A multicentre, clinical evaluation of a hydro-responsive wound dressing: the Glasgow experience

Objective: Our aim was to assess the effectiveness of hydro-responsive wound dressing (HRWD) in debridement and wound bed preparation of a variety of acute and chronic wounds that presented with devitalised tissue needing removal so that healing may proceed.
Method: This was a non-comparative evaluation of acute and chronic wounds that required debridement as part of their normal treatment regimen. Clinicians recorded wound changes including a subjective assessment level of devitalised tissue and wound bed preparation, presence of pain, wound status (e.g., wound size) and periwound skin condition. Data was also collected from clinicians and patients to provide information on clinical performance of the dressing.
Results: We recruited 100 patients with a variety of wound types into the study. Over 90% of the clinicians reported removal of devitalised tissue to enable a healing response in both chronic and acute wounds. Specifically, over the course of the evaluation period, levels of devitalised tissue (necrosis and slough) reduced from 85.5% to 26.3%, and this was accompanied by an increase in wound bed granulation from 12.0% to 33.7%. Correspondingly, there was a 40% reduction in wound area, hence a clinically relevant healing response was seen upon treatment with HRWD. It is also noteworthy that this patient population included a significant proportion of chronic wounds (51.4%) that showed no signs of wound progression within <4 weeks before study inclusion. Of these chronic wounds, 93% demonstrated wound progression upon treatment with HRWD. Despite reported pain levels being low pre- and post-dressing change, overall wound pain improved (reduced) in 48% of patients. Periwound skin condition showed a tendency towards improvement, and the fluid management capabilities of the HRWD was reported as good to excellent in the majority of cases. Wound infections were reduced by at least 60% over the evaluation period. A simple cost-effective analysis demonstrated significant savings using HRWD (£6.33) over current standard practice regimens of a four-step debridement process (£8.05), larval therapy (£306.39) and mechanical pad debridement (£11.46).
Conclusion: HRWD was well tolerated and was demonstrated to be an efficient debridement tool providing rapid, effective and pain free debridement in a variety of wound types.
Declaration of interest: This study was supported by Paul Hartmann Ltd.

debridement • eschar • Hydroclean plus • hydro-responsive wound dressing • slough

A recent study by Guest et al.[1] demonstrated UK-wide costs attributable to managing wounds in 2012/2013 were £4.5–5.1 billion, with two-thirds of costs being incurred in the community and the rest in secondary care. A significant hurdle in managing these wounds is the development of devitalised tissue which can severely delay healing.[2,3] Removal of this devitalised tissue (debridement) is necessary for wound healing progression to occur.[4–6] Debridement enables wound bed preparation,[7] optimising the wound bed so it is best able to respond to the healing environment promoted by today's advanced wound care products. It has been suggested that if effective wound debridement is provided the time to wound closure may be reduced.[8,9]

As well as removing devitalised tissue, debridement plays a role in controlling bacterial load and biofilm,[10,11] while promoting a healthy wound bed and stimulating re-epithelialisation.[12] The importance of debridement in optimising the wound edge and periwound skin for wound progression has been considered an integral part in the treatment of chronic wounds, broadening the potential role of debridement in influencing healing.[13]

There is clinical evidence to support the use of debridement to enable wound healing.[14] A recent cohort study in a large number of patients (312,744) with a variety of wounds (predominantly chronic wounds), receiving more frequent debridement, had more rapid healing rates on average.[15] The positive results obtained with the use of debridement has led to

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Table 1. Wound assessment parameters and measurement descriptions

Assessment parameter	Measurement description
Wound size	Length and width
Appearance of wound bed (%)	Re-epithelialisation; granulation; necrosis; slough
Condition of periwound skin	Healthy; eczematous; excoriated; dry; inflamed; macerated; hyper-hydrated
Level of bacterial contamination	Clinically infected; critically colonised
Level of wound exudate	High, moderate, low
Need for debridement	Yes or no
Level of pain	Visual-analogue scale (VAS)
Adverse events	Relating to the wound (inflammation; infection), significant deterioration of the surrounding skin (inflammation; infection; significant deterioration; eczema; erysipelas; erosion; irritation; maceration; blistering; ulceration) or any other deleterious effects that might be harmful to the patient were noted

