

# Clinical experience with a glucose oxidase-containing dressing on recalcitrant wounds

This large open study investigated the clinical benefits of a new hydrogel dressing when used on chronic wounds of different aetiologies in real-life clinical settings.

Nearly three-quarters of the patients assessed either healed or improved

healing outcomes; wound bed characteristics; pain; patient and clinician satisfaction

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**O**xyzyme (Archimed Division) is a new type of hydrogel dressing containing a natural enzyme that is designed to promote a healing environment in superficial wounds. For its registration, two open, non-comparative, clinical trials were undertaken to gather evidence on its safety and efficacy.<sup>1,2</sup> The Canadian four-week study involved 20 patients with 22 hard-to-heal wounds (venous leg ulcers, post-surgical and radiation wounds, diabetic foot ulcers and pressure ulcers).<sup>1</sup> Four wounds healed (18%), 15 improved (68%), one remained static (5%) and two deteriorated (9%) in the four-week study period. The UK study involved 31 patients with chronic venous leg ulcers (median duration 39 months), of whom 21 completed the six-week trial. Of these, 10 patients healed fully (32%), eight improved (26%) and three (10%) derived little or no benefit. While these results are encouraging, the small sample sizes and open nature of the trials meant that further evidence was required.

To gain field experience of the dressing with a large number of patients with a variety of hard-to-heal, chronic wounds, an open, non-comparative, multi-national case-series study was conducted. A randomised controlled trial (RCT) or cohort study approach was considered but not pursued as it was judged that, under these circumstances, it was likely to be more time-consuming and bureaucratic to conduct, and more difficult to oversee effectively. The case-series study design also offered the opportunity for rapid recruitment at a wide range of expert centres, as well as enabling structured feedback from their experienced staff. In addition, this approach gives a direct insight into the effectiveness of the new dressing when applied by nurses in real-life settings.

The study aims were therefore to:

- Gain evidence of the performance of Oxyzyme with a variety of hard-to-heal chronic wounds of various aetiologies in clinical settings
- Evaluate its ability to promote a healing environment in chronic wounds

- Examine its effect on the wound bed, exudate levels, the surrounding skin and pain levels
- Obtain patient and carer feedback on its use and performance.

## The test dressing

Oxyzyme (the test dressing) is a new type of wound dressing that uses a natural enzyme (glucose oxidase) to help create a healing environment. It should be noted that the enzyme is not present as a proteolytic aid to debridement, and does not come into direct contact with the wound. The dressing is indicated for lightly exuding chronic wounds.

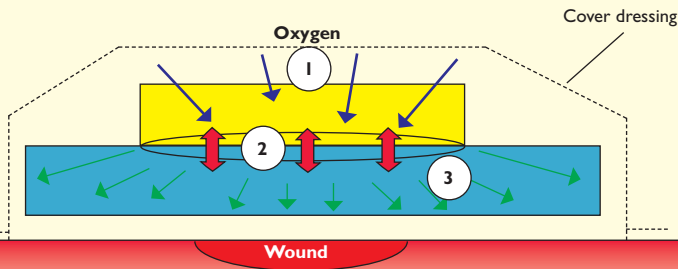
The dressing comprises two advanced polymer sheet hydrogels. One contains a low level of glucose oxidase and the other glucose. When the dressing is placed over the wound, hydrogen peroxide is generated within the hydrogel, which in turn produces iodine, thereby creating a barrier to infection.

Any hydrogen peroxide remaining in the dressing is instantly converted into oxygen at the interface with the wound by endogenous catalase activity. As a result, the concentration of dissolved oxygen beneath the dressing is increased. This may help prevent wound hypoxia, which can result from the use of occlusive or semi-occlusive barrier coverings. Avoiding hypoxia helps promote the healing process.<sup>3</sup> The dressing's mechanism of action is illustrated in Fig 1.

## Method

Patients were recruited from 27 European complex wound clinics (22 in England, two in Germany, one in Iceland, one in Sweden and one in Turkey). All patients had been receiving treatment in the clinics for their chronic wounds before being recruited into the study. Other than the use of the study dressing, each patient's care regimen remained the same both before and during the study. For example, patients continued to be treated in the same care setting and

**Fig 1. Biochemical action of the dressing**



- 1 Diffusion of oxygen from the atmosphere through the cover dressing into the secondary hydrogel (yellow), which contains the glucose oxidase enzyme
- 2 Diffusion of glucose from the primary hydrogel (blue) into the secondary hydrogel dressing and production of hydrogen peroxide by enzyme action
- 3 Diffusion of hydrogen peroxide into the primary hydrogel dressing and reaction with iodide to produce molecular iodine, plus further diffusion

by the same clinician/carer, while the use of 'gold standard' treatments, such as compression bandaging, offloading and pressure redistribution remained unchanged. Previous treatments had included the use of advanced dressings.

