Acceptance evaluation of an impregnated cleansing and debridement cloth

KEY WORDS
- CleanWnd
- Evaluation
- Wound debridement
- Wound healing

Background: Effective debridement is an essential component of the treatment of complex wounds (Frykberg and Banks, 2015). Removal of devitalised tissue is necessary for wound healing progression to occur (Atkin, 2016). **Aims:** This article will describe a product evaluation of the impregnated mechanical debridement cloth CleanWnd, with aim of evaluating efficacy, ease of use, reduction in pain level, ease of handling, reduction in time taken to complete wound debridement and the condition of the surrounding skin. **Methods:** The objectives were evaluated by nurses after a single use of CleanWnd in two separate cohorts of 10 and 11 participants. The experience of using CleanWnd cloths was compared subjectively with the nurse's standard methods of debridement. **Results:** Overall, the debridement objective was achieved in the great majority of cases and pain levels reduced. **Conclusion:** All of the nurses using CleanWnd considered it clinically acceptable and easy to use. The outcome of the evaluation demonstrated the clinical acceptability of CleanWnd cloths for debriding wounds.

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Effective debridement is an essential component of the treatment of complex wounds (Frykberg and Banks, 2015), as the removal of devitalised tissue is necessary for wound healing to occur (Atkin, 2016). Debridement improves the wound bed so it is efficiently responsive to the healing environment (Atkin 2016). There are many types of debridement, each with a set of advantages and disadvantages (Falabella, 2006), however, in this article we will focus on mechanical debridement using a unique impregnated debridement cloth.

Aim

The aim of this independent evaluation was to assess the clinical acceptability of CleanWnd, a wound cleansing and debridement cloth used by tissue viability nurses (TVN) managing chronic wounds and leg ulcers in a busy specialist wound and lymphoedema centre of excellence and innovation (CEI), and in the local community. The CEI already uses mechanical debridement in wound bed preparation and skin cleansing (toiletry) in many forms including sharp debridement, monofilament debridement and a wound cleaning cloth system.

METHODS

Product

CleanWnd (Kadioglu, Medikal) is a cleansing and debridement cloth designed for use in patients with diabetic foot ulcers (DFU), leg ulcers, pressure ulcers (PU) and acute wounds. It is made of needle punched non-woven cloth of short fibres, which enable collection of wound debris without residual linting. The cleansing and debridment cloth is impregnated with sodium hyaluronate (hyaluronic acid) and phospholipids, both of which occur naturally in the skin, and aloe vera to support its cleansing and moistening action.

The sodium hyaluronate is absorbed easily into the wound bed tissue and the skin, hydrating the tissue by attracting water to the extracellular spaces (Essendoubi et al, 2016). Phospholipids, an essential component of cell membranes, are a natural surfactant, increasing the surface tension between liquids and solids, attracting debris that is insoluble in water and thereby lifting the debris from the wound bed (Percival et al, 2017). Well-known for its soothing and hydrating action, aloe vera contains enzymes which break down dead skin

Box 1. Instructions for use

For the cleansing of chronic wounds.

Open the package where indicated and take the pad out. Use the pad to cleanse and debride the wound. After use please dispose of the pad as clinical waste.

Caution: Do not use the pad if the package is torn open. Use only under a doctor's supervision for babies of 0-6 months of age and breastfeeding or pregnant women. Patients with known allergies to the contents of the wipe should not use it. In case of an allergic reaction, stop using the pad immediately and consult your doctor.

Table 1. Baseline wound assessment parameter and measurement descriptions

Baseline assessment parameter	Measurement description
Wound size	Length, depth and width
Wound location	N/A
Wound bed tissue type	Epithelisation, granulating, slough, necrotic, infected and hyper granulating
Amount and appearance of exudate	Heavy, serous, moderate, low; purulent haemoserous
Odour	Yes or no
Surrounding skin	Healthy, dry, oedematous, macerated, cellulitic, eczematous, inflamed, venous staining or fragile.
Level and type of pain	Nil, minimal, moderate, extreme, constant, intermittent, nocturnal and altered sensation

cells and stimulate fibroblast formation (Hekmatpou et al, 2019).

