

Kerraboot[®] vs Allevyn for treating diabetic foot ulcers

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Abstract

Background: Diabetic ulcers are slow to heal and may result in amputation in 10–25% of patients. Kerraboot[®] was designed to encourage granulation, remove exudate away from the wound and enhance patient comfort during dressing changes. **Aims:** In this study of 32 patients, the acceptability of Kerraboot[®] for the management of diabetic foot ulcers was compared to standard wound care treatment, Allevyn[™] by patients and healthcare workers. **Methods:** Questionnaires were completed by patients and healthcare workers to assess acceptability of dressing and impact on quality of life. **Results:** Kerraboot[®] was better than Allevyn[™] in terms of ease of application and removal, convenience and resource utilisation. A 50% reduction in the time taken to change the dressing was noted in the Kerraboot[®] group (mean = 6.8, SD= 4.66 minutes vs Allevyn[™], mean= 9.9, SD= 3.78 minutes; P=0.017). By the first week, 85.7% of the patients in the Kerraboot[®] group were able to change their dressing independently of nurses compared with 62.5% in the Allevyn[™] group. **Conclusions:** Although there was no difference in healing rates between the groups, in the non-healing wounds there was a noticeable difference in the reduction of slough and increase in granulation tissue in the Kerraboot[®] group compared to Allevyn[™]. **Declaration of interest:** Dr M Edmonds is a member of the ARK Therapeutics Advisory Panel.

KEY WORDS

Diabetes nursing
Dressings
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Lower limb ulceration is a common complication of diabetes with the financial costs estimated at £250 million each year in the UK alone (Gordois et al, 2003). Unfortunately, the time taken for foot ulcers to heal

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can be prolonged and some may never heal, with up to 15% of individuals being treated by amputation (Larsson et al, 1995).

Kerraboot[®] (Ark Therapeutics, London) was designed to improve the treatment outcomes of lower limb ulcers. It is a non-contact, non-pressurised, boot-shaped, wound-healing system that comprises a transparent, five-layered, laminate film with a highly absorbent pad in the sole of the boot. The opening of the boot is padded internally and has an elastic Velcro strap to secure the boot around the leg. The product is provided in sterile packs.

Kerraboot[®] facilitates removal of exudate from the wound surface while providing a warm, moist, protective environment to encourage granulation (Williams and Armstrong, 1998). Previous studies have shown that Kerraboot[®] may be useful for the treatment of moderate to severe lower limb ulcers of various aetiology in terms of convenience, ease of application and removal, comfort, and wound odour (Barker et al, 2001; Leigh et al, 2004).

Allevyn[™] (Smith and Nephew, Hull) is a hydrocellular foam dressing that is

used extensively in the UK to manage chronic wounds. It is composed of a foam-based central layer and a bacteria- and water-proof outer layer. It absorbs excess wound exudate and maintains a warm moist environment.

Aims

The primary objective of this study was to compare the use of Kerraboot[®] with Allevyn[™] in terms of patient and healthcare professional acceptability, when used to manage diabetic neuropathic foot ulcers. The secondary objectives were to:

1. Evaluate the healing rates of Kerraboot[®] and Allevyn[™], a commonly used standard foam dressing
2. Evaluate the safety of Kerraboot[®]
3. Compare the healthcare resource requirement for Kerraboot[®] and Allevyn[™].

Patients and methods

This was a five-centre study in the UK involving 32 patients with diabetes who were aged ≥ 18 years of age with neuropathic foot ulcers ($\geq 0.25\text{cm}^2$) of more than 14 days duration. Only one foot was assessed, although the included foot could have multiple ulcers, of which the largest three were evaluated.

Patients had to have adequate arterial perfusion, assessed by the ability to palpate both the dorsalis pedis and posterior tibial arteries, one of which had to have biphasic flow when assessed using a hand-held Doppler with an 8MHz probe.