**Inclusion criteria**

- Aged over 18 years
- Superficial (non-cavity), hard-to-heal (static or deteriorating during the previous 4 weeks) chronic wound of over 12 weeks' duration that were suitable for treatment with one or more 10 x 10cm test dressings.

**Exclusion criteria**

- Wound infection, based on clinical signs as assessed by the clinicians
- Known or suspected sensitivity or allergy to iodide or iodine
- Thyroid disorder, such as Hashimoto's thyroiditis or non-toxic nodular goitre
- Pregnancy or breast-feeding
- Continuing medication with lithium.

**Wound types**

Consecutive patients who met the inclusion criteria were recruited into the study by the investigating clinicians. All patients provided written informed consent for treatment. As the test dressing was used in accordance with its approved indications, ethics committee approval was not required.

**Procedures and assessments**

The test dressing was applied directly to the cleansed wound in accordance with the manufacturer's

instructions. Dressing change frequency was based on the wound status and local practice. The dressing was used for the duration of the six-week study period, unless full healing occurred sooner. Six weeks was considered sufficient to show an effect; the investigators considered that the dressing should be discontinued if there were no signs of improvement by this point.

The following parameters were assessed at the patients' entry into the study and at their weekly clinic visits:

- Size — the wound (plus ruler) was photographed at entry (before the test dressing was first applied), at the weekly clinic visits, at the study end (or on early discontinuation) and at a subsequent four-week follow-up
- Depth
- Condition of wound margins, which was visually assessed by the treating clinician
- Condition of wound bed and peri-wound skin, visually assessed by the treating clinician
- Exudate type and amount, which was visually assessed by the treating clinician
- Patient-rated comfort/pain score, assessed at every clinic visit on an unvalidated five-point scale: very comfortable, comfortable, mild discomfort, painful, not applicable (for neuropathic wound patients). No distinction was made between pain at dressing change and persistent/ongoing pain
- Patient-rated overall satisfaction with the test dressing, assessed at every clinic visit on a five-point scale: very satisfied, satisfied, neutral, not satisfied, very dissatisfied
- The secondary dressing and any other wound treatments used, such as barrier creams and skin protectants on the peri-wound skin
- Any changes in the patient's medication
- Comments on other aspects of the test dressing's performance.

At the end of the study, the treating clinicians assessed the overall clinical outcomes. These were defined as:

- Healed — the wound had fully re-epithelialised
- Improved — the wound area had reduced in size, or there was an overall improvement in the condition of the wound bed, based on visual assessment
- Static — no significant change in wound size or condition of the wound bed
- Deteriorated — wound had increased in size (not as a result of debridement), or there was a general deterioration in the condition of the wound bed.

Wound area measurements were derived from the digital photographs by a single, trained operator (to minimise inter-operator variability), using proprietary software (Leg Ulcer Telemedicine wound area measuring software, see [www.lutm.com](http://www.lutm.com)). Clinician's area assessments were used if digital photographs were not available.

Finally, at the end of the study the patients' and the clinicians' overall assessments of the product were recorded.

## Results

One hundred patients were recruited into the study; 46 were male and 54 female. There was an average of three patients (range 1–12) from each clinic. The mean ages are given in Table 1, along with data on the wound type and duration.

Wound types included arterial ulcers, diabetic foot ulcers, mixed aetiology leg ulcers, other miscellaneous chronic wounds (such as non-healing surgical wounds and radiation burns), pressure ulcers and venous leg ulcers. Venous leg ulcers were the largest cohort (39/100 wounds). The mean duration of all wounds was over two years (31.8 months) and the median 18 months. Only nine patients had a wound of 12 weeks' duration.

## Patient withdrawals

Thirty-eight patients were withdrawn before the end of the six-week study period:

- 7/14 (50%) arterial leg ulcer patients
- 3/13 (23%) diabetic foot ulcer patients
- 4/13 (31%) mixed aetiology leg ulcer patients
- 3/6 (50%) other chronic wound patients
- 8/13 (62%) pressure ulcer patients
- 13/41 (32%) venous leg ulcer patients.