Study design

The evaluation was investigator led and conducted by nurse practitioners working in a wound and lymphoedema CEI team in London and the local community area. CleanWnd samples were supplied free of charge by Regen Medical. All CleanWnd cloths were used according to the manufacturer's instructions for use *(Box 1)*. All nurses participating in this assessment were experienced in wound care.

The nurses recorded the use of CleanWnd at a single dressing change. The baseline conditions of each of the wounds were recorded from the patients' wound history presented in *Table 1*. The demographic details, medical history and concomitant treatments of the patients other than the baseline wound condition were not collected. Photographs were taken of the wound before and after use of CleanWnd.

Nurses also recorded the treatment plan in place for each patient, detailing which primary dressings were used during treatment *(Table 2)*.

Upon use of the impregnated cleansing and debridement cloth a wound assessment questionnaire was completed by the nurse who carried out the treatment for that particular patient. The treating nurse recorded their subjective assessment as to whether the clinical objectives had been met. The questions in *Table 3* were answered using a five point scale with 5 representing 'strongly agree' and 1 'disagree'.

Table 2. Primary dressing types used by subjects during treatment

Dressing type	Number
Nexodyn	1
Paste bandage	1
Hydrocolloid	1
Hydrogel	1
Gauze	2
Non-adherent	3
Hydrofibre	3
Silver	9

RESULTS

Subjects

We included 21 patients from two care locations; 'community' (patients treated at home) and the CEI clinic. Of the subjects 52% had venous leg ulcers (VLU) and all but two wounds (a burn on the head caused by radiotherapy and a sacral ulcer) were on the lower limb. There were 19 patients with open wounds, one had skin erosion due to lymphoedema and for one patient CleanWnd was used for skin toiletry only. There were 8 (38%) wounds with a surface area>10cm^2 *(Table 4)*. Each patient had only one wound and the use of CleanWnd was recorded on this single reference location per patient.

Types of dressing used

There were nine wounds managed with silver-

Table 3. Evaluation criteria questions
Baseline assessment parameter
Was it easy to open the pack?
Debridement — did you achieve the required debridement?
Was there a reduction in time to prepare the wound as a result of CleanWnd?
Did the pain levels increase for the patient during use?
Were you impressed by the quality of packaging?
Did the patient report any pain after use of CleanWnd?
Did CleanWnd provide good moisturising on the surrounding areas?
Do you think this product has clinical acceptability?
Did CleanWnd provide wound cleansing, complete removal of debris,exudate and fibrin excess without further trauma (product efficacy)* to the tissues in an acceptable manner?
Did CleanWnd help prevent further inflammation and maceration?
*In this article the response to the question from the questionnaire 'Did CleanWnd provide wound cleansing, complete removal of debris, exudate and fibrin excess without further trauma' is referred to for brevity as the nurse's assessment of 'product efficacy'.

Table 4. Summary of key demographics in the centre of excellence and innovation and community

Aetiology	Wound area (mean) cm^2	Location	No of patients recorded (%)
Venous leg ulcer	20.26	Leg	11 (52%)
Sickle cell ulcer	15.47	Leg	3 (14%)
Mixed aetiology	7	Leg	1 (4.8%)
Pressure ulcer	5.4	Sacrum	1 (4.8%)
Surgical wound	5.7	Leg	1 (4.8%)
Trauma wound	8	Leg	1 (4.8%)
Burn scald	1.61	Top of head	1 (4.8%)
Lymphoedema skin erosion	45	Leg	1 (4.8%)
Skin toiletry	N/A	Leg	1 (4.8%)