Table 2. Patient inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Male or female, aged ≥18 years	Known allergy/hypersensitivity to any components of the dressing
Subjects required removal of devitalised tissue as part of their routine treatment regimen	Subjects who will have had problems following the protocol
Signed consent form	Subjects with severe underlying disease(s) judged by the investigator likely to interfere with the study treatment

it becoming an integral part of clinical guidelines and a basic tenet of wound treatment.[5,13,16]

A number of different debridement methods are available including, surgical/sharp, autolytic, enzymatic, biological, and mechanical.[13] The specific method chosen is based on a number of criteria including the patient's general condition, wound status, skills of the clinician, and the availability of resources.[5,17,18] Autolytic debridement harnesses the naturally-occurring enzyme action found in wounds to remove devitalised tissue, and this is aided by the use of modern wound dressings that promote a moist wound environment.[19] This method is considered to be safe, painless and cost-effective.[19]

Aim

The aim of this study was to evaluate the clinical performance of a hydro-responsive wound dressing (HRWD, HydroClean plus), that cleanses, debrides, desloughs and absorbs (wound exudate) hence enabling the rapid and effective (autolytic) debridement of wounds.[3]

The HRWD comprises a soft and comfortable pad, which contains a hydro-responsive matrix at its core. Superabsorbent polyacrylate (SAP) particles containing Ringer's solution form part of the matrix, and provide a continuous rinsing and absorption effect for supporting effective wound bed preparation.[3] Pre-activation of the SAP with Ringer's solution allows for rapid and sustained cleansing of the wound bed.[20–22]

The primary objective of the investigation was to evaluate the clinical efficacy of HRWD plus in wound bed preparation (i.e., debriding the wound of slough/necrotic tissue), generation of granulation tissue, and healing progression in patients with a variety of different wound types.

Methods

Ethical approval

All study participants were provided with patient information and were asked to sign an informed consent form before inclusion into the investigation. The study protocol, patient information and consent form were approved by an Independent Ethics Committee before patient enrolment. The investigation was performed in accordance with the Declaration of Helsinki and applicable regulatory requirements. Participants were identified by patient number only.

Study design

The study was designed as an open, non-comparative, multicentre investigation. Inpatients and outpatients were included. To evaluate the clinical efficacy of a HRWD in wound bed preparation, subjective assessment of the percentage of devitalised tissue present and its subsequent removal, and development of granulation/epithelial tissue was undertaken at each assessment time point. Secondary objectives included the evaluation of dressing-related pain, measured using a validated visual-analogue scale (VAS) at both dressing changes and between dressing changes, changes in wound size and healing phase, exudate management, assessed according to the condition of periwound skin (Table 1) and clinician/patient opinions of the dressing. The parameters were evaluated in terms of changes from baseline assessments.

Patients

Inclusion and exclusion criteria are outlined in Table 2. Patients were drawn from across the Glasgow and Clyde region, and selected by the clinical investigator(s) if their wound required debridement. Patient participation was voluntary and they were required to complete patient consent forms to allow further use of data in educational or commercial settings. Any and all patients had the right to refuse to enter the study.

Test procedure and dressing evaluation

Each patient was treated according to the local clinical routine and evaluated during a treatment period of two weeks or for a minimum of four dressing changes (in some cases, data was collected after the designated evaluation period and was included in the analysis). All dressings were applied according to the manufacturer's instructions. Patients were assessed at baseline and again at subsequent dressing changes according to their clinical requirements. At baseline, the following information was

Table 3. Summary of wound types

	Number
Pressure ulcer	43
Blister	4
Traumatic wound	7
Burn	7
Surgical wound	12
Malignant	1
Ulcer	9
Moisture damage	3
Arterial ulcer	2
Diabetic foot ulcer	5
Pyoderma	2
Mixed aetiology ulcer	2
Abscess	2
Cellulitis	1
Hematoma	1
Unknown	10

collected: patient's characteristics, status of the wound (wound bed, periwound skin condition, exudate levels). Previous wound treatment history medical and surgical history, concomitant medications, including antibiotics, were also recorded.