Of these 38 patients:

- 13 (34%) were withdrawn due to an infection
- Seven (18%) due to wound deterioration (maceration or an increase in wound area)
- Seven (18%) because of non-dressing-related issues, such as hospitalisation
- Six (16%) due to pain or discomfort
- Five (14%) due to other dressing-related reasons: bleeding from a large non-healing surgical wound (n=1); the wound become static after 3–4 weeks (n=3); suspected pyoderma gangrenosum (n=1).

A breakdown of patient withdrawals by aetiology is illustrated in Fig 2.

## Healing outcomes

Of the 100 patients, 10 healed, 63 improved, 16 remained static and 11 deteriorated. Results for the various wound types is given in Table 2.

The mean percentage reduction in ulcer area after six weeks for all wound types was 35%, with the median baseline area of 5.0cm<sup>2</sup> reducing to 2.5cm<sup>2</sup>. The biggest percentage reduction (53.7%) was reported for diabetic foot ulcers, followed by arterial leg ulcers (46.3%) and venous leg ulcers (33.2%). Full details are given in Table 3.

## Pain/comfort scores

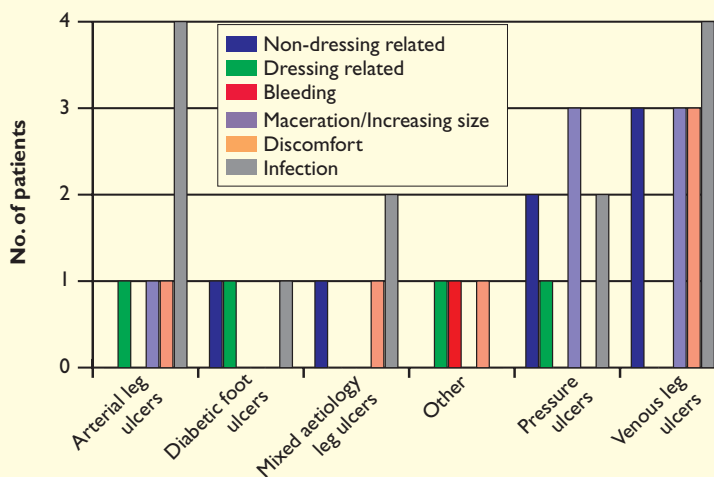
Of the entire sample, 85 patients rated comfort/pain at the final clinic visit. Of these, 55 patients (65%)

**Table 1. Baseline wound characteristics**

Wound type	No. of wounds	Mean patient age (years) (median, range)	Mean wound duration (months) (median, range)
Arterial leg ulcer	14	77.4 (77, 62–90)	21.6 (19, 3–48)
Diabetic foot ulcer	13	63.8 (66, 46–75)	20.8 (18, 5–48)
Mixed aetiology leg ulcer	13	81.6 (85, 54–93)	19.8 (24, 3–60)
Other chronic wounds (radiation burns, surgical wounds)	8	61.3 (74, 39–77)	18.1 (24, 3–36)
Pressure ulcer (EPUAP grades 3–4)	13	73.4 (74, 52–93)	12.0 (12, 3–24)
Venous leg ulcer (18 treated with compression, 21 without)	39	71.5 (74, 36–94)	52.5 (18, 3–360)
<b>Total</b>	<b>100</b>	<b>72.1 (74, 36–94)</b>	<b>31.8 (18, 3–360)</b>

None of the pressure ulcers were judged to be cavity wounds by the clinician investigators

**Fig 2. Reasons for patient withdrawals from the study by aetiology**



rated the test dressing as comfortable, nine (11%) had experienced discomfort and 21 (25%) had reported pain.

## Clinicians' overall assessment

Responses were obtained from 51 clinicians: 18 (35%) stated that the test dressing was much better than previous dressings used, 24 (47%) that it was better, five (10%) that it was similar and four (8%) worse.

