A comparative trial of long stretch compression bandaging versus multi-layer compression bandaging in the treatment of chronic venous ulcers

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Abstract

Venous ulcers are a common problem associated with venous incompetence, chronic venous hypertension and venous stasis, leading to oedema, skin necrosis and ulceration. Compression therapy has been found to be the most efficient means of treatment but remains expensive due to the chronic nature of this problem.

The major aims of this study were to compare the effectiveness in terms of time to healing, complications experienced and patient comfort of the long stretch compression therapy bandaging system (LSB) to the multi-layer compression bandaging therapy (MLB) in patients with chronic venous ulcers. Secondary aims were to compare the cost of different forms of bandaging and to assess the ease of application by nurses trained in the technique of both bandaging types. Within our study, a total of 30 patients, randomly divided into two treatment groups, participated in the experimental trial conducted over a 30 month period commencing in 1999. Group 1 comprised 16 patients – they were treated using MLB; Group 2 comprised 14 patients – they were treated using LSB. Although the results were not conclusive with regards to superiority between systems when examining the issue of time to healing, MLB does appear to be superior in other ways to LSB, as revealed by the following findings:

- The MLB group experienced significantly fewer complications, on average, than the LSB group.
- The MLB group experienced significantly fewer incidences of evidence of inappropriate pressure, on average, than the LSB group.
- The MLB group received significantly fewer non-routine bandage changes, on average, than the LSB group.
- A significantly higher number of the MLB group experienced greater comfort levels with their treatment than the LSB group.
- A significantly higher number of the LSB group had their treatment discontinued than the MLB group.
- The healing duration did not vary significantly between the treatment groups.

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Introduction

At the time of this study, the leg ulcer clinic at the Royal Hobart Hospital saw approximately 85 new venous ulcer cases per year. At total of approximately 750 patients annually were seen either in the leg ulcer clinic, conducted by the medical specialist, or in the nurse-led leg ulcer review clinic.

Venous ulcers are a common problem associated with venous incompetence, chronic venous hypertension and venous stasis, leading to oedema, skin necrosis and ulceration. Although the exact aetiology of venous ulcers is poorly understood, it is known that ulceration is more commonly found in women and the prevalence of ulcers increases with advancing age.

Compression therapy has been found to be the most efficient means of treatment, but remains expensive due to the chronic nature of this problem. Ideal treatment would be one that provides therapeutic compression to the limb whilst being significantly cheaper than the multi-layer system.

An extensive literature review failed to locate studies comparing multi-layer high compression bandaging (MLB) – i.e. wool layer, crêpe, Elset, Coban – routinely used within the leg ulcer clinic at the Royal Hobart Hospital with long stretch bandaging (LSB) – i.e. Surepress: wool layer & LSB manufactured by ConvaTec – or similar. Therefore, the major aims of this study were to compare the effectiveness

– in terms of time to healing, complications experienced and patient comfort – of the MLB and LSB systems in patients with chronic venous ulcers. Secondary aims were to compare the cost of different forms of bandaging and to assess the ease of application by nurses trained in the technique of both bandaging types.

As stated, at the time of this study, no research was found within the literature comparing MLB and LSB (or similar) systems. However, the results of a study comparing a 4-layer bandage system with a short stretch system were presented at the European Wound Management Association Conference in May 2003, concluding that the ulcer healing rates in that trial were similar 1 .

Methodology

Individuals attending the leg ulcer clinic for the first time for treatment of chronic venous ulcers were invited to participate in the study. Those consenting were randomly allocated to one of the two groups; the MLB group or the LSB group. The criteria for admission to the study were:

 Confirmed venous ulcers with ankle brachial index (ABI) of 0.8 or greater.

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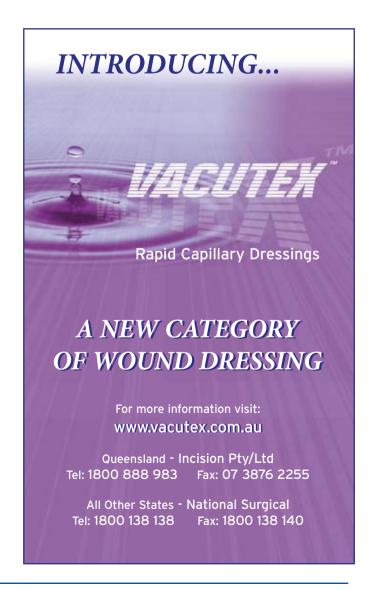
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- Ulcers of at least 1 month duration.
- Ulcer 2cm or more at the widest point.
- Ulcers not previously treated with compression therapy.