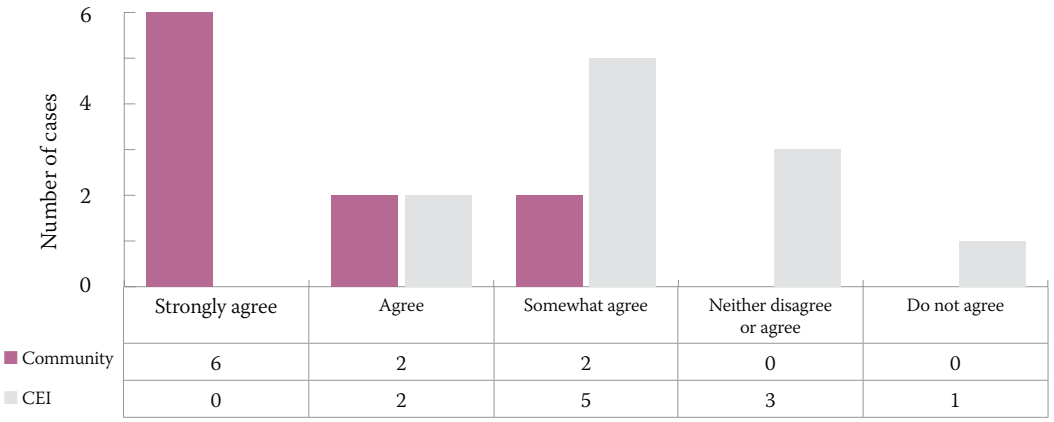
containing dressings, three with a hydrofiber dressing and three with non-adherent dressings. The exact type of dressing in each case was not recorded *(Table 2)*.

Debridement

The nurses were asked at the end of the debridement therapy for their assessment of the effectiveness of CleanWnd. In 100% of the cases treated in the community the nurses had positive views (consisting of strongly agree, agree and somewhat agree) of the product efficacy. This included wound cleansing, complete removal of debris, exudate and fibrin excess without further trauma to the tissues in an acceptable manner *(Figure 1)*.

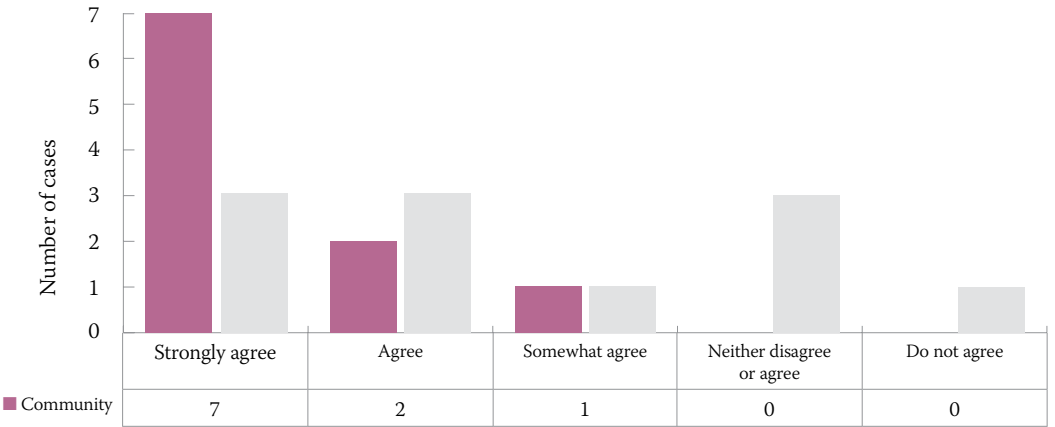
In more than 80% of the cases the nurses across both treatment areas assessed the primary objective of reaching the required debridement level as having been achieved *(Figure 2)*. In one case, a VLU with heavy exudate and slough, treated at the CEI, the nurse considered that the debridement objective had not been met, but an improvement was seen in the degree of pain as the level after debridement was recorded as none compared with intermittent before. *Figures*

Figure 1. Product efficacy evaluation



	Strongly agree	Agree	Somewhat agree	Neither disagree or agree	Do not agree
Community	6	2	2	0	0
CEI	0	2	5	3	1

Figure 2. Did use of CleanWnd achieve the required level of debridement?



	Strongly agree	Agree	Somewhat agree	Neither disagree or agree	Do not agree
Community	7	2	1	0	0
CEI	3	3	1	3	1

3 and 4 show a leg ulcer before and after cleaning with CleanWnd.

