Comparison of the healing rates and complications of three four-layer bandage regimens

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This randomised controlled study compares the healing rates, complications and patient and staff acceptability of three four-layer bandage regimens for leg ulcers. A total of 149 patients were recruited into the study, of whom 50 received the original Charing Cross system (CX4L), 50 a modified Charing Cross system (Parema) and 49 a commercially available kit, Robinson Ultra Four (Robinson).

No significant difference was found in the healing rates of the three systems. Overall 12 weeks' healing was 65%, while the 20-week healing rates for the individual systems were 87% (CX4L), 84% (Parema) and 83% (Robinson). Analysis of known risk factors for delayed healing showed that no bandaging system had an advantage over the others. Staff familiarity resulted in an initial preference for the CX4L but there was no bandage preference by the end of the study. The data suggest that none of the systems has an advantage over the others and that cost savings can be made by pursuing a competitive pricing policy.

Four-layer bandages; Leg ulcers; Healing rates

Leg ulceration, which is associated mostly with venous disease, is a common clinical problem, with the incidence increasing with age. Venous ulcers tend to be chronic and many are present for over one year. Healing rates of ≤30% have been reported,[1-4] although the norm is higher, with 12-week healing rates approaching 70%.[5,6] As venous ulcers are often associated with social isolation, immobility and pain and odour,[7] effective treatment and prompt healing are important.

The value of compression in the healing of venous ulcers has been recognised for centuries, but it was not until the 1980s that increasing understanding of the pathological process involved and improved methods of measuring sub-bandage pressure allowed the development of a safe, effective, multilayer bandage system, the Charing Cross four-layer bandage system.[8] The effectiveness of this type of compression therapy has been recognised in *Effective Health Care*[9] and in national guidelines published in Scotland[10] and the rest of the UK.[11]

Recent changes in the *Drug Tariff* have resulted in a number of four-layer compression systems and alternative bandage products becoming available to both community and hospital leg ulcer managers, yet little or no comparative data are available to assist consumer choice.

This study aims to compare a commercially available kit system (Robinson and Son), which contains a wound dressing, with a modified Charing Cross four-layer system in which crepe (Smith and Nephew) was replaced by K-Lite (Parema) and Elset (Seton Scholl) by K-Plus (Parema). Both systems were compared with the standard Charing Cross system (CX4L), which is the bandage system of choice in our clinic (Table 1). To prevent the need for variation in the bandages, the trial protocol limited recruitment to patients with a venous ulcer, an ankle circumference of <25cm and an ankle brachial pressure index (ABPI) of ≥0.8.

When designing the study it was decided to limit the recruitment phase to one year, which past clinic activity indicated would allow a recruitment sample of 150 patients. Fifty patients were recruited into each arm of the study. This was considered sufficient to identify any major differences in the treatment groups but not to exclude any minor advantages in any of the bandage systems under investigation.

Table 1. Bandage system components

System	CX4L	Parema	Robinson**
Components	Soffban Crepe Elset Coban	Soffban K-Lite K-Plus Coban	Sohfast K-Lite K-Plus Cohfast
Cost	£5.82*	£4.10*	£5.83*

*Exact cost will vary **Includes dressing

Table 2. General patient data recorded in the study

	CX4L (n=50)	Parema (n=50)	Robinson (n=49)
Age in years (range)	66.4 (39–88)	67.1 (24–88)	68.9 (29–86)
Male:female	29:21	27:23	23:26
Recurrent ulcer (%)	35 (70)	33 (66)	33 (67.3)
Duration in weeks (range)	142 (1-1040)	177 (1-2500)	112 (1–1400)
Ulcer size (cm^2) (range)	4.9 (0.5-16.5)	6.76 (0.5-51)	5.8 (1-28)

Table 3. Data relating to the subjects' leg ulcers and their effects

	CX4L	Parema	Robinson
Mobility			
Ankle (G:M:P) (% poor)	22:16:12 (24)	15:18:17 (34)	20:16:13 (26.5)
Patient (G:M:P) (% poor)	24:17:9 (18)	19:20:11 (22)	19:15:15 (30.6)
Venous disease			
History of deep-vein thrombosis (%)	20 (40)	20 (40)	7 (14)
Number of patients who had duplex ultrasound	42	44	37
Popliteal reflux time			
>0 <=1.5 seconds	10	11	10
>1.5 seconds	13	8	16

G = good; M = moderate; P = poor

(Parema), K-Plus (Parema) and Coban
- Group 3 (Robinson) received the Ultra Four kit (Sohfast, K-Lite, K-Plus and Cohfast).

Ulcers were photographed and mapped, and the entry ulcer size documented along with details on pre-treatment ulcer duration, ankle and general mobility, and the individual's history of venous or ulcer disease. All patients received disease-specific information and education as well as trial information in accordance with the local ethics committee requirements. When patient mobility allowed, all patients were referred for venous duplex ultrasound to assess deep and superficial venous incompetence. As this is a tertiary referral centre some patients had undergone compression therapy before entering the study. All patients received treatment on a weekly basis and were followed up for 20 weeks or until ulcer healing, whichever occurred first.

