

# Managing leg and foot ulcers: the role of Kerraboot®

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Leg and foot ulcers are defined as a slow or non-healing breakdown of epidermal and dermal tissue on the foot or below the knee. They frequently last more than 6 weeks and are characterized as chronic wounds. The majority of leg ulcers are associated with venous disease, peripheral arterial disease, mixed arterio-venous disease and diabetes. Ulcers in people with diabetes are caused by a variety of factors, in particular peripheral vascular disease and loss of sensation because of peripheral neuropathy (Pudner, 1998). Furthermore, leg ulceration can promote more serious morbidity leading to eventual limb loss. In diabetes, effective treatment of ulceration is seen as key to the reduction in the number of amputations, as highlighted in the St Vincent Declaration (Anon, 1989).

## The burden of lower limb ulcers

Venous leg ulcers are thought to affect up to 3.5% of the general population (Kerstein, 2003) while 15% of all diabetic patients are affected by foot ulceration at some time (Jiwa, 1997). Women suffer more than men from lower limb ulcers, outnumbering them by a ratio of more than 2:1 (Callam et al, 1985).

The burden of leg and foot ulcers is enormous both

for the NHS and the individual patient. The cost of treating leg and foot ulcers is not simply the cost of a dressing multiplied by the frequency of dressing change, but also includes the nursing time, hospital stay, home health costs, risks and costs of complications, for example infection (Kerstein, 2003). The unit cost of a 1-hour home visit from a district nurse has been calculated to be £56, while 1 hour in the clinic is £40 (Netten and Curtis, 2003). Community clinics have been shown to reduce the burden of leg and foot ulcers on the NHS, releasing district nurse time for other services and to improve healing rates and patients' quality of life (Bosanquet, 1992).

Regardless of aetiology, leg and foot ulcers cause considerable and prolonged distress for patients. Acute pain or continuous aching discomfort is usual, exacerbated with changes of dressings. Often, ulcers become secondarily and heavily infected, with the production of a foul-smelling slough and copious exudate that promote general unhappiness and increasing social isolation, ultimately reducing quality of life. Other issues for patients include restricted mobility, embarrassing dressings, inability to continue working and socializing and interference with bathing and sexual activity (Bauling, 1998).

The duration of the ulcer impacts on the patient and as many as half of all patients will have had their ulcer for longer than a year (Cornwall et al, 1986). Poor patient compliance, which is influenced by many of the above factors, can exacerbate the problem of non-healing ulcers. Once the ulcer has cleared many patients are likely to suffer from recurrent ulcers: in one study of 555 patients, 67% were suffering from recurrent ulcers of which 35% had had four or more episodes (Callam et al, 1987).

## Clinical management

Care for patients with leg and foot ulcers is provided by many different specialties and by almost every element of the health service, with the largest share of the workload falling on the district nurses (Callam et al, 1985). Despite this, more than half of all district nurses questioned in one survey felt their knowledge of wound treatment was inadequate (Haram et al, 2003).

## ABSTRACT

Foot and leg ulcers are chronic wounds characterized by slow or non-healing breakdown of epidermal and dermal tissue on the foot or below the knee. The prevalence is high and ulcers are a significant drain on the NHS in terms of nursing time and cost of dressings, and are incredibly burdensome to the individual patient. This article reviews the evidence for a new wound management system, Kerraboot®, designed for the management of leg and foot ulcers. It is a boot-shaped dressing that completely surrounds the ulcer creating an optimum healing environment. In clinical investigations, Kerraboot® offered patients relief from pain, was comfortable, easy to use and effectively controlled embarrassing odour, while also saving nursing time. Currently, Kerraboot® is recommended for the management of diabetic foot ulcers and venous ulcers where the patient is unable to tolerate compression therapy.

**Key words:** Ulcers, chronic wounds, Kerraboot®, diabetic foot

Figure 1. Kerraboot®.



The Royal College of Nursing (RCN) guidelines for the management of patients with venous leg ulcers (RCN, 1998) state that a health professional trained in leg ulcer management should provide a holistic assessment of the patient. Diagnosis should be based on a thorough clinical history, physical examination, appropriate laboratory tests and haemodynamic assessment, allowing the underlying cause and any associated diseases to be diagnosed.

Use of an appropriate wound dressing is essential and is highly dependent on the ulcer's aetiology. The first line treatment for venous leg ulcers is

compression therapy, although often patients are unable to tolerate these tight dressings on their painful wounds. Arterial ulcers are not suitable for high compression therapy and treatment is directed towards correcting the underlying problem, i.e. surgery to improve the poor arterial blood supply and hasten healing, and careful management of the ulcer. With diabetic foot ulcers, an aggressive multidisciplinary approach to management can assist in the saving of the lower extremity and be cost-effective (Apelqvist and Larsson, 2000).