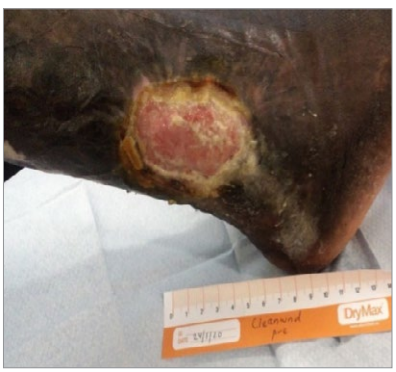


Figure 3. **Photograph showing a venous leg ulcer pre-debridement using CleanWnd**

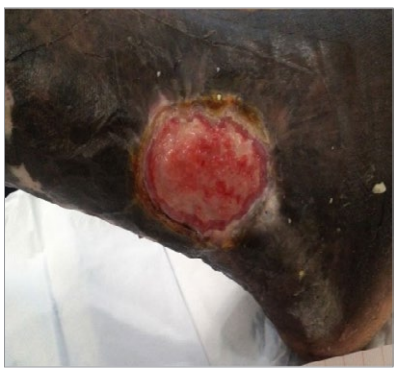
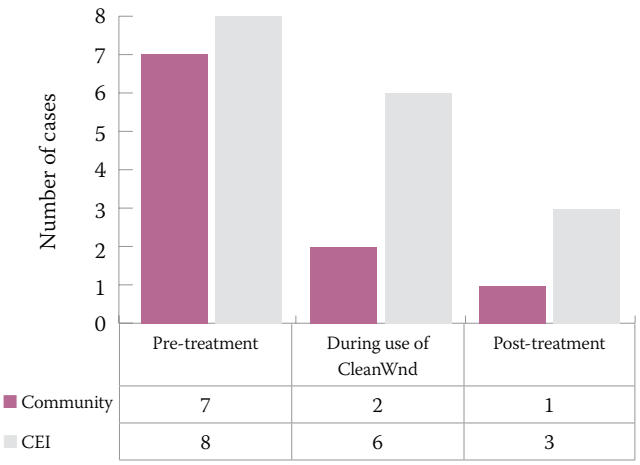


Figure 4. **Photograph showing a venous leg ulcer post-debridement using CleanWnd**

Pain

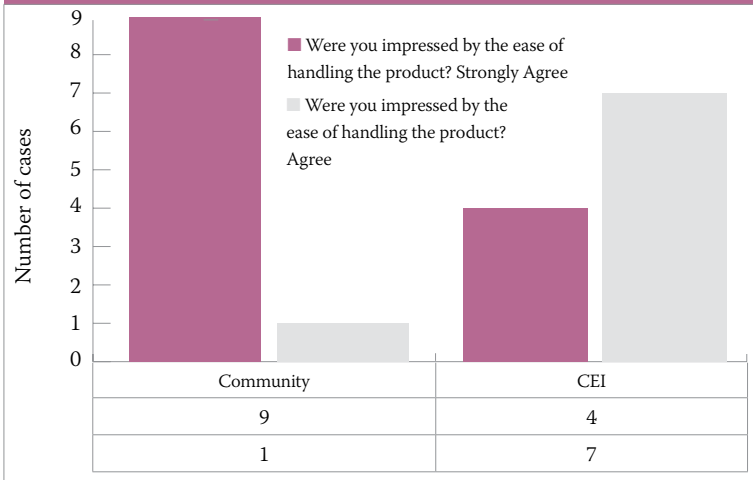
There was no increase in the pain score after the use of CleanWnd *(Figure 5)*. Before debridement 71% of the patients reported pain, 24% intermittent, 14% moderate and 33% minimal levels of pain. An increase in pain during the use of CleanWnd was reported by 38% of patients and 19% reported pain after treatment. There were two patients treated in the community who recorded an increase in pain during use compared with six in CEI. The difference in incidence could be attributed to the chronicity of the wounds managed in the CEI requiring extensive debridement and the fact that two of the patients at CEI reporting increased pain, albeit a slight increase, had sickle cell ulcers.