At the end of the study period patients either received compression hosiery (healed) or compression using the Charing Cross system (unhealed at 20 weeks or withdrawal). Data were analysed using life-table methods, Wilcoxon (Gehan) and the chi-squared test.

Patient comfort and acceptability were assessed by direct questioning at the weekly bandage changes. Staff recorded their comments on bandage handling, performance and complications at the same visits.

Results

A total of 149 patients were recruited into the study as one patient (Robinson) withdrew before the treatment started. The sample consisted of 79 men and 70 women, with a mean age of 67.5 years (range: 24–88). Ulcers were recurrent (67.8%) in 101 patients. Overall pre-treatment ulcer duration was extensive, the mean being 144 weeks (range 1–2500), with 63 patients (42%) having had their ulcer for more than 6 months at referral. Ulcer size varied from 0.5 to 51 cm^2 (mean: 5.8 cm^2), and 20% of the ulcers were 10 cm^2 or greater. The data for each of the treatment groups are given in Table 2.

The three treatment groups were similar in terms of age, sex and number of recurrent ulcers. There were, however, differences in pre-treatment ulcer duration: the Robinson group had the lowest and the Parema group the highest pre-treatment ulcer duration. Similarly, the largest ulcer size was recorded in the Parema group but this was not significant as the results were skewed by two large ulcers in this group.

Further risk-factor analysis for delayed healing showed that 42 (28.2%) patients were assessed as having poor ankle mobility and 35 (23.5%) as immobile. Forty-seven (31.5%) had a history of a deep vein thrombosis. A total of 123 patients were able to undergo a full venous duplex examination; of these, 68 showed evidence of deep vein reflux and 37 of a reflux in the popliteal vein of >1.5 seconds. The figures for each bandage system are given in Table 3.

The Robinson group had a far lower history of deep vein thrombosis but the highest number of patients with detected popliteal reflux: 16 patients had a reflux of >1.5 seconds. Combined group analysis demonstrated that increasing ulcer size and pre-treatment ulcer

Fig 1. Overall healing rates at 12 and 20 weeks

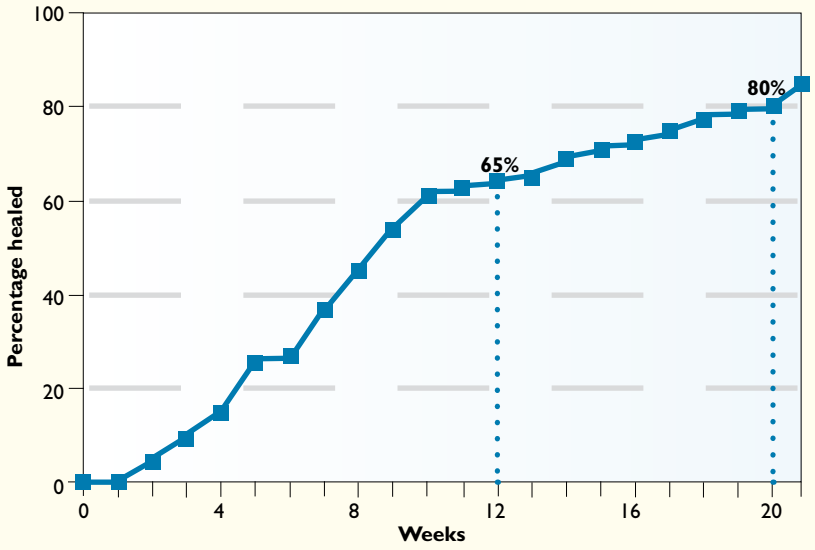
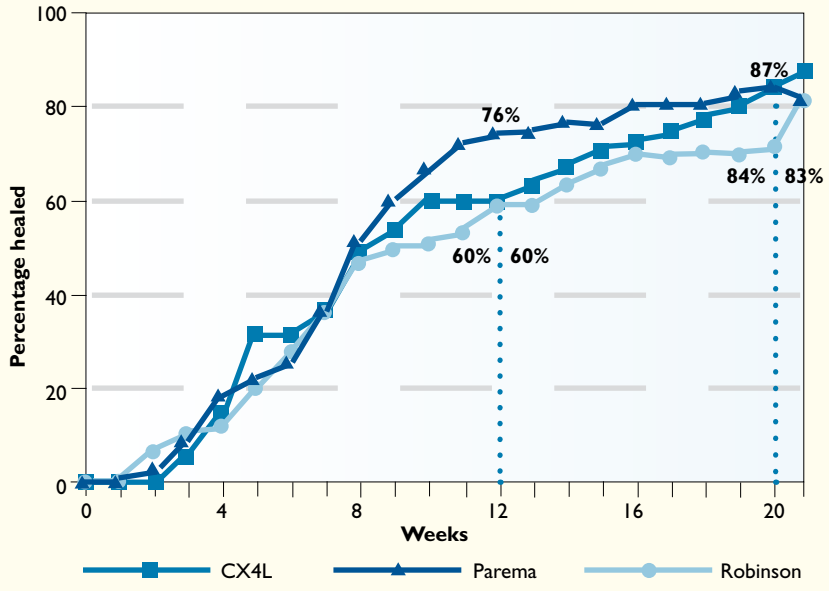


