Management of neuropathic and neuroischaemic leg and foot ulcers: 
A preliminary assessment of a novel wound dressing device; the Kerraboot™

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Abstract

Foot ulceration remains a significant burden in diabetes. Healing can be frustratingly slow, time-consuming and costly. The Kerraboot™ is a novel wound dressing that provides a warm, moist, protected environment conducive to wound healing. This study assessed its use in the treatment of lower limb ulceration.

Fifteen acute/chronic leg and foot ulcers of neuropathic and neuroischaemic aetiology were dressed for 28 days solely with the Kerraboot™. Dressings were changed at 24 or 48 hour intervals by healthcare workers or by patients competent in application. Applicants completed weekly questionnaires to assess ease of administration, patient comfort and acceptability. Ulcer size and healing was recorded.

Over the study period all ulcers reduced in size: 82% by up to 50% and 18% by over 50%. Ulcer related odour was virtually eliminated. Of the patients asked (n=7) all reported that the Kerraboot™ was ‘convenient’ and ‘secure’. Six of these seven patients reported that the Kerraboot™ was ‘better’ or ‘much better’ than previously used dressings. Healthcare professionals confirmed the ease of application and removal. No serious adverse events were reported in the use of the Kerraboot™.

These results confirm the utility and safety of the Kerraboot™ as an alternative wound dressing in the management of leg ulcers.

Introduction

Ulcerations of the leg and foot can cause pain and disability affecting a patient’s quality of life. This places a significant burden on healthcare resources in in-home visits, dressing changes, debridements and cleansing of chronic wounds, where healing rates are protracted and outcomes often poor. Diabetic foot ulceration can be particularly difficult to heal, often taking several months. The healthcare priority of the ‘St Vincent declaration’ (1989) to halve the rate of amputations in patient with diabetes by 2010 has not yet been seen. This emphasises the need for new approaches to wound care.

Kerraboot™

Kerraboot™ is a boot shaped dressing constructed from a multi-laminate plastic containing a super-absorbent, sodium polyacrylate-derived pad.

The key elements of Kerraboot™ are:

- to provide a warm, moist and protected wound healing environment to promote granulation and healing.
- a super-absorbent pad to remove excess moisture and contain exudate.
- a textured base to prevent slipping during patient mobilisation.

Methods

Inclusion criteria: Patients aged 18 or over with neuropathic, neuro-ischaemic or arterial ulceration on the leg or foot. Inpatient for at least 48 hours after the commencement of the study and were capable of self-application of the Kerraboot™.

Patients with venous ulcers excluded.

The protocol was approved by the joint University College London/University College London Hospital Committee on the Ethics of Human Research.

The Kerraboot™ was applied and changed either every 24 hours (n = 5) or every 48 hours (n = 9) based on clinical need (this was often determined by the amount of exudate). No other dressing was used.

Dressings were applied for 28 days, at which point patients completed a questionnaire to assess comfort, acceptability, mobility, security and convenience. Health professionals completed a questionnaire assessing ease of management.

Results

Fourteen patients with 15 ulcers entered the study (9M: 5F; age range 37 - 92 years). Aetiology of the ulcers: 3 neuropathic, 5 neuro-ischaemic, 6 arterial.

Mean duration of ulcer at entry was 20.5 weeks (range 0.5 - 75 weeks) and the mean ulcer size at entry was 25.4 cm² (range 0.5 - 94 cm²).

Six patients completed the full 28 days of application.

Four patients completed 14 days of application:

- Two patients’ with neuropathic ulcers sufficiently granulated to allow skin grafting.
- Two patients withdrew due to vascular complications.
- Four patients withdrew before the first evaluation visit:
  - One patient required surgery for a deep foot abscess.
  - Two patients were withdrawn due to vascular complications.
  - One patient died from aspiration pneumonia.

All patients in whom complete follow up data are available (n=7) assessed the Kerraboot™ as convenient and secure.

Acceptability: 6 out of 7 patients reported that the Kerraboot™ was “better” or “much better” than their previous dressing. 5 reported mobility as “easy” and 5 reported comfort as “comfortable” or “very comfortable”. Ulcer-related odour was almost entirely eliminated. Healthcare professionals confirmed the ease of application and removal of the Kerraboot™.

The mean time taken to change the boot was 7.6 minutes at week one (range 2 - 35 minutes) and 8.2 minutes (range 2 - 20 minutes) at the final assessment. The dressing was well tolerated with no protocol-emergent serious adverse events reported.

Healing: (See Figure 1) No ulcers increased in size during the study. A marked reduction in size occurred in neuropathic or neuro-ischaemic ulcers (from 17.3 cm² to 13.3 cm²) whereas the arterial ulcers remained more static (from 21.5 cm² to 20.5 cm²).

Figure 1: Patient with diabetic neuropathic foot ulceration. Kerraboot™ applied every 48 hours.

Summary

Patients found the dressing comfortable and convenient to wear. Ulcer-related odour was almost entirely eliminated. Healthcare professionals confirmed the ease of application and removal and most rated the Kerraboot™ as better than previously used dressings. Kerraboot™ appears to be an appropriate dressing for use in neuropathic and neuro-ischaemic ulcers. These ulcer types showed a marked reduction in size during the trial.

The majority of patients who withdrew from the study had severe arterial complications. Arterial ulcers of patients who completed the study remained static following application of the Kerraboot™.

The Kerraboot™ may be a significant new type of dressing for use in the management of patients with neuropathic ulceration.