Figure 5. Pain experienced



	Pre-treatment	During use of CleanWnd	Post-treatment
Community	7	2	1
CEI	8	6	3

Figure 6. Were you impressed by the ease of use of the product?



	Community	CEI
Were you impressed by the ease of handling the product? Strongly Agree	9	4
Were you impressed by the ease of handling the product? Agree	1	7

Ease of handling versus reduction in time

When asked whether the product was easy to use, the nurses in the community 'strongly agreed' for 90% of their cases and of those at CEI four cases 'strongly agreed' and seven 'agreed' *(Figure 6)*. All of the nurses agreed that the packaging was easy to handle.

Although the nurses at CEI assessed the cloth as easy to use overall, in five cases the nurse had a neutral opinion as to whether the time taken to prepare the wound had been reduced by using CleanWnd, and in three cases (all VLUs managed with silver dressings) disagreed that the time required had been shortened. In contrast, in 80% of cases in the community the nurses did experience a reduction in time to prepare the wound *(Figure 7)*.

Surrounding skin

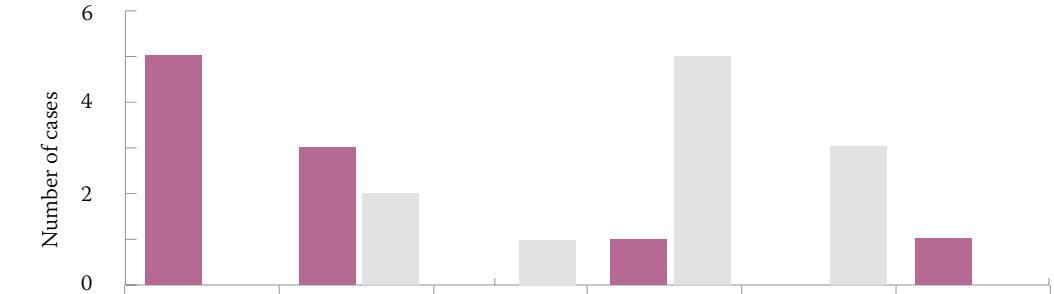
In 10 out of the 21 cases the periwound skin was identified to be dry. In 80% of those cases recorded as dry, CleanWnd was assessed as having provided a good moisturising effect. In 20% of all wounds the nurses neither disagreed nor agreed as to the efficacy of a moisturising effect. In one case CleanWnd was used only on the wound bed and not on the periwound skin.

Clinical acceptability

For each individual case the questionnaire asked whether the product was clinically acceptable. All of the nurses agreed that in all of the cases CleanWnd was clinically acceptable. The nurses working in the community agreed more strongly than those at CEI.

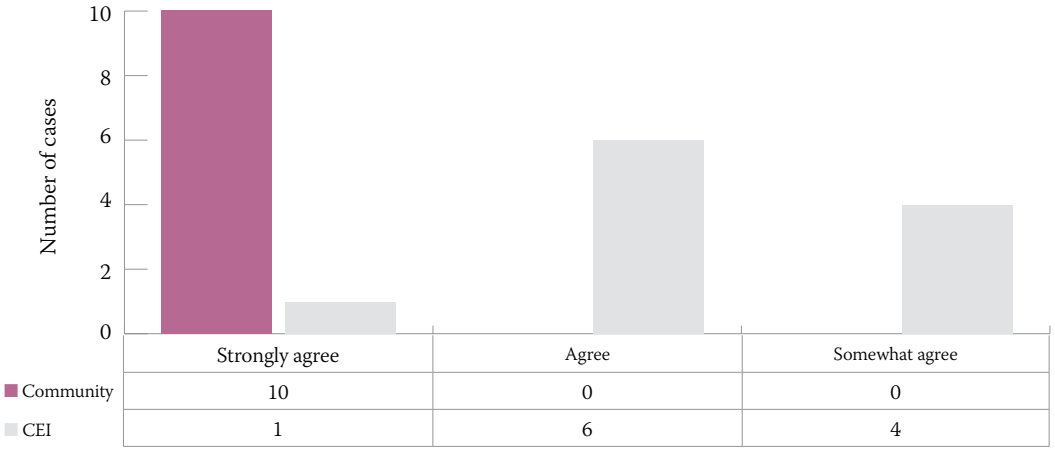
This reflects the success that the two nurses had in the community with the product, achieving the level of debridement required, reduction in pain

