statistical significant influence on the handling. The product rating for users with small hands shows no significant deviation from users with large hands.

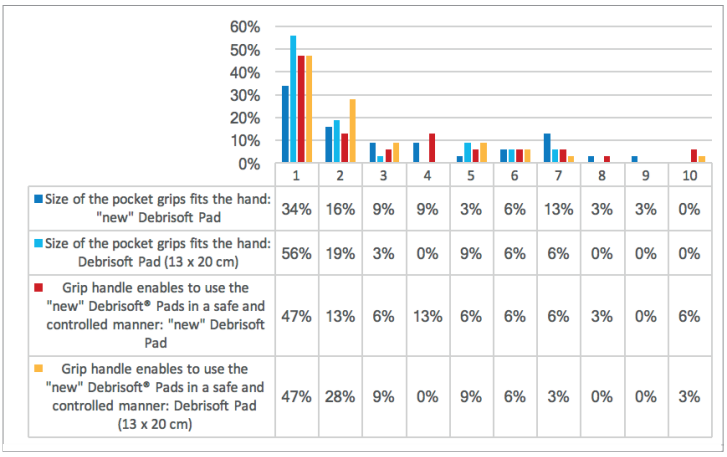
DISCLOSURES AND CONFLICT OF INTEREST

This study was sponsored by Lohmann & Rauscher GmbH & Co. KG, CR & MA are employees of the sponsor



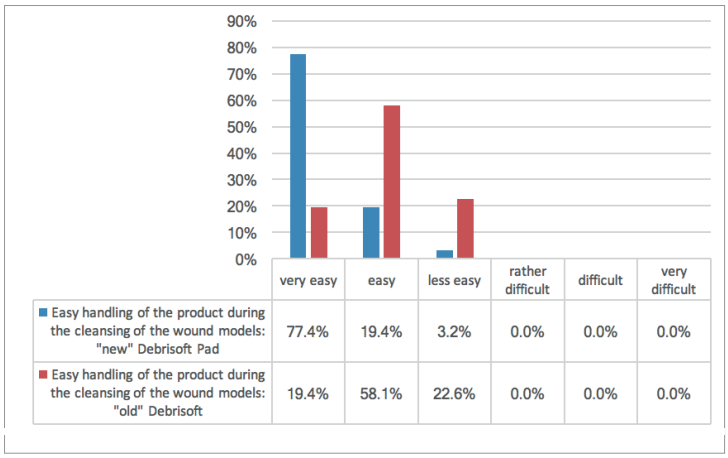
	very good	good	satis-factory	sufficient	deficient	in-sufficient
Product lies in the hand "new" Debrisoft Pad	74.2%	19.4%	6.5%	0.0%	0.0%	0.0%
Product lies in the hand "old" Debrisoft	6.5%	51.6%	35.5%	3.2%	3.2%	0.0%
Grip respectively hold of the product in the hand during the cleansing of the wound model: "new" Debrisoft Pad	71.0%	25.8%	3.2%	0.0%	0.0%	0.0%
Grip respectively hold of the product in the hand during the cleansing of the wound model: "old" Debrisoft	0.0%	54.8%	41.9%	0.0%	3.2%	0.0%

Figure 3. Holding and gripping the products



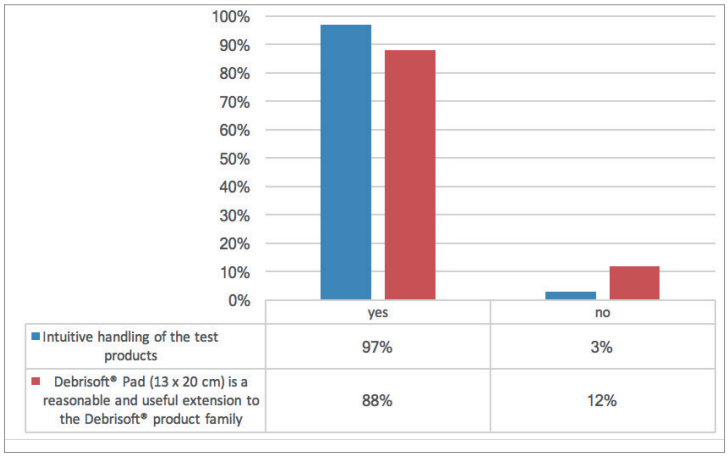
	1	2	3	4	5	6	7	8	9	10
Size of the pocket grips fits the hand: "new" Debrisoft Pad	34%	16%	9%	9%	3%	6%	13%	3%	3%	0%
Size of the pocket grips fits the hand: Debrisoft Pad (13 x 20 cm)	56%	19%	3%	0%	9%	6%	6%	0%	0%	0%
Grip handle enables to use the "new" Debrisoft® Pads in a safe and controlled manner: "new" Debrisoft Pad	47%	13%	6%	13%	6%	6%	6%	3%	0%	6%
Grip handle enables to use the "new" Debrisoft® Pads in a safe and controlled manner: Debrisoft Pad (13 x 20 cm)	47%	28%	9%	0%	9%	6%	3%	0%	0%	3%

