

The effect of specialist footwear on the quality of life of patients with lower leg ulcers

Abstract

Background: In the UK, patients with lower limb ulcers requiring specialist medical footwear can usually only access it via secondary care, e.g. a diabetic foot clinic or podiatry service. In primary care, this type of footwear for patients who have to wear bulky bandages or dressings as part of their treatment is often not available. **Aim:** This study aimed to assess whether there was a change in quality of life for patients with lower limb wounds, when provided with specialist medical footwear. **Methods:** Twelve patients with foot or lower limb ulcers were provided with Kerraped® specialist footwear and the Cardiff Wound Impact Schedule was used to assess the effect of the footwear on 3 domains of quality of life: 'physical symptoms and daily living', 'wellbeing' and 'social life'. **Results:** In patients with foot or lower limb ulcers with no previous access to medical footwear devices, changing from their own sourced footwear to wearing Kerraped® resulted in a marked improvement in two of the three key quality of life domains of physical symptoms and daily living (10.7% improvement) and wellbeing (11.1% improvement) within two weeks. There was a slight increase in the social life domain (2.4% improvement). **Conclusion:** This study showed improvement in two key quality of life domains indicating that provision of specialist footwear would be of benefit to patients with lower limb wounds, whether in primary or secondary care. **Conflict of interest:** Richard Leigh is a Member of the advisory panel to Ark Therapeutics and Steven Barker is a former co-founder of Ark Therapeutics.

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KEY WORDS

Medical footwear
Health-related quality of life
Wound care
Off-loading

The wearing of inappropriate or inadequate footwear is well recognised as being a factor in chronic diabetic foot ulceration (Uccioli et al, 1995; The International Working Group on the Diabetic Foot, 2003; Nixon et al, 2006) as well as being associated with, or the cause of, instability and consequent falls (Barbieri, 1983; Gabell et al, 1985; Sherrington and Mentz, 2003; Jessup, 2007). Falls and ulceration of the lower limb and foot are documented as being a large financial burden to the NHS

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as a result of increased hospitalisation cost and social care (Parrott, 2000; Gordois et al, 2003; Ragnarson et al, 2005). However, a recent audit of four primary care trusts found that 66% of patients attending primary care leg ulcer clinics were wearing inappropriate footwear for their wound (King and Wesley, 2007).

Kerraped®, (Figure 1), is one of a number of offloading/accommodative devices which may be selected for routine use in the hospital setting (Van Scie, 2005). Unfortunately, for some patients there can be difficulty in accessing such devices in primary care due to a lack of alignment in demand and supply with the procurement of goods by the NHS (Cox et al, 2005).

This study was carried out in an attempt to provide evidence, where no similar evidence exists, for the procurement of specialist medical footwear by all practitioners providing lower limb wound care, in both primary and secondary care, in order to improve patient quality of life.

Objectives

The objective of this study was to determine the effect of supplying a specialist medical footwear device (Kerraped®) on the quality of life of foot or lower limb ulcer patients attending either the podiatry or leg ulcer clinics at University College Hospital, London. With specialist medical footwear devices not available on prescription, most lower limb ulcer patients who wear bulky dressings and are treated in primary care source and adapt their own consumer footwear in an attempt to find a way to walk. This footwear may be inadequate



Figure 1. Kerraped®, specialist medical footwear for patients with lower limb ulcers.

Table 1
Patient demography

		Number	%
Age (years)	< 65	2	17
	60–69	2	17
	>70	8	66
Gender	Male	5	42
	Female	7	58
Wound site	Legs	7	58
	Feet	5	42

or inappropriate and can affect the patient's quality of life. Offloading and accommodative footwear is routinely used in hospital settings, for patients

referred from community clinics requiring wound care management. This footwear offers a degree of offloading in patients with diabetic foot ulcers (Van Scie, 2005) and in the leg ulcer clinic where bulky bandaging of oedematous limbs often causes problems for the patient with wearing normal footwear (Heinen et al, 2007).

Methodology

Sample

Twelve subjects were entered into the study. The demography of the patients is shown in Table 1. Patients were newly presenting referrals to the outpatient clinics for wound care treatment. Participants were mobile and required bulky bandaging because

of a foot ulcer or a lower-limb ulcer associated with oedema. The patients had previously been sourcing and adapting their own footwear in the community before receiving Kerraped specialist medical footwear. To avoid bias, they were asked what type of footwear they had used to date. All subjects naïve to specialist medical footwear were accepted into the trial over a 6-week period. Participants had previously worn: deck shoes (n=1); trainers (n=1); slippers (n=3); sandals (n=5) and extra large shoes purchased by catalogue (n=2).