Figure 8. Was there a reduction in time to prepare the wound bed



	Strongly agree	Agree	Somewhat agree	Neither disagree or agree	Do not agree	Did not answer
Community	5	3	0	1	0	1
CEI	0	2	1	5	3	0

Figure 8. Clinical acceptability



post-treatment at that specific time point, ease of handling and reduction in the time needed to prepare the wound *(Figure 8)*.

DISCUSSION

This independent acceptance evaluation, of a short fibre impregnated mechanical debridement product (CleanWnd), was conducted in order to determine whether its performance was considered clinically acceptable by experienced wound care nurses when used under normal working conditions. The assessments were made subjectively by two separate groups of nurses and necessarily, therefore were open to a high degree of influence from variables such as differences in the wound treated, location of care, experience and expectation of the nurse, and time available for treatment.

Debridement is a fundamental component of the treatment of complex wounds and so the provision of debridement that health professionals finds easy to use and trust is essential. All of the nurses evaluating CleanWnd found it clinically acceptable in all cases, although the assessment of whether the debridement objective had been fully achieved differed between the two care locations. Nurses were asked to rate the product efficacy for each case they treated. In all of the community cases the nurses agreed with the statement regarding product efficacy. In five CEI cases the nurses did not see a difference in efficacy with their previous debridement product, and in one case disagreed that CleanWnd performed efficiently. Nevertheless, at the end of the treatment, in four of these six cases it was recorded that the level of debridement required had been achieved.

There were four of the above-mentioned patients at CEI who presented with VLUs of a larger surface area; 19.25cm^2, 27.73cm^2, 31cm^2 and 83.7cm^2. Such large surface areas naturally require more time for full cleansing and removal of debris. The difference in the opinions on efficacy may also be related to the difference in the condition of the wound bed treated; in CEI 10/11 cases reported the presence of slough; four of which also recorded heavy exudate. The one patient at CEI who did not have slough did have high levels of exudate.

In all of the cases in community the required level of debridement was assessed as having been reached, supporting the evaluation of product efficacy. In a case of a patient with lymphoedema and extensive skin erosions in the community (surface area: 45cm^2), with slough and heavy exudate, the nurse agreed strongly that CleanWnd was efficient and that they had reached the level of debridement required.

The experience of the nurses in the community in this evaluation suggests that there may be potential cost savings associated with the use of the CleanWnd through a reduction in time taken to achieve satisfactory debridement. In the community in 8/10 cases the nurse agreed that the time taken to prepare the wound bed was reduced.

Although the cost of debridement may not form a significant portion of the actual cost of care, a reduction in healing time brings benefits to both the nurse and the patient and leads to significant cost savings. At the CEI, in 73% of cases, nurses had either a neutral opinion as to any reduction in time or disagreed that the time taken was reduced. Factors influencing this opinion may lie in the large surface area of wounds presented at CEI, compared with the community and in other factors specific to the patient and care location not captured in this evaluation.

Out of the entire cohort (n=21) it was identified that 10 cases had dry periwound skin, with the associated risks to skin integrity and the consequent need for protection and hydration (Wounds UK, 2018). When asked whether CleanWnd provided good moisturising effects, 80% of the cases with dry periwound skin were recorded by the nurses to have had good moisturising at the point of dressing change.

Wound pain and the pain experienced at dressing changes have a significant impact on a patient's quality of life (QoL) and unresolved pain can have a negative impact on wound healing (Price et al, 2008). The degrees of pain reported during the use of CleanWnd varied between CEI and in the community; two patients recorded pain during use in the community, whereas six patients recorded pain during use in CEI.