At each dressing change a wound assessment was undertaken and recorded on evaluation forms developed for the study. Photographs were taken upon dressing removal to monitor and record wound status. At baseline and each assessment point, the investigators' opinions of the dressing were noted on the evaluation form. Patients' opinions of the dressing were also recorded.

At the end of each patient evaluation, a summary assessment form was completed identifying whether the clinical objectives had been reached, and providing an overall evaluation of dressing performance from both patient and clinician perspectives.

Statistical methods

All statistical analyses were performed on the subjects who completed the study. Only descriptive statistical analyses were undertaken on the relevant data including mean, standard deviations (SD) or trendlines, where appropriate.

Results

A total of 100 patients, with 111 wounds and 544 assessment time points, were included in this analysis. There were 43 males (average age: 68.3±15.5 years) and 57 females (average age: 71.3±15.7 years) in the study. A variety of different wound types were included in the study, but the majority were pressure ulcers (Table 3). A number of different wound dressings were used before enrolment to this study (Fig 1). The mean value of the frequency of dressing change was 2.71 days (SD: 0.66), and the total number of times the HRWD was used in this study was calculated to be 544.

Debridement

The results show that, at baseline, there was a significant level of necrosis/slough (devitalised tissue) in the wound bed, with a mean overall coverage of devitalised tissue of 85.5% (Fig 2). After treatment with HRWD,

Fig 1. Dressing types used by the patients before this study

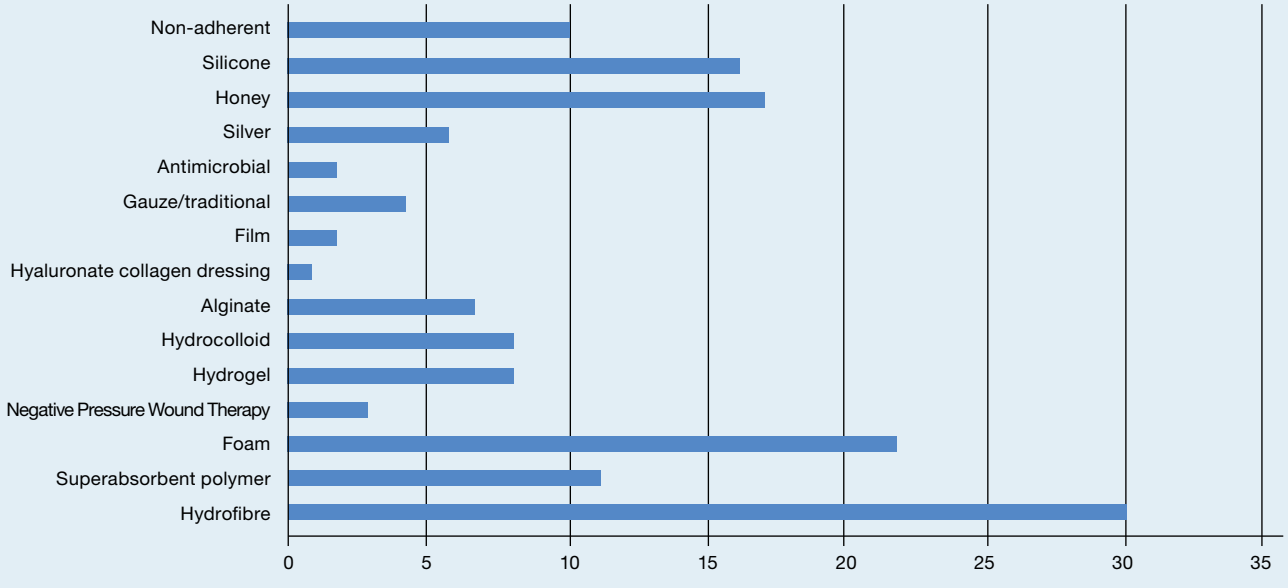


Fig 2. Wound bed evaluations showing changes in the levels of devitalised and granulation tissue over course of evaluation period