Patients entering the trial agreed to using Kerraped specialist medical footwear while ambulatory both indoors

Physical symptoms and daily living

Have you **experienced** any of the following during the past week?

	Not at all/Not applicable	Seldom	Sometimes	Frequently	Always
Disturbed sleep					
Difficulty in bathing					
Immobility around the home					
Immobility outside the home					
Leakage from the wound(s)					
Pain from the wound site					
Discomfort from the bandaging/dressing					
Unpleasant odour or smell from the wound(s)					
Problems with everyday tasks (eg shopping)					
Difficulty in finding appropriate footwear					
Problems with the amount of time needed to care for the wound site					
Financial difficulties as a result of the wound(s)					

Physical symptoms and daily living

How **stressful** has this experience been for you?

	Not at all/Not applicable	Slightly	Moderately	Quite a bit	Very
Disturbed sleep					
Difficulty in bathing					
Immobility around the home					
Immobility outside the home					
Leakage from the wound(s)					
Pain from the wound site					
Discomfort from the bandaging/dressing					
Unpleasant odour or smell from the wound(s)					
Problems with everyday tasks (eg shopping)					
Difficulty in finding appropriate footwear					
Problems with the amount of time needed to care for the wound site					
Financial difficulties as a result of the wound(s)					

Figure 2. Example of one domain in the CWIS questionnaire (Price and Harding, 2004).

Table 2.
Results of CWIS evaluations

Domain	Baseline score			Score After 2 weeks			Change over Baseline
	Mean	Max	Min	Mean	Max	Min	Mean
Physical symptoms and daily living	35.59	52.08	2.08	39.4	58.3	2.1	3.81(10.7%)
Wellbeing	32.14	64.29	0.00	35.7	64.3	3.6	3.56(11.1%)
Social life	37.50	89.29	0.00	38.4	89.3	0.0	0.9 (2.4%)

and outside. However, concordance measurement was not possible once the patient had left the clinic.

Outcome measurement

The Cardiff Wound Impact Schedule (CWIS) (Price and Harding, 2004) was used to determine specific changes in health-related quality of life (HRQoL) before and after wearing Kerraped. The CWIS is a condition-specific quality of life tool that has been developed at the Wound Healing Research Unit in Cardiff.

The tool underwent testing and review in the paper by Price and Harding (2004) to establish its psychometric properties and the results suggested that the contents of the CWIS is appropriate for individuals with chronic wounds. It was found to have high internal consistency to discriminate between health states and good reproducibility. Each domain (such as 'physical symptoms and daily living') is divided into sub domains (such as 'disturbed sleep') which are graded from 'not at all' to 'always' and ticked by the patient. These grades form a 5 point scale (1 = 'not at all' to 5 = 'always')(Figure 2). The mean differential between baseline and the subsequent result in each domain provide the HRQoL measure for that particular domain. The CWIS is designed to be self-administered and completed on an individual basis. There are no right or wrong answers as the aim is to record the impact of the wound, or wound treatment, on the individual's everyday life.

In this evaluation, patients completed the CWIS questionnaire at the beginning of the study to provide their own baseline control data and then again at the end of the 2-week study

period. Each patient was asked if they were happy and able to complete the questionnaire. A 2-week assessment interval was selected for this group of patients to minimise any confounding effect of wound healing on the HRQoL scores. This ensured that HRQoL outcomes related to the impact of the footwear alone.

Results

All patients completed the questionnaires in full. Results of the responses to the three key domains of physical symptoms and daily living, wellbeing and social life are summarised in Table 2.

Physical symptoms and daily living domain

The physical symptoms and daily living domain assesses a number of everyday living activities including:

- ▶▶ Pain from wound site
- ▶▶ Disturbed sleep
- ▶▶ Immobility outside and around the home
- ▶▶ Problems with everyday tasks such as shopping.

Seventy-five percent (n=9) of the patients who changed from their own sourced and adapted consumer footwear to Kerraped® reported an improvement in the physical symptoms and daily living domain after two weeks (Figure 3). The remaining 25% (n=3) of patients reported the same scores of physical symptoms and daily living domain after two weeks. Overall, following the use of Kerraped, patients reported an average improvement of 10.7% in their physical symptoms and daily living score. This improvement is seen as an increase in mean score (Table 2).