Exclusion criteria included: steroids or immunosuppressant users; renal impairment (creatinine levels $\geq 180\mu\text{mol/l}$ [2mg/dl]); uncontrolled diabetes (recent glycosylated haemoglobin [HbA_{1c}] $> 11\%$); claudication or rest pain; history of, or current alcohol or drug abuse; any allergy to the components of Kerraboot® or Allevyn™; clinical infection of the ulcers at the beginning of the study, or inpatient treatment at the time of recruitment.

Methods

Patients were randomised either into the Kerraboot® or Allevyn™ group. Site-specific randomisation schedules were provided to each site by the study statistician in individual sealed envelopes.

The study consisted of five once-weekly visits (baseline and visits one to four) to the clinic facility where a questionnaire was completed by both

the patient and healthcare workers to assess acceptability of the dressing. A quality of life (QoL) questionnaire (based on the Cardiff Wound Impact Schedule) (Price and Harding, 2004) was also completed at the baseline visit and on the final week visit (visit four). Ulcers were debrided (using sharp debridement) before beginning treatment at the baseline visit. At each visit, ulcers were debrided, cleaned and assessed. Between visits, dressings were changed every other day or as frequently as required by either healthcare workers or the patient.

The primary objective of this study was to compare Kerraboot® with Allevyn™ for the management of neuropathic foot ulcers in terms of patient and healthcare worker acceptability. This was measured by:

- ▶▶ Time required for dressing change
- ▶▶ Resource utilisation
- ▶▶ Convenience
- ▶▶ Ease of dressing application and removal.

The secondary objectives were to assess the clinical efficacy in terms of mean changes in ulcer size/severity, QoL and safety profile for each of the treatments.

The protocol was approved by the local and central ethical committees and informed consent was obtained from each patient.

Statistical analysis

A total of 32 patients entered the study, two dropped out of the Kerraboot® group (one on the request of patient and one on request of the investigator) and four dropped out of the Allevyn™ group (three from healed ulcers and one because of a protocol violation). Evaluation for safety was carried out on 32 patients and evaluation for efficacy was carried out on 30 patients (14 on Kerraboot® and 16 on Allevyn™).

Analysis populations

Two analysis populations were defined: an 'intent-to-treat' (ITT) population and 'evaluated for safety' (EFS) population. The EFS population consisted of all patients who were randomised and used in the safety analysis. The ITT population was defined as those patients who were randomised and had at least one efficacy assessment, and were used in the efficacy analysis. A valid efficacy assessment was considered to be when at least one question on either the healthcare worker questionnaire or the patient questionnaire had been completed.

Statistical methods

Statistical analyses were performed using SAS version 8.2 or later. Where appropriate, categorical variables were summarised by presenting the number and percent of observations in each category. Continuous variables were summarised by presenting the number of patients in the category, the number of observations, means, standard deviations, medians and the minimum and maximum values. Data were listed in full by treatment group and randomisation number.

Results

Time for dressing change by healthcare workers

The time required by healthcare workers to change dressings at each visit was significantly shorter for Kerraboot® than Allevyn™ (Table 1). The mean time for the last observed value for Kerraboot® was 6.8±4.66 minutes

Table 1

Time required for dressing changes by the healthcare worker

Visit		Kerraboot™ n=14 (100%)	Standard dressing n=16 (100%)
Visit 1	Number of values (%)	13 (92.9)	15(93.8)
	Mean ±SD (min)	5.7±4.01	10.2±3.53
	Range	2-15	5-15
Visit 2	Number of values (%)	13 (92.9)	13(81.3)
	Mean ±SD (min)	5.7±2.72	11.3±4.33
	Range	2-10	5-20
Visit 3	Number of values (%)	13 (92.9)	12 (75.0)
	Mean ±SD (min)	6.1±3.52	10.3±3.15
	Range	3-15	5-15
Visit 4	Number of values (%)	13(92.9)	12(75.0)
	Mean ±SD (min)	6.7±4.84	10.3±3.98
	Range	2-20	5-15
LOV	Number of values (%)	14 (100)	15 (93.8)
	Mean ±SD (min)	6.8±4.66	9.9±3.78
	Range	2-20	5-15

LOV=Last observed visit

compared to 9.9 ± 3.78 minutes for the standard dressing ($P=0.017$).