Patients had to meet all criteria for entry into the study. Twenty patients were sought for each group. However, given the passage of time and the increased occurrence of comorbidities in newly diagnosed patients, the data collection was abandoned after a period of 30 months, with a total of 30 patients completing the treatment regime.

Diagnosis of venous ulceration was made through a medical assessment of the patient which included Doppler ultrasound performed by the wound care medical specialist. The patient was then randomly allocated to a treatment method. Graphing of ulcer size took place and a duplicate diagram stored in the research files to maintain a record of the change in ulcer size over the duration of treatment. Following the visit to



the leg ulcer clinic, patients were referred to community nursing services for continuation of treatment. Patients were followed up, as per usual practice, in the ulcer clinics every 6 weeks where subsequent reassessment/ graphing of ulcers and treatment regimes took place.

Ulcers continued to be monitored and progress graphed until healed, at which point compression bandaging was no longer required. Any ulcer reported healed prior to the routine 6 week attendance at the leg ulcer clinic was attended by a specialist nurse at the leg ulcer review clinic, referred by the community nurse.

Prior to commencing data collection, a series of workshops were held with community nurses to inform and educate the nurses regarding the project and forms of bandaging already practised by these nurses. All researchers provided information as resource persons for the community nurses.

Community nurses were asked to complete a short questionnaire regarding the ease of use of bandages on participants. This information provided valuable anecdotal evidence by the nurses. The questionnaire (Appendix 1) was kept with the patient and a response completed at each dressing change, as the community nurse attending the patient may change over the course of treatment. These data were summarised to indicate the ease of application and suitability of both groups of bandages from the point of view of the clinicians who will routinely be involved in this form of care. Patients consenting to participate in the study completed consent forms and were provided with information sheets regarding the study and contact persons.

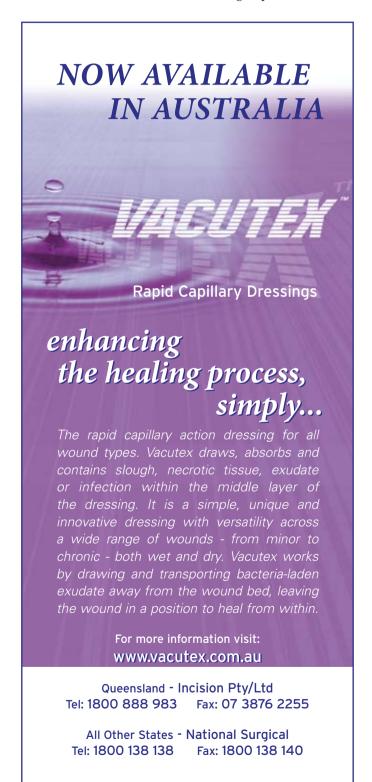
Results

The age and gender distributions within each treatment group were not significantly different, and therefore these variables were not considered further in the detailed analysis below. In addition, the average number of co-morbidities per patient did not vary significantly between the two groups. As a result of this, the presence, or otherwise, of co-morbidities was not a factor which was considered in the analysis. Furthermore, without assigning weights to individual co-morbidities, it was not possible to say which were the most influential on the state of a patient's health. Therefore, the type of co-morbidity was also not considered in the analysis.

Age

The patient age range was very similar for each group. The MLB group had a minimum age of just over 38, compared to the LSB group that had a minimum age of just over 46. The maximum ages differed by an even smaller amount, with a maximum age of 95 for the MLB group compared to 91 for

the LSB group. The average age was approximately 71 for the MLB group, compared to 75 for the LSB group. Neither the average ages, nor the age-distributions, were significantly different between the treatment groups. Consequently, it would not be expected that age differences would explain other differences between the treatment groups.



Gender

The gender composition of the two treatment groups was not quite as uniform as the age distribution, with 11 females in the MLB group compared to only six in the LSB group. Conversely, there were five males in the MLB group compared to eight in the LSB group. However, analysis revealed only a modest, and statistically insignificant, association between gender and treatment group. Therefore, as with age, it would not be expected that differences in the gender distribution would explain other differences between the treatment groups.

Healing status

The actual number of patients who were healed after treatment was higher for the MLB group (13) than for the LSB group (8), while there was a higher number of patients in the LSB group for which treatment was discontinued (6) compared to the MLB group (1).

However, a Chi-squared analysis revealed only a modest, and statistically insignificant, association between treatment groups and whether or not a patient was healed as a result of the treatment (Cramer's V=0.262, p=0.151). Therefore, it cannot be concluded from the data that there is a difference in healing success between the two treatment groups.

Conversely, there was a fairly strong, and statistically significant (at the 95% confidence level) association between whether a patient's treatment was discontinued and treatment group (Cramer's V=0.432, p=0.018). Therefore it can be reasonably concluded from the data that application of the LSB is more likely to result in the treatment being discontinued than if the MLB was applied.

