

The K-Four bandage system: evaluating its effectiveness on recalcitrant venous leg ulcers

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This evaluation examined the effectiveness of the K-Four (Parema) high compression bandage system on 50 patients with recalcitrant 'hard-to-heal' venous leg ulcers and relates the outcome to an earlier randomised study which compared three other four-layer bandage systems.

Twelve-week healing rates were 53.2% in the current series, which included patients with poor mobility, large ulcers and long pretreatment ulcer duration, rising to 69.5% at 20 weeks.

When account was taken of known risk factors for delayed ulcer healing, no significant difference could be identified between either K-Four or the earlier evaluated bandages, which included the original Charing Cross system, where the overall healing rates were 64.5% and 80%, respectively, at 12 and 20 weeks.

It would seem more likely that treatment outcome is related to patient risk factors for delayed healing and bandaging expertise than to the bandage system employed.

0.84–1.5). Analysis of venous Duplex results showed a high proportion of patients with popliteal vein reflux. This has been noted to be associated with delayed ulcer healing.^{3,4} These results are detailed in Table 1.

Results

The limb was only considered healed when all ulcers had healed; in other words, the researchers were concerned with the limb and not the healing of a reference ulcer. Healing rates were 53.2% at 12 weeks and 69.5% at 20 weeks. This is very much in line with expectations, given the shift in the change in the patient population and their higher mean score on the scoring system reported by Margolis et al.²

This product evaluation was conducted using the same withdrawal criteria as in the initial randomised study: any patient requiring a period of treatment with reduced compression was withdrawn, as were patients who were unable or unwilling to continue with this form of treatment.

Five patients were withdrawn during the evaluation but continued to receive compression and four returned to an alternative four-layer compression system (Charing Cross). This incidence of withdrawal (10%) is typical for high compression bandaging tri-

als.^{5,6} One patient died due to myocardial infarction; in this case the ulcer had almost healed (80% reduction in ulcer size). A further four patients initially reported that the new system was less comfortable than the previous bandage regimens used within their clinic or community but these symptoms soon resolved and they chose to continue with the trial system.

The life curve for healing, taking into account the withdrawals, is given in Fig 1. Although no direct comparison can be made with the earlier study, no significant difference was noted between this and the earlier study groups when group comparisons were carried out.

Discussion

The trial bandage system produced acceptable healing in this group of patients with proven recalcitrant ulcers. The change in referral practice which has followed the introduction of local PACE guidelines, and which has been confirmed by local audit, has in turn resulted in a change in the clinic leg ulcer population, with a significant increase in the proportion of patients who have failed to heal with high-compression four-layer bandaging in the community. This can be seen in the clinic's overall ulcer healing rate,

Table 1. Comparison of patient populations in this and the previous study

Bandage system	Previous study ¹			This study
	Charing Cross*	Parema**	Robinson (Ultra-Four)***	Parema (K-Four)****
Age in years (range)	66.4 (39–88)	67.1 (24–88)	68.9 (29–86)	66.8 (23–86)
Male:female	29:31	27:23	23:26	32:18
Recurrent ulcer (%)	35 (70)	33 (66)	33 (67.3)	35 (70)
Duration in weeks (range)	142 (1–1040)	177 (1–2500)	112 (1–1400)	205 (2–2500)
Ulcer size (cm ²) (range)	4.9 (0.5–16.5)	6.76 (0.5–51)	5.8 (1–28)	5.67 (0.5–32)
Mobility				
Ankle (G:M:P) (% poor)	22:16:12 (24)	15:18:17 (34)	20:16:13 (26.5)	17:10:23 (46)
Patient (G:M:P) (% poor)	24:17:9 (18)	19:20:11 (22)	19:15:15 (30.6)	17:12:21 (42)
History of DVT (%)	20 (40)	20 (40)	7 (14)	14 (28)
Duplex popliteal reflux time >1.5 seconds	13 (26)	8 (16)	16 (32)	22 (44)

*Soffban (Smith & Nephew), Crepe (Smith & Nephew), Elset (Seton Scholl), Coban (3M)

** Soffban, K-Lite (Parema), K-Plus (Parema), Coban;

*** Soffast, K-Lite, K-Plus, Cohfast;

**** K-Soft, K-Lite, K-Plus, Ko-Flex

G:M:P=good:moderate:poor; DVT=deep vein thrombosis

In an earlier randomised study the authors compared the clinical effectiveness of three four-layer high-compression bandage regimens for the management of venous ulceration:

- Charing Cross system (CX4L)
- Modified Charing Cross system (Parema)
- Ultra Four (Robinson).¹

The study findings indicated that there were no significant differences in the healing rates of the three systems.¹

This non-randomised follow-up study was conducted at the request of the manufacturer (Parema) of a new bandage system, K-Four, which consists of K-Soft, K-Lite, K-Plus and Ko-Flex, to establish its effectiveness in the treatment of venous ulceration.

Method

Fifty patients who had been referred to the Bradford Leg Ulcer Clinic were invited to take part in the study. The same recruitment criteria were used as in the previous study:¹ patients had to have a venous ulcer, an ankle brachial pressure index above 0.8, an ankle circumference of less than 25cm and be willing to participate in the evaluation of this new product. Ethical committee approval was obtained before the study onset.