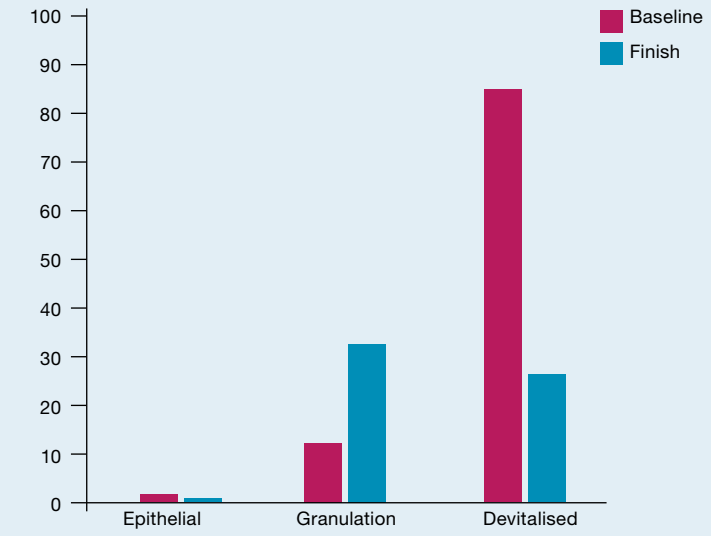


Fig 3. Summary of wound bed change and the number of wounds in each wound progression transition state

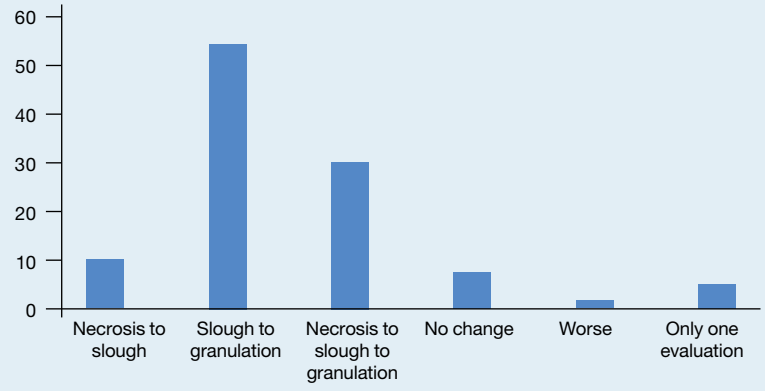
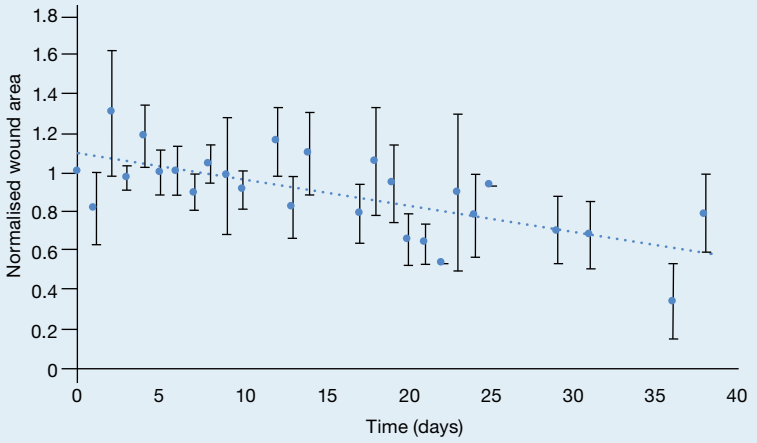


Fig 4. Change in normalised mean wound area over the course of the evaluation period



there was a decrease in the level of devitalised tissue to a mean overall coverage of 26.3 0%, a reduction of nearly 60% overall, with many wounds achieving total removal of devitalised tissue. There was a corresponding increase of granulation tissue, from 11.95% to 33.7% within the wound bed, corresponding to a healing response. Generally, the removal of devitalised tissue followed a sequence of transition states through wound progression, from necrotic tissue, slough, and clean granulation tissue, to healing/re-epithelialisation and wound contraction. Fig 3 summarises the number of wounds in each wound progression transition state, and highlights that most wounds transitioned from sloughy to granulation tissue, and from necrosis to granulation tissue (via sloughy).