Resource utilisation

The healthcare resource utilisation was also assessed in terms of time taken for patients to change their dressings, time required and the reason given for healthcare professional visits. The main difference was in the time to change dressings by the healthcare workers, which was a median of 5 minutes for Kerraboot® (range 2–20 minutes) compared to 10 minutes (range 5–20 minutes) for the Allevyn™ dressing.

By the first week, 85.7% of the patients in the Kerraboot® group were able to change their dressing independently of nurses, compared with 62.5% in the Allevyn™ group. By the end of 2 weeks, 100% of the patients in the Kerraboot® group were able to change their dressing independently of nurses compared with 92.3% in the standard group (Figure 1).

Convenience

Patients were asked to rate the use of the dressing at each visit as very convenient (+2), convenient (+1), or inconvenient (-1). The majority of patients reported that they found Kerraboot® convenient or very convenient. The mean score for convenience at each visit was similar between the groups for patients (Figure 2).

Ease of dressing application/removal

Patients were asked to rate the ease of dressing application/removal as very easy (+2), easy (+1), difficult (-1) or very difficult (-2). At all visits, most patients considered Kerraboot® as easy/very easy to apply. The mean score for the dressing application at each visit was higher for Kerraboot® (range: 1.5–1.8) compared to the standard (range: 1.1–1.6) (Figure 3); this did not reach significance.

Kerraboot® rated as very easy to remove. The mean score for dressing removal was higher for Kerraboot® (range: 1.5–1.8) compared to the standard dressing (range: 1.4–1.6) (Figure 4); however, this did not reach significance.

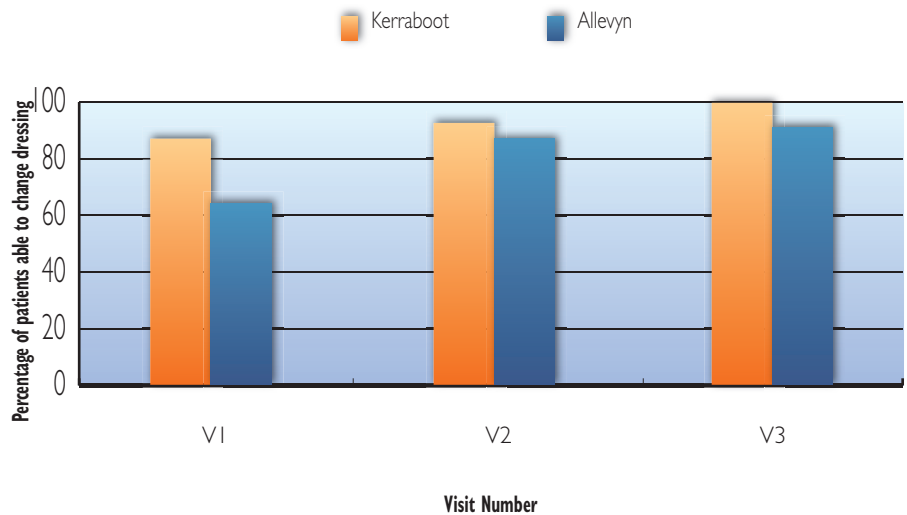


Figure 1. Number of patients able to change their dressings at baseline, and visit one, two and three.