**Table 2. Healing outcomes\***

Wound type	Healed No. (%)	Improved No. (%)	Static No. (%)	Deteriorated No. (%)
Arterial leg ulcer	0 (0)	11 (79)	1 (7)	2 (14)
Diabetic foot ulcer	0 (0)	10 (77)	2 (15)	1 (8)
Mixed aetiology leg ulcer	1 (8)	9 (69)	1 (8)	2 (15)
Other chronic wounds	2 (25)	2 (25)	3 (38)	1 (12)
Pressure ulcer	0 (0)	9 (69)	3 (23)	1 (8)
Venous leg ulcer	7 (18)	22 (56)	6 (15)	4 (10)
<b>Total</b>	<b>10 (10)</b>	<b>63 (63)</b>	<b>16 (16)</b>	<b>11 (11)</b>

\*Outcomes were recorded at six weeks or earlier if the ulcer healed sooner or the patient withdrew from the study

**Table 3. Mean baseline and endpoint wound areas, and mean percentage reduction in wound area**

Wound type	Mean baseline wound area (cm <sup>2</sup> ) (median, range)	Mean endpoint wound area (cm <sup>2</sup> ) (median, range)	Mean % area reduction over 6 weeks
Arterial leg ulcer	42.8 (17.2, 1.0–250)	23.0 (15.7, 1.7–96)	46.3%
Diabetic foot ulcer	10.1 (7.2, 0.2–31)	4.7 (2.1, 0.2–20)	53.7%
Mixed aetiology leg ulcer	13.0 (9.0, 2.0–38)	9.9 (8.0, 0–36)	23.7%
Other chronic wounds	15.1 (6.1, 1.0–70)	13.8 (4.4, 0–70)	8.4%
Pressure ulcer	11.9 (9.1, 0.4–35)	10.3 (6.5, 0.1–35)	13.1%
Venous leg ulcer	10.2 (5.0, 0.3–50)	6.8 (2.5, 0–34)	33.2%
<b>Total*</b>	<b>15.7 (5.0, 0.2–250)</b>	<b>10.2 (2.5 0–96)</b>	<b>35.0%</b>

\* All ulcers were included in this analysis. At baseline, 10 ulcers measured <1cm<sup>2</sup>, 49 ulcers measured 1–10cm<sup>2</sup>, 39 measured 10–100cm<sup>2</sup> and two measured >100cm<sup>2</sup>. At the study end, 10 ulcers had completely re-epithelialised; of the remainder, 16 measured <1cm<sup>2</sup>, 43 measured 1–10cm<sup>2</sup> and 31 measured 10–100cm<sup>2</sup>; no ulcers measured >100cm<sup>2</sup>.

**Patient satisfaction**

Patient satisfaction scores were obtained for 88 out of the 100 patients (Table 4). Overall, 85% of patients were satisfied or very satisfied with the dressing.

**Case study examples**

Six case studies, which are considered to be typical examples of the healing outcomes achieved with the various wound types, are included in Table 5.

**Discussion**

The number of patients included in this study was thought to be sufficient to give a broad indication of the efficacy and performance of the test dressing in real-life clinical settings, although this was not based on a formal statistical analysis. The patient demographics reflect the general incidence of hard-to-heal, chronic wounds in the population, with the expected preponderance of elderly patients.

As expected, the largest cohort, in terms of wound aetiology, was venous leg ulceration (39%). Future studies will seek more details on the initial wound classification, such as the vascular assessment of arterial ulcers, including Doppler values.

The average percentage reduction in wound area for the sample as a whole at six weeks was encouraging at 35%. There was some variation within the different aetiologies, with the average area of the 13 diabetic foot ulcers reducing by over 50%, compared with only 8% for the eight ‘other’ chronic wounds. In the absence of rigorous statistical assessment it is impossible to draw any firm conclusions, but these results indicate that, for patients in this case-series study, the test dressing produced the best outcomes for diabetic foot ulcers, arterial leg ulcers and venous leg ulcers. This was not thought to be related to the baseline wound area: the diabetic foot ulcers were, on average, the smallest at baseline (10.1cm<sup>2</sup>), whereas the arterial leg ulcers, which had the second largest average percentage reduction in wound area (46.3%), had the largest average baseline area (42.8cm<sup>2</sup>).

The clinicians reported that 73% of the wounds either healed or improved. In the absence of a control group, it is impossible to make any firm conclusions about how the test dressing compared with other dressings, other than to note that 82% of the clinicians’ considered the test dressing to be better or much better than dressings used previously.

The largest number of withdrawals (13 patients) was due to infection breakthrough. This was assessed by the clinicians, based on the clinical signs of infection: heat, redness, pain and increased exudate. The test dressing provides an antimicrobial barrier, but is not intended for use on overtly infected wounds. Although wound infection was an exclusion criterion, it is difficult to exclude the possibility of a low-level incipient wound infection on entry. Nevertheless, it is also possible that some wounds may have developed an infection during the course of the study.