Wound status

The change in wound area was calculated against each patient's own baseline data which was then normalised (i.e., the patient's baseline wound area was expressed as '1'). Fig 4 shows an overall decrease in wound area, approaching 50% of baseline values. Using the trendline to forecast a trajectory of healing, wound closure would be expected in around 50 days after the start of treatment with HRWD plus.

Periwound skin condition

There were a number of different periwound skin conditions associated with the patients. Over the course of the evaluation period, 48 (43.2%) patients showed an improvement in periwound skin condition with 41 (36.9%) of patients' skin condition remaining the same. The periwound skin condition in 12 (10.8%) patients was reported as worse at the end of the evaluation period (Fig 5). A complete data set was not available for nine (8.1%) of the patients where either no data had been collected or only one assessment had been collected.

Pain

Pain levels both at pre- and post-dressing changes were generally low throughout the evaluation period, with 76.1% of patients experiencing no pain. However, nearly 50% of patients who did experience pain reported a significant improvement (generally these patients started the study with a higher pain score) and pain remained at similar (low) levels in 40% of patients (started and maintained low pain scores). In 12% of patients an increase in pain was experienced, and in 48% of the patients the levels remain unchanged.

Clinical signs of infection

There were 22 wounds assessed as they were showing clinical signs of infection at the start of the evaluation period. By the end of the study, 13 (59.1%) of these wounds showed no signs of infection.

Summary assessment results

When asked as part of the end-of-study summary assessment process whether the clinical objective of

removal of devitalised tissue had been achieved, over 90% of clinicians that responded answered 'yes'. In particular, when clinicians were questioned as to whether the dressing effectively managed wound exudate, the majority expressed a positive response, with over 80% reporting that there was no fluid leakage. Good exudate management control was reflected in the high percentage of 'good' or 'excellent' surrounding skin condition ratings by clinicians (Fig 7). In addition, the majority of clinicians rated the dressing's conformability to the wound, ease of removal and the dressing's ability to remain in position as 'good' or 'excellent' (Fig 7). The positive feedback from clinicians was echoed by comments from patients when asked about their experience with the dressing.

Cost Comparison

Cost comparisons were undertaken using three examples of wound dressings used to treat wounds requiring debridement. Table 4 summarises costings of representative clinical examples. Typical savings per patient of using HRWD versus B, C and D were approximately 21%, 98% and 45%, respectively. Not included in these calculations is the reduction in clinical time.

Case 1

Fig 8 highlights the experience of a 72-year-old female patient with a sacral pressure ulcer treated with HRWD, and the wound's status transition from necrosis to granulation tissue. The wound presented with 100% coverage with black necrotic tissue and the periwound skin showed signs of reddening (Fig 8a). Wound exudate level was low and there were no clinical signs of infection. HRWD was applied and fixed in position using a film dressing, and the dressing was changed every three days. Within eight days of application the black necrosis had debrided from the wound leaving a layer of yellow slough that was seen to be detaching from healthy wound margins. Healthy-looking granulation tissue could also be seen (Fig 8b). HRWD treatment was continued with slough levels decreasing, and there being a corresponding increase in granulation tissue, until the wound was at a point where sharp debridement was applied to clean the wound of the remaining devitalised tissue, after 14 days (Fig 8c). The patient reported that the dressing