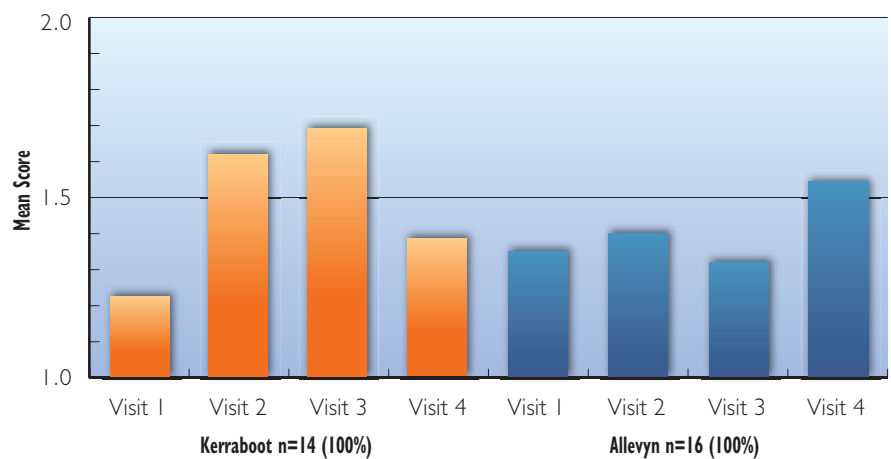


Figure 2. Mean scores for convenience at each visit: patient questionnaire.

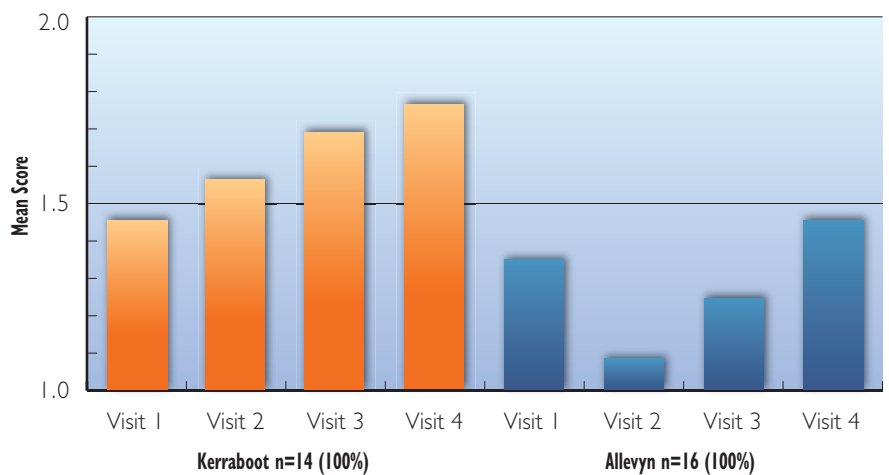


Figure 3. Mean scores for ease of dressing application at each visit: patient questionnaire.

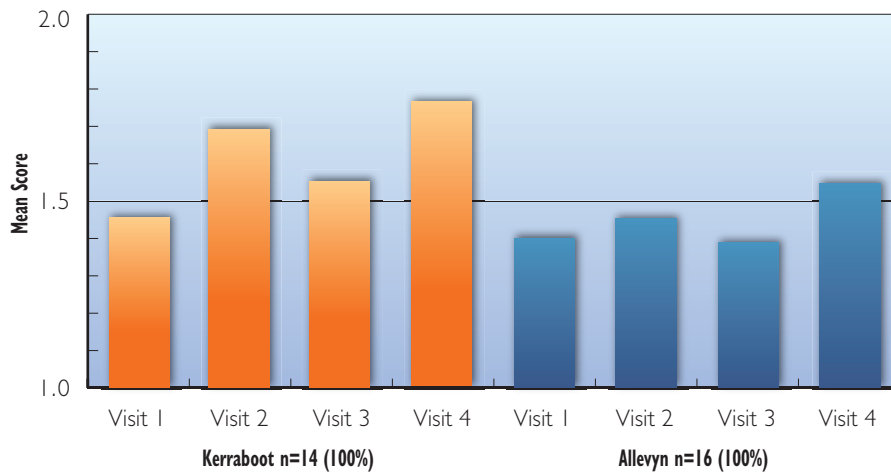


Figure 4. Mean scores for ease of dressing removal at each visit: patient questionnaire.