Healing duration

The average number of days a patient spent under treatment varied between the groups, from a value of 87.31 for the MLB group to a value of 62.86 for the LSB group. While this difference appears substantial, it was not statistically significantly different at the 95% confidence level due to high variability within each group. This is further indicated by the spread of patients amongst the healing quintile periods, as seen in Table 1, where minimal difference was observed. A Chi-squared analysis supported this, revealing only a weak, and statistically insignificant, relationship between treatment groups and healing duration (Cramer's V=0.27, p=0.702).

Complications

A total of six of the MLB group did not experience any complications during treatment. This is in contrast to the LSB group, where every patient experienced at least one complication during treatment. The range of complications is detailed in the discussion section of this paper. The average number of complications per patient for the MLB group was 0.75 versus 1.64 for the LSB group. This difference was statistically significant at the 99% confidence level.

To enable a valid Chi-squared analysis, this variable was recoded to contain only three categories – no complications, one complication and two or more complications. The resulting Chi-squared analysis revealed a fairly strong, and statistically significant (at the 95% confidence level), relationship between the number of complications and treatment group (Cramer's V=0.54, p=0.013). Therefore, it can be reasonably concluded from the data that the MLB treatment results in fewer patient complications than the LSB treatment.

Comfort level

Twelve of the MLB group patients reported that they were "completely comfortable" with their treatment, compared with only two patients in the LSB group. Conversely, only four of the MLB group reported that their treatment was "always uncomfortable", "mostly uncomfortable", or "uncomfortable at times", compared to 12 patients in the LSB group. Chi-squared analysis supports this observation that the MLB appears to be more comfortable than the LSB, revealing a very strong, and statistically significant (at the 99% confidence level), relationship between treatment group and comfort level (Cramer's V=0.643, p=0.002). Recoding the comfort variable to "yes" and "not completely comfortable" resulted in the same conclusion (Cramer's V=0.607, p=0.001).

Frequency of inappropriate pressure

The average number of incidents of inappropriate pressure (demonstrated by complaints of pain, redness, horizontal wrinkles on the limb) per patient during treatment was 2.31 for the MLB group and 5.43 for the LSB group. This difference was statistically significant at the 95% confidence level.

Table 2 shows that the distribution of incidences of inappropriate pressure being applied varied between the two treatment groups, with a higher concentration of the MLB group in the bottom two quintiles than for the LSB group. This conclusion was borne out by a Chi-squared analysis that revealed a fairly strong relationship between treatment group and frequency of inappropriate pressure (Cramer's V=0.549, [one-tailed] p=0.03). Therefore, it can be reasonably concluded from the data that the MLB treatment results in fewer incidences of inappropriate pressure than the LSB treatment.

Table 1. Days taken to healing quintiles – treatment group (i.e. MLB or LSB) crosstabulation.

Days taken to healing quintiles	Treatment group (i.e MLB or LSB) Group 1 Group 2		Total	
≤ 25 days	3	4	7	
≥ 25 days	0	7	,	
> 25 days & ≤ 46 days	3	5	8	
> 46 days & ≤ 82 days	2	1	3	
> 82 days & ≤ 127 days	4	2	6	
> 127 days & ≤ 263 days	4	2	6	
Total	16	14	30	

Bandage change frequency

The data demonstrated distinct differences in the distribution of the number of non-routine bandage changes between the treatment groups, with 12 of the MLB group patients not requiring any non-routine bandage changes compared to only three for the LSB group. This observation was supported by the results of a Chi-squared analysis, which revealed a fairly strong, and statistically significant (at the 99% confidence level), relationship between treatment group and frequency of bandage change (Cramer's V=0.581, p=0.006).

Further, the average number of non-routine bandage changes per patient appeared to be much higher for the LSB group (1.21) than for the MLB group (0.25). A standard T-test revealed that this difference was statistically significantly different at the 99% confidence level. Therefore, it can be reasonably concluded from the data that the MLB treatment results in fewer non-routine bandage changes than the LSB treatment.

Discussion

Current treatment regimes for venous ulcers address the issues of venous hypertension and oedema ². Arguably the most effective treatment for chronic venous ulcers, both clinically and

Table 2. Frequency of inappropriate pressure quintiles – treatment group (i.e. MLB or LSB)

Frequency of inappropriate pressure quintiles	(i.e MLE	ent group 3 or LSB) Group 2	Total
0	7	_	7
> 0 & ≤ 2	4	4	8
3	1	3	4
<i>></i> 3 & ≤ 7	3	4	7
> 7 & ≤ 13	1	3	4
Total	16	14	30

with regard to cost, is compression therapy ³⁻⁵. This form of bandaging is derived from the theory that a 40mmHg pressure is required at the ankle to reverse chronic venous hypertension ⁶. The reduction in venous hypertension and oedema by using continual compression bandaging has been demonstrated to increase the blood velocity in deep veins, reduce oedema and reduce distension of superficial veins, in turn reversing venous hypertension, thereby reducing healing time ⁴, ⁶.