Fig 5. Change in periwound skin condition from baseline

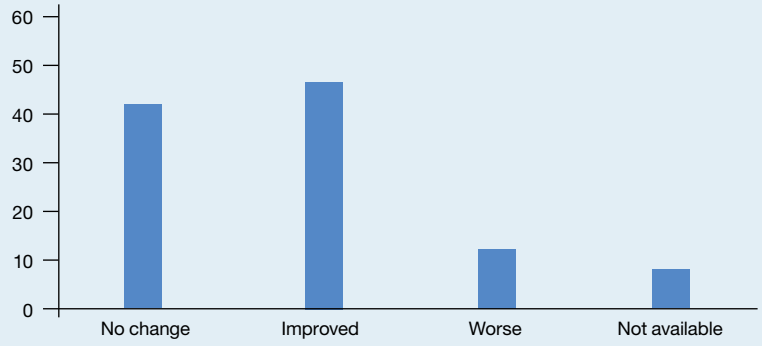


Fig 6. Assessment of wound infections during evaluation period

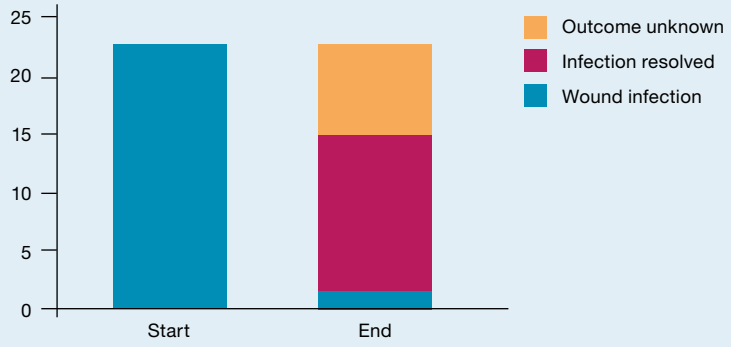


Fig 7. Assessment of dressing performance at end of evaluation period

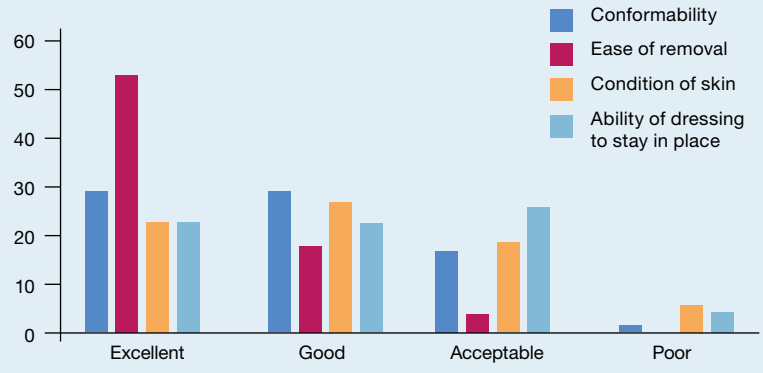


Table 4. Cost comparisons of methods used before HRWD for the treatment of wounds requiring debridement

A	Application of HRWD (£5.95) and secondary film dressing (365 Healthcare, £0.38)	£6.33
B	4-step process using a wound cleanser (Prontosan, £0.59) and gauze swabs (10 pieces, £0.40) to cleanse the wound, followed by application of honey (Activon Tube, £2.05) to the wound bed and covered with a Hydrofiber wound dressing (Aquacel Extra, £2.38) and a hydropolymer adhesive dressing (Tielle Plus, £2.63)	£8.05
C	Larval therapy (requiring special order of live larvae) (Larvae Biobag, £306.39)	£306.39
D	Application of a monofilament fibre debridement pad (Debrisoft, £6.45) and secondary dressing (Tielle Plus, £2.63, Aquacel Extra, £2.38)	£11.46

Cost obtained from Wound Care Handbook, 2017–2018;[44] HRWD—hyrdro-reponsive wound dressing

Fig 8. A 72-year-old female patient with a sacral pressure ulcer. On presentation (**a**), at eight days (**b**) and 14 days after starting treatment (**c**)