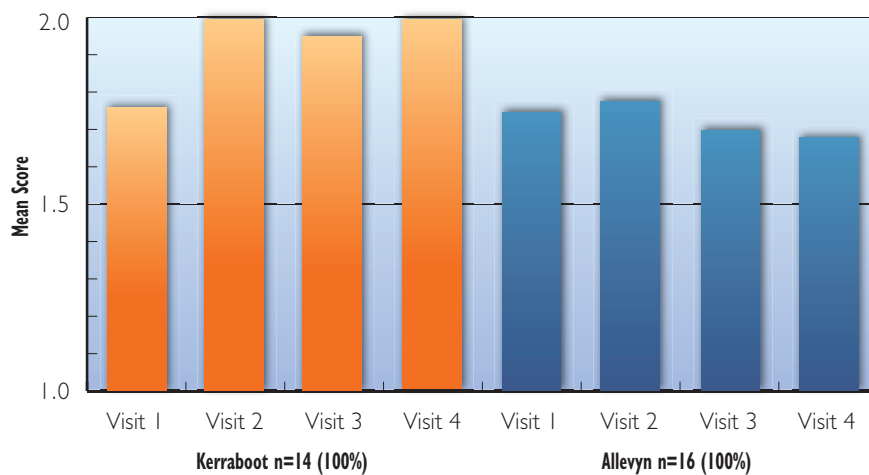


Figure 5. Mean scores for ease of dressing application at each visit: healthcare worker questionnaire.

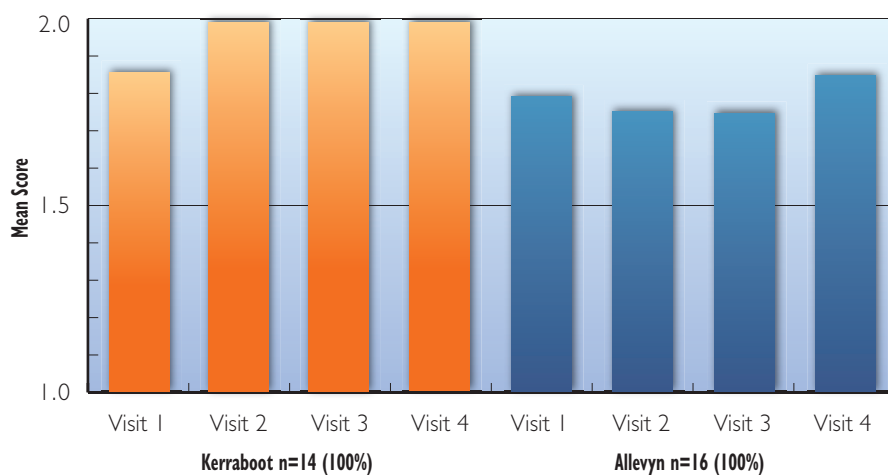


Figure 6. Mean scores for ease of dressing removal at each visit: healthcare worker questionnaire.

The results observed for ease of application/removal of dressing for the patients was also reflected in the assessment of the healthcare workers. The mean score for ease of dressing application was higher for Kerraboot® (range: 1.8–2.0) compared to Allevyn (range: 1.7–1.8) (Figure 5). The mean score for ease of dressing removal was also higher for the Kerraboot® (range: 1.8–2.0) compared to standard dressing (range: 1.8–1.9) (Figure 6).

Clinical efficacy

Ulcer size reduced to the same extent in both groups (Figure 7); however, it should be noted that the only ulcers to heal in the Allevyn™ group were newly established ulcers whereas Kerraboot® healed both newly formed ulcers and those that had failed to heal with previous standard care.