The wound deteriorated in seven patients. The clinicians observed that the test dressing can stimulate a brief inflammatory phase and encourage autolytic debridement, thereby causing an increase in exudate, as demonstrated by one of the case studies in Table 4. However, in the withdrawals the deterioration caused sufficient concern for the test dressing to be discontinued and an alternative dressing applied.

**Table 4. Case study examples**



**The arterial leg ulcer at the start of the study and at week 6**

**Arterial leg ulcer**

A 71-year-old female presented with an arterial ulcer of three months' duration. She had no relevant medical history.

On entry into the study, her wound measured 24cm<sup>2</sup> and was described as shallow with indistinct wound margins. The wound bed comprised 80% slough and 20% granulation tissue. There was a moderate amount of clear wound exudate. The surrounding tissue was described as healthy but fragile.

After one week of treatment there was a slight increase in wound area due to debridement of the sloughy tissue. The wound bed was assessed to be 30% slough and 70% granulation tissue.

During the following weeks, there was a slight reduction in wound area and an overall improvement in the condition of the wound bed.

At the end of the study, the wound measured 20cm<sup>2</sup>, a reduction of 16%. The wound was described as having distinct edges. The wound bed comprised 5% slough and 95% healthy granulation tissue.

The patient was 'very satisfied' with her overall treatment experience and rated the test dressing as very comfortable at both dressing change and during wearing

**Mixed aetiology leg ulcer**

An 85-year-old female presented with a mixed aetiology leg ulcer of 12 months' duration. She had rheumatoid arthritis, for which she was taking paracetamol. Her wound had been treated with several types of dressings over the past 12 months, including Hydrofiber, silver and povidone-iodine-impregnated ones, pus compression therapy.

On entry, the wound measured 8cm<sup>2</sup> and was described as a shallow ulcer with distinct wound margins. The wound bed was assessed as 5% necrotic, 80% slough and 15% granulation tissue. There was a moderate level of clear exudate. The wound healed by week 6.

The patient had initially experienced mild discomfort when wearing the dressing, but this reduced as the healing progressed. She was 'very satisfied' with her treatment experience and outcome

**Diabetic foot ulcer**

A 67-year-old male presented with a diabetic foot ulcer of 12 months' duration. He had non-insulin-dependent diabetes, which was well controlled by diet, a history of hypertension and had undergone a peripheral bypass graft. He regularly took anticoagulants and diuretics. He was treated for his ulcer twice weekly in a wound management clinic in Germany. His wound had previously been treated with sharp debridement and dry dressings.

On entry, his wound measured 16cm<sup>2</sup>. The wound bed was described as comprising 20% necrotic, 60% thick slough and 20% granulation tissue. There was a moderate level of blood-stained wound exudate. The surrounding skin was described as healthy.

After one week of treatment, a 47% reduction in wound area was documented. The wound bed was described as 80% granulation and 20% sloughy tissue. The level and type of exudate remained unchanged.

At the study end, the wound measured 2cm<sup>2</sup>, representing a 90% reduction. The wound bed was described as 100% healthy granulation tissue; exudate levels had reduced.

The patient said he was 'very satisfied' with the test dressing and rated it as comfortable.

The clinician continued using the test dressing after the study.



**The diabetic foot ulcer at the start of the study and at week 6**



**The mixed aetiology leg ulcer at the start of study and at week 6**

**Table 4. Case study examples (continued)**

**Other miscellaneous (non-healing surgical) wound**

A 77-year-old male presented with non-healing surgical wounds following a coronary bypass graft three months previously. He had diabetes and was taking gliclazide, aspirin, allopurinol and quinine. His wound had previously been treated with Hydrofiber and hydrocolloid dressings.

On entry, this patient had several small open wounds along the suture line, with a total area of approximately 1.5cm<sup>2</sup>. The clinician described the wounds as shallow with distinct wound margins. They had been static for two months. The wound bed was assessed to be 50% slough and 50% granulation tissue. There were low exudate levels, and the surrounding tissue was healthy.