Fig 2. Comparative healing rates for the three four-layer systems



Method

All patients referred to the vascular leg ulcer clinic between June 1998 and August 1999 were assessed using the clinic's structured assessment form. Those who met the inclusion and exclusion criteria were invited to participate in the study, which had received local ethics committee approval. All routine clinical data were recorded. Patients were entered into the following treatment groups:

- Group 1 (CX4L) received Soffban (Smith and Nephew), crepe (Smith and Nephew), Elset (Seton Scholl) and Coban (3M)
- Group 2 (Parema) received Soffban, K-Lite

duration and decreasing patient and ankle mobility had an adverse effect on healing times. However, the distribution of these factors within the treatment arms of the study did not bias the outcomes. The duplex reflux results failed to demonstrate any significant adverse effect on healing, although there was a trend towards slower healing in the group with severe deep reflux (>2 seconds popliteal reflux).

Overall healing rates were 64% at 12 weeks, rising to 80% at 20 weeks (Fig 1). Healing rates for each treatment group are given in Fig 2. Although the Parema bandage group appeared to perform better than the other groups at 12 weeks (76% Parema versus 60% CX4L and Robinson), there was no statistically significant difference between the groups (χ^2 analysis p=0.16) and all three bandage systems had similar healing rates at 20 weeks (χ^2 analysis p=0.56). The log-rank test and Wilcoxon test failed to demonstrate any statistical significance between the three groups.

Three patients withdrew from the study due to non-compliance. A further 10 patients were withdrawn from it: five for medical reasons (falling ABPI, skin malignancy on another site on the leg, medical admission for respiratory disease, cellulitis and death unrelated to treatment) and five for complications which may have arisen from the bandage (persistent skin reddening and discomfort in one Robinson and two Parema patients, and superficial skin damage in one Parema and one Robinson patient). These latter five patients continued with compression bandaging, using an extra-padded Charing Cross system; all healed within 4 weeks of withdrawal. The authors believe that these patients would have healed in the same time period with the original bandage.

Patients' opinion on the bandages were sought and recorded during the study. The patients, including those who had previously experienced compression therapy, were equally tolerant of each of the bandage systems. Staff were also interviewed before, during and after the study, and asked to grade each bandage on an arbitrary scale, detailing handling, ease of application, bandage performance over the 7 days between changes and ease of removal. They initially expressed a preference for the CX4L system but this became less marked as the trial progressed and may have reflected their familiarity with the product.

Initially, the K-Lite and K-Plus bandages were slightly narrower than those in the Charing Cross system which they replaced. The width of these bandages was therefore modified to a full 10cm, and the modified

Fig 3. Healing rates of 60% or more can be achieved in specialist clinics using multilayer bandaging systems

bandage was used for the rest of the study. This original width may have been responsible for the bandage complications noted in the early phase of the study. However, these were resolved by the introduction of the modified bandage.

Discussion

The overall healing rates were similar to those reported in previous studies undertaken in the author's clinic[6,12] and are in line with those of Moffatt et al.[5] and analysed by Carr et al.[13] These papers demonstrate that healing rates of 60% or more can be achieved in specialist clinics using multilayer bandaging systems.

Taylor and Taylor[14] have recently demonstrated that there was no significant difference in the sub-bandage pressures between the Charing Cross system and a modified system (the Parema system used in this study, although our research used the initial rather than the 10cm K-Lite and K-Plus bandages used in most of the Parema and Robinson group patients). The present study supports these data, demonstrating that there is no difference in the healing rates obtained from individual four-layer systems.

Only when equivalent healing rates can be demonstrated should user and patient acceptance and cost become the overriding purchasing issues. It is not possible to directly compare individual product prices as these can vary dramatically, depending on purchasing arrangements. However, quoted product costs indicate that the Ultra Four kit is cost neutral when compared with the individual bandages in the Charing Cross system and that the modified Charing Cross system, which incorporates K-Lite and K-Plus, offers a potential saving per week treated. Both costs compare favourably with the prices of other kit systems.

Conclusion

This study and the analysis by Carr et al.[13] have shown that the Charing Cross four-layer substitutes achieve equivalent healing rates. Our study demonstrates that there is no significant difference in the healing rates obtained with three alternative four-layer bandage systems and confirms that, with expert bandaging, 12-week healing rates of >60% can be expected when treating venous leg ulcers, irrespective of the multilayer compression system used. ■

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