Patients in the Kerraboot® group were in general heavier (Kerraboot® = 100.46±18.19kg vs Allevyn™ 94.39±26.48kg) with larger ulcers at baseline (Kerraboot®=1.66±1.92m², range 0.30–7.00cm² vs Allevyn™ 1.33±1.64cm², range 0.22–5.50cm²). In addition, despite the fact that more wound slough was reported at entry in the Kerraboot® group than in the Allevyn™ group (see Table 2), by visit three the slough in the Kerraboot® group had reduced and was comparable to that in the standard group for the rest of the study (Table 2).

Safety profile

A total of 69 adverse incidents (AIs) were reported in 19 patients. Fifty-one AIs occurred in 11 patients in the Kerraboot® group. Eighteen AIs occurred in eight patients in the standard dressing group. The most common AIs were: headaches (five in four patients in Kerraboot® group), toe pain (three in three patients in Kerraboot® group), infections in ulcer (two in two patients in standard group), application site rash (two in two patients in standard group), dermatitis (two in two patients in Kerraboot® group) and general rash (two in two patients in Kerraboot® group).

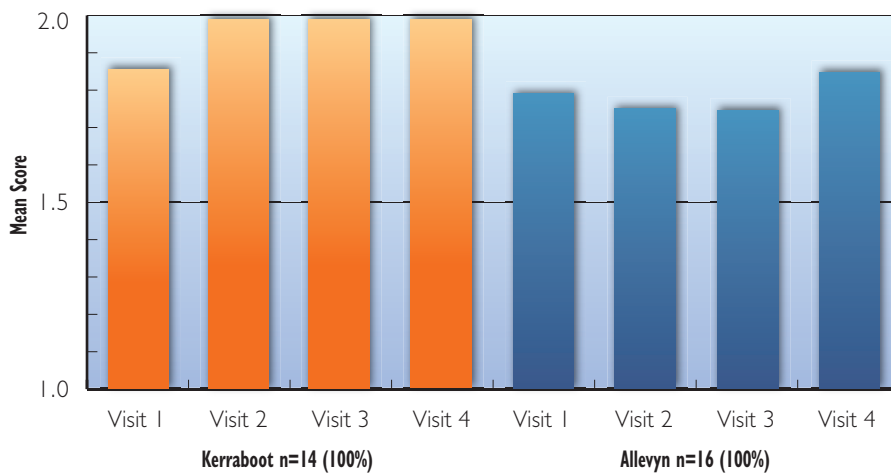


Figure 6. Mean scores for ease of dressing removal at each visit: healthcare worker questionnaire.

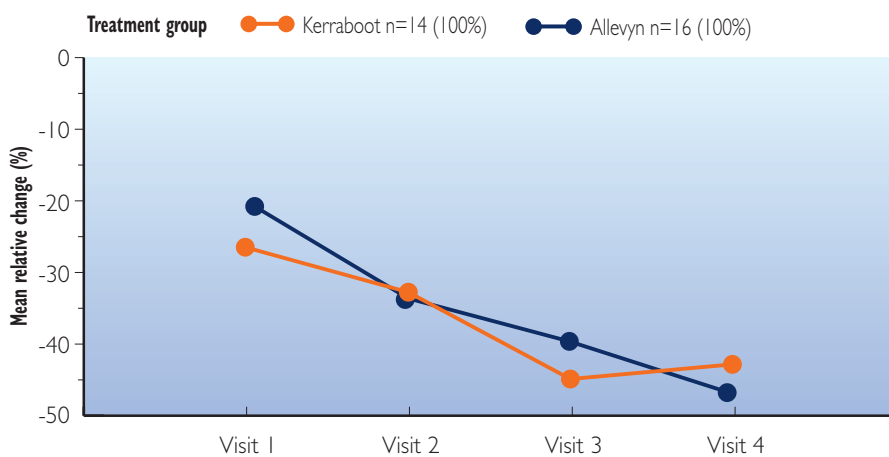


Figure 7. Mean healing rates.