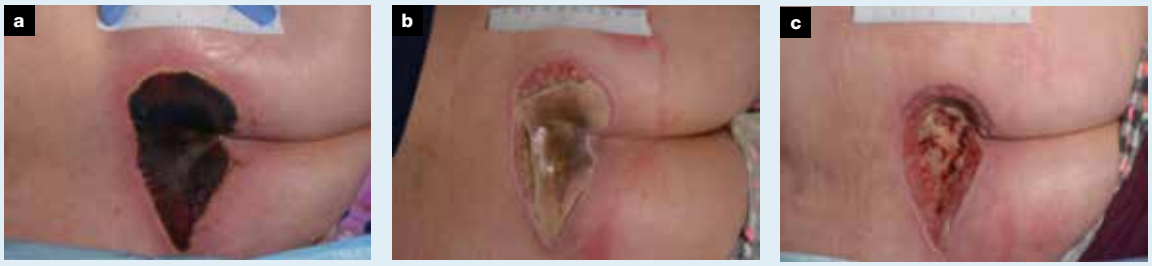
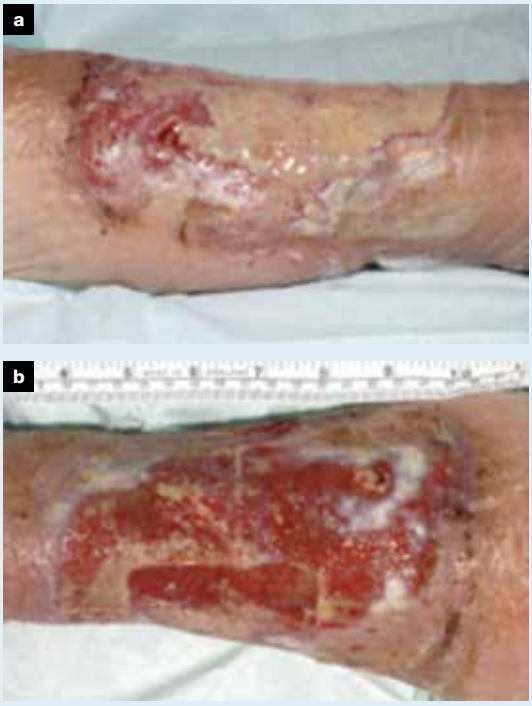


Fig 9. An 84-year-old female sustained an injury to her shin that resulted in the formation of a haematoma. On presentation (**a**) after 10 days (**b**)



was comfortable to wear and the clinician remarked that the dressing promoted quick separation of devitalised tissue from healthy margins that enabled early sharp debridement.

Case 2

An 84-year-old female who sustained an injury to her shin that resulted in the formation of a haematoma. Debridement had been started with other wound dressing options but was unsuccessful, and there was difficulty removing a layer of slough using the current treatment methods of the clinic (Fig 9a). The pain/discomfort experienced by the patient also contributed to limiting the treatment options. HRWD was applied to the wound with wound pad and bandages to retain the primary dressing in position. Within 10 days of initial dressing application, the layer of slough had successfully been debrided (Fig 9b). The patient reported an improvement in her quality of life, noting that the dressing was comfortable to wear and that there was now no issues with pain.

Case 3

A 53-year-old female patient with metastatic synovial sarcoma affecting the right hip and chronic lymphoedema. The presenting ulcer was several months old and featured recurrent cellulitis which was treated with multiple courses of antibiotics. The wound presented with a significant layer of slough over the entire wound surface, the periwound skin showed erythema and the patient suffered with the malodour emitted (Fig 10a). The consultant physician requested larval therapy to debride the wound. However, the patient was against the use of maggots and it was decided that use of larval therapy would not have been in keeping with any patient-centred care plan. HRWD was applied to the ulcer and by week three debridement of the wound was visible and there was a significant improvement in the condition of the periwound skin (Fig 10b). The wound malodour, which was the most upsetting aspect of the wound for the patient, had resolved.

Discussion

Our results show that after treatment with HRWD, there was a decrease in the level of devitalised tissue and where all devitalised tissue had not been removed, any remaining tissue had softened and loosened from the underlying wound bed, and was easily and painlessly removed by minor surgical debridement.

The results also show tangible benefits with regards to the debridement of pressure ulcers (PUs) which formed a high percentage of this patient population (category III or ungradeable). Clinical practice recommends that necrotic tissue or slough should be removed, both to promote healing and to enable easier staging of the wound.[23] This study supports HRWD use in PU debridement, as effective devitalised tissue removal supports the clinician in easier/rapid wound assessment (staging of PU – important for treatment). Overall, our data supports the use of debridement for wound bed preparation and enabling healing progression as part of the clinical treatment regimen. Furthermore, the study's results supports the premise

that HRWD is a good option for the management of a variety of wounds that require rapid debridement.