Since Winter's landmark study of 1962, in which he demonstrated that wounds healed faster with an occlusive dressing rather than by air drying (Winter, 1962), occlusive dressings have been developed that are designed to create a moist micro-environment to promote wound healing. The sheer variety of dressings can be overwhelming for health professionals. Dressings vary according to their composition; the amount of exudate they are able to absorb, whether a secondary dressing is required, and their cost (Table 1). The selection of wound dressings is likely to remain a complex decision with more and more products becoming available as technological advances increase.

**Kerraboot®  
Product overview**

Kerraboot® from Ark Therapeutics is a new type of dressing for leg and foot ulcers described as a 'wound management system' (Figure 1). Available through UK hospitals since November 2003 and listed on the Drug Tariff since May 2004, it provides a completely different approach to existing dressing options in the form of a non-contact, non-pressurized boot-shaped dressing that surrounds the ulcer(s) on the leg or foot, creating an optimum healing environment. The design of Kerraboot® keeps the ulcer moist, warm and protected while maintaining high humidity to encourage granulation tissue and the production of growth factors to aid the healing process. Kerraboot® has a number of key design features that differentiate it from existing dressings (Box 1).

**Clinical evidence**

Clinical evidence for the use of Kerraboot® is growing steadily. Two clinical investigations involving patients with leg and foot ulcers of various aetiologies, severity and duration have already been published (Barker et al, 2001; Leigh et al, 2004). These were designed to obtain an evaluation from both health professionals and patients on the acceptability of Kerraboot®.

The first study used a prototype boot and involved eight subjects with leg ulcers of various aetiologies

**Table 1. Currently available occlusive dressings**

Category	Key features
Films	Vapour-permeable adhesive dressings Do not absorb exudates Used as secondary dressing only
Foams	Polyurethane-based Can absorb large volumes of exudates Generally require secondary dressings
Hydrogels	High water-content dressings Designed to create moist micro-environment Can not absorb large volumes of exudate Require secondary dressings
Hydrocolloids	Made from adhesive, absorbent and elastomeric materials Can absorb low to moderate volumes of exudate Suitable as primary or secondary dressings
Alginates	Made of soft, non-woven fibres derived from seaweed Can absorb large volumes of exudate Require secondary dressings

(Barker et al, 2001). The duration of ulceration ranged from 2 weeks to 6 years. In six cases the boot was changed twice daily for 5 days and in the two remaining cases, twice daily for 2 weeks. The results demonstrated that Kerraboot® was comfortable, easy to use and preferred to standard dressings. Nursing time was greatly reduced; nurses estimated the time taken for standard dressing to be 15–45 minutes, this was reduced to 5–8 minutes with Kerraboot®. Doctors were able to see the wound with ease, although some patients were not happy with the ulcer being visible. Odour was completely eliminated and patients were able to remain ambulant. Although healing was not the primary end point, rapid ulcer healing was noted in the two patients with diabetes who used the boot for 14 days.

In the second study 14 patients were recruited with both leg and foot ulcers (Leigh et al, 2004). Again, the aetiology was varied (neuropathy, neuro-ischaemic disease, arterial disease) and the duration of the ulcer ranged from 0.5–72 weeks. Kerraboot® was changed either every 24 or 48 hours depending on the levels of exudate, for up to 28 days. Patients assessed Kerraboot® as comfortable and convenient to wear, with 85% reporting it as 'better' or 'much better' than their previous dressings (Figure 2). The time to change the boot was reduced by up to 70%, with 2 minutes being the minimum time to change. Ulcer-related odour was almost entirely eliminated. Healing was not a primary end-point, although it should be noted that no ulcer increased in size, and the neuropathic and neuro-ischaemic ulcers showed a marked reduction in size. Health professionals rated Kerraboot® as easy to apply and remove, and as being 'better' than standard dressings with regard to skin presentation and their overall assessment.

In addition to the savings in nursing time, these studies also demonstrated the patient benefits of Kerraboot®, namely comfort, ease of use, relief of pain associated with dressing change and control of embarrassing odour. In short, Kerraboot® provided a major advance compared to current dressings by reducing patients' dependency on health professionals, so allowing them to regain control and improving their quality of life.

Two further clinical studies are in progress with Kerraboot® from which data should be available by the end of 2004. These are a controlled, comparative study to investigate use of the Kerraboot® in patients with diabetic neuropathic ulcers compared to a standard management protocol, and a pilot study examining the use of the Kerraboot® in patients with venous ulcers for whom compression therapy is inappropriate.