Figure 6. How the pocket grip fits the hand and enables safe use



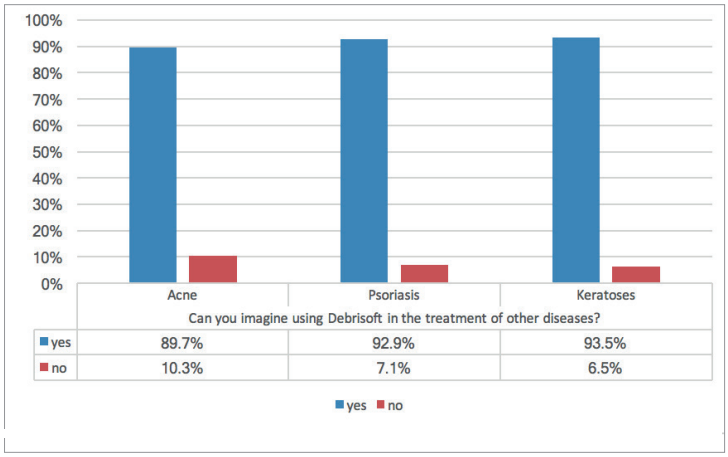
	very easy	easy	less easy	rather difficult	difficult	very difficult
Easy handling of the product during the cleansing of the wound models: "new" Debrisoft Pad	77.4%	19.4%	3.2%	0.0%	0.0%	0.0%
Easy handling of the product during the cleansing of the wound models: "old" Debrisoft	19.4%	58.1%	22.6%	0.0%	0.0%	0.0%

Figure 4. Ease of handling the products during wound cleansing



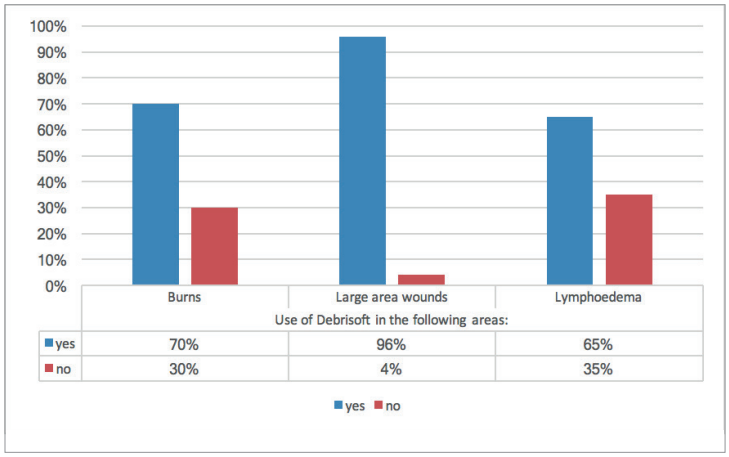
	yes	no
Intuitive handling of the test products	97%	3%
Debrisoft® Pad (13 x 20 cm) is a reasonable and useful extension to the Debrisoft® product family	88%	12%