As this clinic acts as a tertiary referral centre, most patients had received compression therapy before entering the study. By definition most of the ulcers could be classed as 'hard to heal' as they were either recurrent,

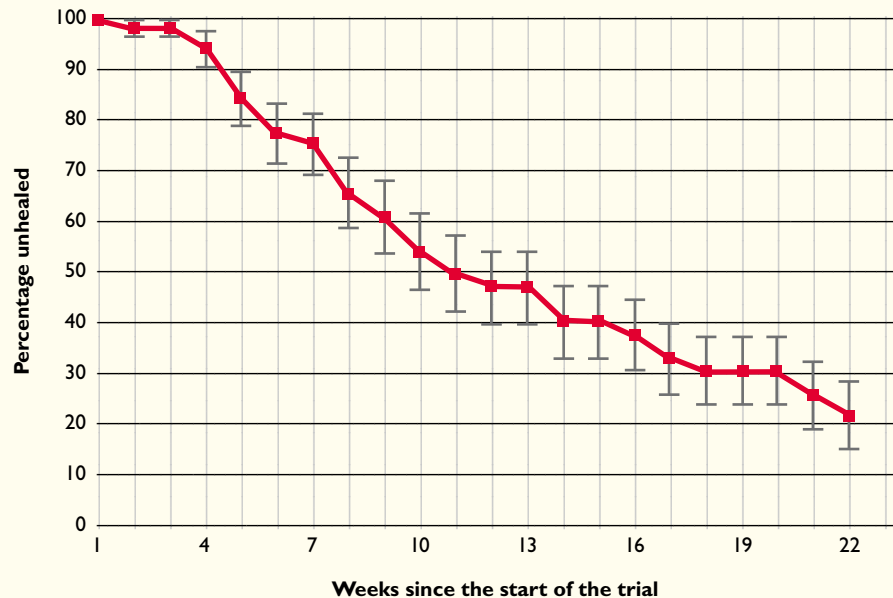
with a previous record of slow healing, or had been treated unsuccessfully elsewhere for a minimum of 12 weeks. This was confirmed by analysing the patient population using the criteria by Margolis et al.,² which are based on a simple scoring system using ulcer size (greater than 5cm) and ulcer duration (more than six months). Applying the criteria by Margolis et al., in the initial study¹ 62% of the patients had a score of 1 or above compared with 78% in the present one.

Four staff were responsible for applying the K-Four bandages. All were trained in the application of four-layer bandage systems and had regularly applied more than 50 bandage systems per week.

The sample consisted of 32 men and 18 women with a mean age of 66.8 years (median: 67; SD: 13.42; range: 23–86). Twenty-four patients (48%) had multiple ulcers on the trial leg. The mean size of the largest ulcer on the study leg at recruitment was 5.67cm² (median: 3.125; SD: 6.26; range: 0.5–32). The mean duration of ulceration before recruitment was 205.3 weeks (median: 32; SD: 523.9; range: 2–2500).

Fourteen patients had a history of a deep vein thrombosis and 35 had recurrent ulcers. Based on the criteria used in the initial study,¹ 23 patients were classified as having reduced or poor mobility and 33 as having fixed or poorly mobile ankles. All patients had an ankle brachial pressure index above 0.8 (mean: 1.1; median: 1.075; SD: 0.13; range:

Fig 1. The healing curve



Box 1. Summary of the main findings of the research study

This non-randomised study aimed to examine the effectiveness of the new K-Four bandage system by Parema on a sample of patients with recalcitrant 'hard-to-heal' venous leg ulcers

Healing rates of 53% at 12 weeks and 70% at 20 weeks were achieved. Such rates would be expected for this patient population and are comparable with those obtained from an earlier randomised study by the same researchers which compared three alternative four-layer bandage systems

The authors conclude that no four-layer bandage system has an advantage over its rivals and state that cost savings can be made by pursuing a competitive purchasing policy

which has dropped from a mean of 62% at 12 weeks to 54% in the past year. At the same time there has been an increase in the mean ulcer size and pre-referral ulcer duration, with most patients receiving at least three months of compression bandaging before referral, as well as overall ulcer duration.

Taking into account the chronicity of the ulcers in the present study, the poor ankle and patient mobility and the ulcer size, these results are comparable with those obtained in the earlier randomised study, which compared three alternative four-layer regimens.¹ These results and those published by other centres show the influence of patient- and ulcer-related factors on ulcer healing.^{2,4,7}

As Nelson states, differences in bandaging techniques and patient characteristics may account for the variation in healing rates reported in bandaging trials.⁸ Bandaging expertise and differences in patient populations are the most likely causes of the differences in treatment outcome. Differences between individual bandages within a four-layer system are unlikely to have a major impact on treatment outcome as the specification and characteristics of the bandages are very similar.

The data obtained in this product evaluation and from our earlier study indicate that no system has an advantage over the others and that cost savings can be made by pursuing a competitive purchasing policy without compromising patient outcome. ■

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