The wound healed within five weeks. The patient was 'very satisfied' with his treatment experience and rated the dressing as comfortable throughout the study



**The non-healing surgical wounds at the start of the study and (healed) at week 5**



**The pressure ulcer at the start of the study and at week 6**

**Pressure ulcer**

A 90-year-old female presented with a grade 4 pressure ulcer on her left heel of five months' duration. She had had a total hip replacement and deep vein thrombosis and epilepsy. She was taking paracetamol and Fortisip (Nutricia Clinical). Her wound had been treated with sharp debridement, hydrocolloid and hydrogel dressings.

On entry, the ulcer measured 12.5cm<sup>2</sup>. The wound bed comprised 60% thick, stringy slough and 40% granulation tissue, with a low to moderate level of clear wound exudate. The surrounding skin was healthy

At week 6, the wound measured 6cm<sup>2</sup>, a reduction of 48%. The wound bed now comprised healthy granulation tissue

**Venous leg ulcer**

A 94-year-old female presented with two venous leg ulcers on her right leg of six months' duration. She had a medical history of osteoarthritis and mild cardiac disease which had led to mild bilateral leg oedema. She was taking mild diuretics.

On entry, the upper wound measured 7.5cm<sup>2</sup> and comprised 50% slough and 50% granulation tissue, with a low level of clear wound exudate. The lower wound measured 6cm<sup>2</sup> and comprised 80% slough and 20% granulation tissue. The skin surrounding both wounds was dry. The test dressing was applied and covered with a film dressing. The patient did not wear compression bandages as she was unable to tolerate them.

After one week the clinician documented an improvement in the condition of both wound beds and the surrounding tissue had rehydrated. Both wounds healed by week 5.

The patient rated the dressing as comfortable and was 'satisfied' with her treatment experience



**The venous leg ulcers at the start of the study and healed at week 5**

**References**

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Six patients were withdrawn due to pain or discomfort during treatment. This is at odds with the widespread perception that hydrogels are cooling, soothing and comfortable, particularly for burns and venous leg ulcers.<sup>4</sup> However, just over half of the patients (53%) indicated that the dressing was comfortable or very comfortable. It is not known whether the withdrawn patients had experienced high levels of pain before recruitment into the study.

The overall number of patients who withdrew from the study was unexpected, given the patient population and the range of wound types.

Further investigation is needed to verify whether the patients reporting discomfort/pain attributed it to the dressing or the wound. Future studies will elicit more detailed information to establish whether the test dressing influenced the patient's pain experience. More detail on the use of analgesia will also be requested.

Eighty-two percent of the clinicians indicated that the test dressing was either better or much better than previous dressings used. Not surprisingly, the clinicians whose patients did not respond well to the treatment were less impressed. Overall, 85% of patients were satisfied or very satisfied with the dressing.

Study limitations include: lack of a control group; differences in 'best practice' procedures at the various clinics; and inter-clinician variability in the wound assessments, many of which were subjective.

### Conclusion

This case-series study provides a valuable insight into the performance of Oxyzyme in real-life clinical settings.

### Clinicians/centres involved in the study

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**Table 5. Patient satisfaction**

Wound type	Not satisfied	Satisfied	Very satisfied
	No. (%)	No. (%)	No. (%)
Arterial leg ulcer	1/12 (8%)	4/12 (33%)	7/12 (58%)
Diabetic foot ulcer	0/12 (0%)	5/12 (42%)	7/12 (58%)
Mixed aetiology leg ulcer	1/12 (8%)	8/12 (67%)	3/12 (25%)
Other chronic wounds	3/6 (50%)	11/6 (7%)	2/6 (33%)
Pressure ulcer	1/11 (11%)	2/11 (22%)	6/11 (67%)
Venous leg ulcer	7/37 (19%)	15/37 (41%)	15/37 (41%)
<b>Total</b>	<b>13/88 (15%)</b>	<b>35/88 (40%)</b>	<b>40/88 (45%)</b>

A surprisingly large number of the intractable wounds either healed or started on a healing trajectory within the six-week treatment period, while 82% of clinicians considered the dressing to be better or much better than other advanced dressings previously used. In many cases, the investigating clinicians noted that the dressing triggered an improvement in the wound bed during the first week, removing slough and encouraging a healthier appearance.

Further studies are being undertaken with other indications, including acute wounds such as burns, surgical wounds and graft sites. ■

### Authors' roles

Lisa Wood and Zoe Wood monitored the practical conduct of the case studies, helped with the assessments and gathered and verified the data. Andrew Eaton and John Wilkins collated the data. Prof Paul Davis and John Wilkins drafted the paper