Figure 7. Intuitive handling of the test products



	Acne	Psoriasis	Keratoses
yes	89.7%	92.9%	93.5%
no	10.3%	7.1%	6.5%

Figure 5. Product in the treatment of other diseases



	Burns	Large area wounds	Lymphoedema
yes	70%	96%	65%
no	30%	4%	35%

Figure 8. Product in the treatment of other diseases

Table 1. Possible indications and areas of application for the products

	Debrisoft 10×10 cm	Debrisoft 13×20 cm
Large area wounds, e.g. gaiter ulcer, MRSA-washing		Yes
Keratosis, acne, psoriasis, gaiter ulcer	Yes	Yes
Gaiter ulcer, burns (depending on size), hyperkeratotic skin diseases	Yes	Yes
Large area abdominal wounds and malignant wounds, gaiter ulcers		Yes
Gaiter ulcers, large area wounds		Yes
Ulcerations, secondary healing wounds	Yes	Yes
Pressure ulcer, ulcer, sloughy covered wounds	Yes	
Removal of keratosis, stimulation of perfusion at lower leg ulcer	Yes	Yes
Infection control	Yes	Yes
Removal of skin scales	Yes	
Desloughing, removal of crust	Yes	Yes
Exfoliating hyperkeratosis, removing/controlling biofilm	Yes	Yes
Smoothing hyperkeratotic plaques	Yes	Yes
Removal of devitalised tissue on oedematous legs	Yes	Yes
Cleansing gravel wounds, leg ulcers, hyperkeratosis debridement	Yes	Yes
Venous leg ulcers, fungating breast wounds		Yes
Burns, leg ulcers, toxic epidermal necrolysis, trauma wounds		Yes
Skin and wound cleansing, back large areas, showering and bathing		Yes
Lymphoedema, hyperkeratosis larger limbs		Yes

The handling of the product was rated as intuitive by 97% of users *(Figure 7)*. The Debrisoft Pad (13×20 cm) was found to be a reasonable and useful extension to the Debrisoft product family by 88% *(Figure 7)*.

In addition to the existing indications for use, several wound types were rated as possible to treat with the larger Debrisoft Pad (13×20 cm): burns (*n*=19), large area wounds (*n*=27) and lymphoedema (*n*=17) *(Figure 8)*.

In an open question, the clinicians were asked to name other indications and areas for which they thought the products would be suitable *(Table 1)*. Some of these suggestions are already part of the certified indications/areas of application (e.g. chronic and acute wounds, ulcers, pressure ulcers, acute and secondary healing wounds).

In confirmation of the first acceptance trial, acne, psoriasis and keratosis were mentioned as uses for the Debrisoft Pad (13×20 cm). This product was designed for larger surface wounds like gaiter ulcers, and these were highlighted as potential uses by the clinicians.

DISCUSSION

The existing Debrisoft monofilament debridement pad is a well-established and proven product for the soft debridement of a wide range of indications and fields of application (Bahr et al, 2011; Haemmerle et al, 2011; Strohal et al, 2013; NICE, 2014; Meads et al, 2015; Lorenzeli et al, 2018).

While sharp debridement is considered to be the most efficient way to debride a wound, the monofilament fibre debridement pad offers benefits as well in this regard. Since mechanical debridement with Debrisoft can be done by a nurse in a matter of minutes and no operating room is needed, it is both cost and time effective (Bahr et

al, 2011; Haemmerle et al, 2011; Strohal et al, 2013; NICE, 2014; Meads et al, 2015; Lorenzeli et al, 2018).

Two new variations of the Debrisoft pad have been developed, with the aim of improving handling during the cleansing procedure, safety and control, user satisfaction and a better grip to make it easier to hold the product in the hand. A hand pocket was added at first, and then in the second stage of development, the size was increased from 10 × 10 cm to 13 × 20 cm.

In comparison with the existing Debrisoft pad, the first version with a hand pocket was reported to lie better in the hand, to have a better grip and to have easier handling. Overall, the 10 × 10 cm version with the hand pocket was rated to be better than the existing product.

Healthcare professionals rated acne, psoriasis and keratosis as other conditions which it would be possible to treat with the monofilament product.

In the second acceptance trial, the new 10 × 10 cm product with the hand pocket was compared to the larger 13 × 20 cm version. Both products were rated as fitting the hand very well and were intuitive to handle. Clinicians rated the larger version of product as possible for use on burns, large area wounds and lymphoedema.

Limitations

The acceptance trials did not aim to gather clinical data on debridement efficacy. The test products were not used on patients. Consequently, the results do not convey information concerning the use and the efficacy of the test products on wounds.

CONCLUSION

The first new Debrisoft product was the 10 × 10 cm pad with a hand pocket. This met the design criteria regarding flexibility and stretchability of the hand pocket, softness of the sewn edge, grip and easy handling during the cleansing of the wound model. The clinicians rated acne, psoriasis and keratoses as additional indications suitable for the use of the test product.

The second "new" product was the Debrisoft Pad (13 × 20 cm) with a hand pocket. This met the design criteria regarding the fit of the pocket grip to the hand, safe and controlled use and intuitive handling. The clinicians confirmed the indications burns, large area wounds and lymphoedema for this product.

The hand pocket is a useful addition to Debrisoft, that increases handling and efficiency properties. The larger product is a reasonable and useful extension to the Debrisoft product family. WUK

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