Most AIs were mild/moderate in severity except for blurred vision, chest infection and one case of osteomyelitis in the patients treated with Kerraboot® (possibly pre-existent) and severe toe pain in the Allevyn™ group. In the Kerraboot® group, eight patients had AIs, possibly or probably related to treatment, and in the standard care group there was one patient. No deaths occurred. These AI reports for Kerraboot® gave no cause for clinical concern in the opinion of the investigator who considered that the majority of the reported AIs were not related to the use of Kerraboot®.

Discussion

This study has shown that Kerraboot® resulted in less healthcare resource utilisation than the standard treatment, Allevyn™. The time of dressing change was significantly reduced with Kerraboot® compared with Allevyn™ throughout all four visits. This reduction in time was confirmed when comparing time assessments by healthcare workers.

The design of Kerraboot® also enhances patient comfort by improving the ease of handling during dressing changes, reducing odour and allowing assessment of the ulcer without the need to remove the dressing. By the

end of two weeks, 100% of the patients in the Kerraboot® group were able to change their dressing independently of nurses; a factor that could significantly reduce resource costs.

There was a marked improvement in convenience for visits two to three with Kerraboot® compared to the standard treatment in the patient population. In the healthcare worker population, there was a small but consistent improvement reported by patients after visit one, once they had got used to the new dressing.

When the acceptability was assessed in terms of ease of dressing application, there was an improvement among both patients and healthcare workers for Kerraboot® compared with Allevyn™. Although this was not significant, the pattern was observed throughout all four visits and again repeated for ease of removal.

Kerraboot® achieved similar healing to standard treatment with increases in convenience and acceptability. Despite the greater severity of ulceration for the Kerraboot® group at baseline, there was a comparable decrease in mean ulcer size in both treatment groups. The higher rate of slough in the Kerraboot® group reduced and was comparable to standard care from visit three onwards. The overall healing profile by the end of the 4-week study period favoured the Kerraboot® group when complete healing and the amount of increased granulation were taken into consideration.

Although healing was a secondary end point and the number of wounds healed were the same in both groups, the non-healing wounds were progressing better in the Kerraboot® group and demonstrating a better healing profile in terms of wound appearance, reduction of slough and increase in granulation tissue formation. This minimizes matrix metalloproteinases in the ulcer; which can inhibit growth factors and therefore prevent neovascularisation and healing (Bucalo et al, 1993; Barrick et al, 1997).

Table 2

Observations on wound slough by healthcare workers

	Kerraboot® n=14 (100%)	Standard n=16 (100%)
Visit 0		
Mean	11.9	7.4
Standard deviation	15.21	12.96
Median	5.5	0
Range	0-50	0-50
Visit 1		
Mean	11.1	2.0
Standard deviation	21.68	6.49
Median	0	0
Range	0-75	0-25
Visit 2		
Mean	4.6	6.5
Standard deviation	13.76	15.23
Median	0	0
Range	0-50	0-49
Visit 3		
Mean	4.8	5.4
Standard deviation	13.78	14.50
Median	0	0
Range	0-50	0-50

Conclusions

The results from this study complement two previous studies (Barker et al, 2001; Leigh et al, 2004). These studies showed that Kerraboot® was an effective treatment for neuropathic and neuroischaemic ulcers. Patients found the dressing more comfortable, convenient to wear and there was less ulcer-related odour. Healthcare workers also rated Kerraboot® as a better treatment in terms of ease of application and removal.

In conclusion, although healing rates are comparable to standard treatment, this study has shown that Kerraboot®

significantly reduces healthcare utilisation costs by a reduction in dressing time and the ability of patients to self-manage dressing foot ulcers. This can be considered an advance in the armamentarium in diabetic ulcer healing. **WUK**

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Key Points

- ▶▶ Diabetic foot ulcers can be problematic.
- ▶▶ Kerraboot offers a self-management alternative.
- ▶▶ This can lead to a reduction in resource utilisation costs.
- ▶▶ Dressing time significantly reduced using Kerraboot.
- ▶▶ Although healing rates were equal, non-healing wounds in the Kerraboot group showed more slough reduction and granulation tissue formation than Allevyn.

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