### Box 1. Kerraboot® key design features

- A durable, multi-layer film that allows the wound to be inspected without disturbing the granulation tissue and provides an effective barrier to odour
- An absorbent pad to draw exudate away from the wound to encourage healing and help combat superficial infection
- An easy to fasten Velcro strap that enables quick, convenient and pain free dressing changes
- A non-slip sole to provide added security for the patient when mobile

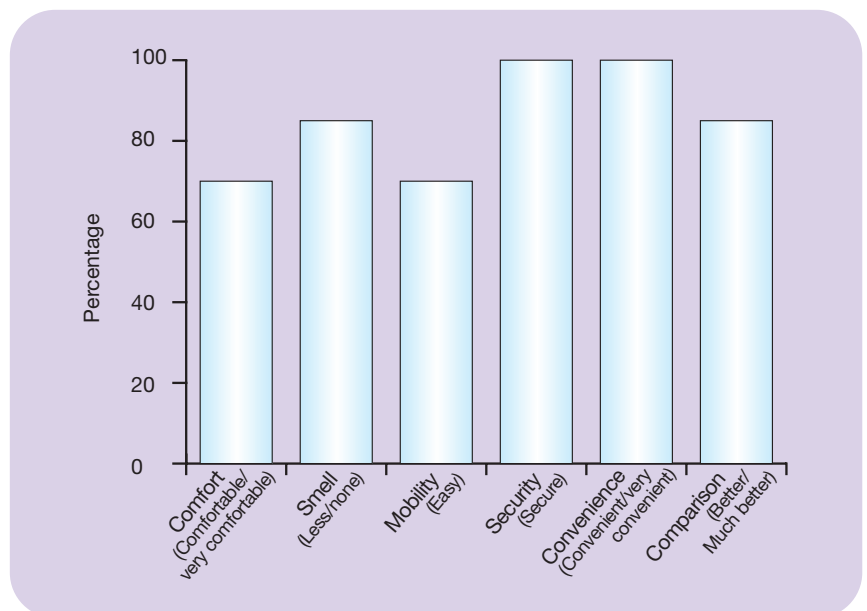
### Product experience

Since its launch at the end of 2003, an open patient evaluation programme has been in progress to assess use of Kerraboot® in hospitals and the community. This is an ongoing programme that has involved, to date, over 55 patients with a range of ulcer types. Based on the evidence so far, Kerraboot® is being used predominantly to facilitate healing of diabetic foot ulcers (Box 2) and to help improve the ulcer bed in venous ulcers to a point where compression therapy can be tolerated by the patient.

### Conclusion

Despite there being a vast array of dressings available, many patients are still faced with chronic, non-healing ulcers. Kerraboot® is a new wound dressing device scientifically designed to facilitate wound healing in lower limb ulcers, in particular diabetic foot ulcers and venous ulcers when compression therapy is inappropriate or cannot be tolerated. It offers potential benefits to both patients and nurses: patients have a reduced dependency on the nurse and an improved quality of life, while for nurses,

Figure 2. Patient evaluation of Kerraboot® (Leigh et al, 2004). Reproduced with permission of John Wiley & Sons Limited.



**Box 2. Case study: diabetic foot ulcer**

A male patient, aged 56 years, was admitted to hospital with cellulitic ulceration to the right heel. The ulcer was infected with *Pseudomonas aeruginosa* and an arterial duplex scan of the right leg revealed the anterior tibial artery and posterior tibial artery to be patent and heavily calcified, and the peroneal artery to be occluded. The patient's medical history included type 2 diabetes mellitus, hypertension, hypercholesterolaemia, chronic renal failure treated with peritoneal dialysis before renal transplantation, neuroischaemia, retinopathy, previous bilateral foot ulcerations. Previous treatment of the ulcer consisted of intravenous antibiotics and surgical debridement of the necrotic tissue before the wound was treated with Vacuum Assisted Closure (VAC®). Further necrosis occurred and surgery was required to remove the necrotic tissue and infected bone (Figure 3).

The patient refused a below-knee amputation, so conservative treatment of the ulcer was required. Kerraboot® was used to aid granulation and closure of the wound by secondary intention. After 10 weeks of daily Kerraboot® changes with saline irrigation, significant granulation was seen (Figure 4). The patient is currently able to mobilise in Kerraboot® with a pressure relief ankle foot orthosis (PRAFO®) and is being treated at an outpatient clinic.

significantly reducing time on dressing changes. Both patients and nurses have rated Kerraboot® as better than previously used dressings. Through ongoing clinical investigations and individual patient experience, the clinical benefits and cost-effectiveness of Kerraboot® in managing leg and foot ulcers will be demonstrated. ●

For enquiries about Kerraboot, please contact freephone 0800 1077 107

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Figure 3. Heel after surgery to remove necrotic tissue and bone.



Figure 4. Heel after treatment with Kerraboot®.

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**KEY POINTS**

- Leg and foot ulcers are chronic, non-healing wounds.
- Prevalence is high and places a large burden on NHS resources.
- Kerraboot® is a new type of dressing for leg and foot ulcers.
- It offers benefits to both patients and health care professionals.
- Initial clinical evidence supports its role in managing diabetic foot ulcers.