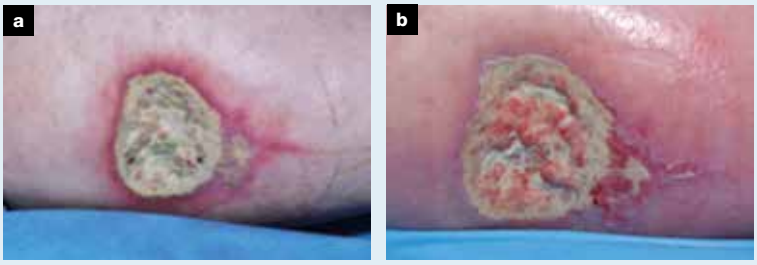
We observed a decrease in wound area, approaching 50% of baseline values. The findings reported here are in agreement with other clinical studies, whereby dressings that promote autolytic debridement promote wound size reduction.[24-28] More than 50% of the wounds were chronic wounds (of duration >4 weeks)[29] and the results show that the majority of these chronic wounds (92%) exhibited wound progression after treatment with HRWD commenced.

Wound pain and the pain experienced at dressing changes have a significant impact on a patient's quality of life (QoL).[30–32] Psychosocial issues related to wounds feeds back and compounds the negative impact of physical wounds such as pain.[33] A number of studies describing the beneficial effects of wound dressings that promote autolytic debridement on wounds have reported reductions in wound pain.[24,25,28,34] When the patients were questioned regarding the change in wound over the course of the evaluation period, a high proportion of respondents reported an improvement in wound pain. As a consequence of the pain reduction experienced and the overall beneficial impact on QoL, some patients were keen for their wounds to continue to be treated with HRWD, hence the fact that the results show extended use beyond the two weeks (or four dressing changes) specified in the protocol.

Devitalised tissue is a focus for bacterial growth and potential infection[35] and, as a consequence of wound infection, wounds may take longer to heal.[36–38] Rapid debridement of the wound by HRWD is likely to reduce the wound bioburden by removing the focus of infection, including biofilm[39] and leading to wound progression. In addition, speed of debridement has been associated with reduced infection rates and infection has been shown to increase the length of follow-up.[40] Our results demonstrate that HRWD was associated with a reduction in the number of wounds showing clinical signs of infection.

Furthermore, the data presented in this study does suggest that there are potential cost savings associated with the use of HRWD. Although the cost of wound dressings may not form a significant portion of the actual cost of care,[41,42] dressings that are able to reduce the frequency of dressing change and shorten the time-to-heal will lead to significant cost savings.[13] As further evidence to support the cost-effectiveness of HRWD, in a recent case study series evaluation, 20 patients with a variety of acute and chronic wounds were treated with a HRWD for debridement. The results showed a significant cost saving compared with that of standard debridement practice.[22]

Fig 10. A 53-year-old female patient with metastatic synovial sarcoma affecting the right hip and chronic lymphedema. On presentation (**a**) and at week 3 after use of HRWD (**b**)



These results are relevant for the 'real-life' clinical treatment of acute and chronic wounds because they were obtained from a varied population that were identified as requiring debridement as part of the routine treatment. This patient population reflects the patient profiles commonly treated in wound care centres, and the observational component of the study allows the assessment of treatments used in complex clinical issues in real-life settings.[43]

Limitations

The observational nature of the study included subjective reporting and there was neither randomisation nor a control arm to the study.

Conclusions

This evaluation study reports the positive outcomes on 100 patients with 111 wounds who received HRWD as an autolytic debridement treatment in a wide range of acute and chronic wounds. The study shows effective, rapid and painless debridement of wounds within the evaluation period, and a corresponding increase in healthy granulation tissue. A wound area reduction was also seen in the patient population corresponding to the fact that a high percentage of patients had wound transition from a non-healing to a healing state. There was also a reduction in the number of patients showing clinical signs of infection which may also have enabled a more positive healing response. The dressing was well tolerated by patients and clinicians were very positive after using HRWD, and the dressing has replaced the previous debridement therapy of Honey with a secondary dressing as the first line debridement choice. JWC

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- Reflective questions
- What is the effect of devitalised tissue on wound healing?
- How will the removal of devitalised tissue impact upon bacterial load including biofilms?
- How could hyrdo responsive wound therapy aid in removal of devitalised tissue?

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