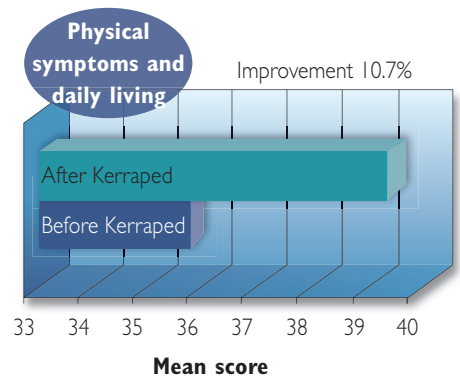


Figure 3. Changes in the 'physical symptoms and daily living' domain.

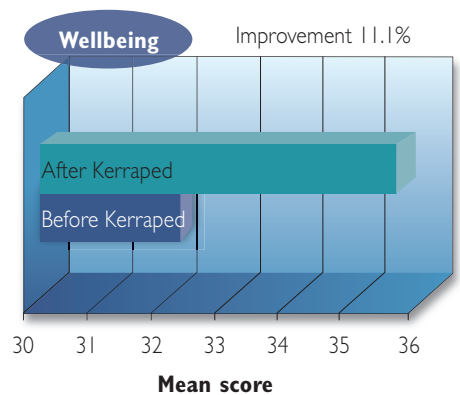


Figure 4. Changes in the 'wellbeing' domain.

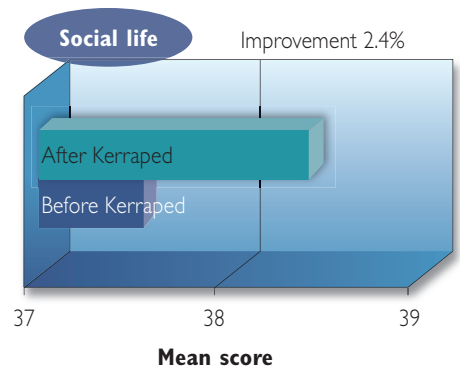


Figure 5. Changes in the 'social life' domain.

Wellbeing domain

The Wellbeing domain focused upon the patient's attitudes in relation to the wound and particularly:

- ▶▶ Anxiety about the appearance of the ulcer
- ▶▶ Anxiety about knocking the wound site
- ▶▶ Anxiety that the wound will not heal.

Sixty-seven percent (n=8) of patients reported an improvement in the wellbeing domain after two weeks of using Kerraped while 33% (n=4) of patients reported no improvement.

Overall, patients reported an average improvement of 11.1% in their wellbeing score following the use of specialist medical footwear (Figure 4).

Social life domain

The social life domain assessed a number of aspects relating to daily living including:

- ▶ Relying more on others
- ▶ Inability to enjoy usual social life (e.g. hobbies)
- ▶ Limited contact with family/friends
- ▶ Wanting to withdraw from people.

In the 2-week study period a small mean improvement of 2.4% was observed in the social life domain. This was anticipated since little significant improvement to the patients' underlying condition was predicted and hence no improvement was expected in the social life assessment score (Figure 5).

Discussion

The wearing of inappropriate or inadequate footwear is associated with falls and delayed healing of lower limb or foot ulcers which are a large cost burden to the NHS (Parrott, 2000; Gordois et al, 2003; Ragnarson Tennvall and Hjelmgren, 2005). Patients with lower limb ulcers frequently depend on referrals to specialist clinics such as those included in this study, to have access to specialist footwear. Unfortunately, not all patients requiring such footwear will be referred and those that are may have a long waiting time before being seen in the clinic.

Comparison of HRQoL data gathered from a small group of patients attending clinics at University College Hospital before and after using Kerraped® specialist medical footwear for two weeks, showed a 10.7% and 11.1% mean improvement respectively in the two key HRQoL domains of physical function and everyday living and wellbeing. Improvements to both of these scores are reflective of the positive clinical advantages specialist medical footwear like Kerraped provides. Although the sample size of this study was small, the results indicate the benefits of using specialist medical footwear on patient HRQoL and

suggests the need for a larger study in primary care to confirm these findings.

Conclusion

The availability of specialist footwear such as Kerraped provides increased postural stability for patients reducing the likelihood of falling (Menz and Lord, 1999; Mentz et al, 2001) and better health-related quality of life as well as improving the probability of faster healing (Edmonds, 2006). The outcome improvements observed in this study indicate that access to appropriate specialist medical footwear such as Kerraped® in primary care could result in marked improvements in the HRQoL for many patients with lower limb and foot ulcers as well as other lower limb disorders that require bulky bandages and dressings. **WUK**

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Key Points

- ▶ Falls and ulceration of the lower limb and foot are documented as being a large cost burden to the NHS.
- ▶ Specialist footwear has not been available from primary care on prescription.
- ▶ Patients with lower limb ulcers often source inappropriate footwear to accommodate bandaging.
- ▶ Provision of specialist footwear can improve patient's health related quality of life.