In the patients that were treated in the community, seven reported pain pre-treatment, post-treatment, six out of these seven patients did not experience any pain. The one patient that did experience pain post-treatment was recorded as having a trauma wound and patients with such a wound may experience very painful dressing changes (Price et al, 2008).

At CEI eight patients were recorded as having experienced pain pre-treatment and three post-treatment. Of these three, one patient needed additional sharp debridement as the target tissue was recorded as 'thick'; there was no record of any local anaesthetic being applied. The other two patients both had sickle cell disease and leg ulcers from this disease type are notoriously painful (El Khatib and Hayek, 2016).

Limitations

This evaluation was limited to an assessment of one episode of debridement with the collection of baseline data on the wound condition only in order to minimise the reporting burden on the participating nurses and, thus, enable it to be conducted under normal working conditions. Follow-up of the duration of the moisturising effect of CleanWnd on the periwound skin, and greater detail such as the timing of debridement were sacrificed to this end, as was an objective evaluation of the quality of debridement by a second clinician independent of the study.

The questionnaire did not include a mean score for the subjective 1–5 point scale, as a threshold value to validate a claim for product performance, and the data collected on pain did not specify its location, type or measure duration, other than as 'constant' and 'intermittent'. The intensity of pain was recorded by the health professionals registering a degree of agreement or disagreement with single terms, such as 'minimal'. Use of a visual analogue thermometer, or a faces scale might provide an assessment more sensitive to the degree of the patient's experience.

Recognising that the objective of this evaluation was to assess the nurses' degree of acceptance of the product, future evaluations should consider objective measurements of debridement achieved, collection of data on previous means of debridement used by the same nurses on the same subjects and greater precision as to the nature of pain reported.

CONCLUSION

All of the nurses using CleanWnd considered it clinically acceptable and easy to use. The debridement objective was achieved in the great majority of cases and pain levels reduced. CleanWnd will be a useful addition to the health professional's options for wound management. Its ease of use will support consistent and effective debridement, enabling wound bed preparation and periwound skin toiletry. WUK

Declaration of interest: CleanWnd samples were supplied free of charge by Regen Medical.

REFERENCES

Atkin L (2016) A guide to wound debridement. *Independent Nurse* 2016(2):20–24

El Khatib A, Hayek S (2016) Leg ulcers in sickle cell patients: management challenges. *Chronic Wound Care Management and Research* 3:157–61. http://dx.doi.org/10.2147/CWCMR.S85455

Essendoubi M, Gobinet C, Reynaud R et al (2016) Human skin penetration of hyaluronic acid of different molecular weights as probed by Raman spectroscopy. *Skin Res Technol* 22(1):55–62. https://doi.org/10.1111/srt.12228

Falabella A (2006) Debridement and wound bed preparation. *Dermatol Ther* 19(6):317–35. https://doi.org/10.1111/j.1529-8019.2006.00090.x

Frykberg R, Banks J (2015) Challenges in the treatment of chronic wounds. *Adv Wound Care (New Rochelle)* 4(9):560–82. https://dx.doi.org/10.1089%2Fwound.2015.0635

Hekmatpou D, Mehrabi F, Rahzani K, Aminiyan A (2019) The effect of aloe vera clinical trials on prevention and healing of skin wound: a systematic review. *Iran J Med Sci* 44(1):1–9

Percival SL, Mayer D, Malone M et al (2017) Surfactants and their role in wound cleansing and biofilm management. *J Wound Care* 26 (11): 680–90. https://doi.org/10.12968/jowc.2017.26.11.680

Price P, Fagervik-Morton H, Mudge E et al (2008) Dressing-related pain in patients with chronic wounds: an international patient perspective. *Int Wound J* 5(2):159–71. https://doi.org/10.1111/j.1742-481x.2008.00471.x

Wounds UK (2018) Best Practice Statement Maintaining skin integrity. *Wounds UK* https://www.wounds-uk.com/resources/details/maintaining-skin-integrity