Dressings have been determined to have little impact upon the healing of venous ulcers and the emphasis regarding dressings is on a low adherent non-irritant dressing in order to protect the surrounding skin 6 , 7 . At the Royal Hobart Hospital leg ulcer clinic conducted by a wound care specialist, moist wound healing techniques are applied where possible, with follow up of patients at a leg ulcer review clinic conducted by expert nurses.

One author ² argues that although the multi-layer bandaging systems (three or more layers) successfully lead to the healing of venous ulcers, the effectiveness of other compression bandages should be compared with the healing rates produced by multi-layer high compression therapy. However, it is



only recently that new trials are emerging as a result of the production of new products for compression therapy ¹. Further, to adequately assess the healing rates of venous ulcers, it has been proposed that researchers follow the patient through to healing with regular assessments of wound size and condition ⁷, ⁸. The study conducted at the Royal Hobart Hospital followed all patients within the study through to healing of the ulcer, cessation of compression bandaging and transfer of the patient into compression stockings.

Current treatments with 4-layer bandaging techniques, although successful, are expensive to the patient. The patient will require compression treatment for, at minimum, 6 weeks following their initial visit (based on leg ulcer clinic data). The outcomes of this study provided information as to the healing time of the ulcers, cost effectiveness of each system, the ease of use of each of the methods, in addition to comparing comfort and complication issues between the two systems. The difference in the number of patients healed and the time to healing was found to be statistically insignificant. Therefore, no conclusion may be made as to the clinical efficacy between the two bandaging types.

The data do reveal, however, the distinct difference between the groups in the incidence of complications and comfort levels experienced by the subjects. The levels of discomfort experienced and the frequency of inappropriate pressure were significantly greater in the LSB group than in the MLB group. The complications, in order of prevalence, reported in the LSB group were slipping, pain, pressure to length of shin and wound infection. This group experienced a significantly higher incidence of complications that the MLB group. The complications experienced, in order of prevalence, reported in the MLB group were, slipping, patient feelings of excess firmness, itching and venous eczema.

The clinical significance of the information with regards to healing rates between the MLB and LSB systems, patient comfort issues and complications therefore lies with the ability of the wearer to comfortably tolerate the LSB system without issues such as slippage and signs of inappropriate pressure arising. Patient comfort was a significant individual concern as bandages remain in place between changes. The data found that if patients were able to tolerate the firmness of the correctly applied bandaging system without pain, discomfort or complications occurring, then they were able to continue with the form of bandaging allocated until the occurrence of healing. The results demonstrated that patients were significantly more able to tolerate the MLB system than the LSB.

As a result of the incidence of increased levels of discomfort and the increased frequency of inappropriate pressure in the LSB group, the frequency of non-routine bandage changing

Appendix 1. Community nurses' questionnaire.

Q1	Was bandage comfortable?
	□ Comfortable□ UncomfortablePatient assessment of bandage
Q2	Reason for bandage change
	□ Routine change□ Bandage too tight□ Other
Q3	Indication of excessive pressure present?
	☐ Yes (go to 4) ☐ No (go to 5)
Q4	Indicate symptoms of inappropriate pressure
	□ Pain□ Red areas on skin□ Broken skin□ Horizontal wrinkles
Q5	Did you feel confident in applying this bandage
	☐ Yes☐ No Comments:

in the LSB group was much higher in than that of the MLB group. Thus the data demonstrated that MLB results in fewer non-routine bandage changes than the LSB system. The questionnaire completed by the community nurses applying the bandaging systems indicated that the nurses were confident in the application of both systems in all bandage changes within the study, with the exception of one.

The frequency of inappropriate pressure and the incidence of non-routine bandage changes have a number of implications with regard to resources for both nurses and patients. Non-routine and unnecessary bandage changes consume the time of nurses within the community and thus their availability to attend to other nursing care requirements. As explained earlier in this paper, the nurses applying both methods of bandaging were provided with education regarding the LSB application, and continuing expert support through the leg ulcer clinic. The community nurses applying the bandages were experienced in the application of this form of treatment as the MLB system had been in use for a number of years.

The provision of wound care is an expensive business, with an audit of the leg ulcer clinic at the Royal Hobart Hospital in 1998 estimating the cost of providing care for leg ulcer patients at \$850,000 ⁹. In addition to nursing resources, the cost of bandaging to the patient is significant; thus the need

to minimise financial outlay on behalf of the patient is an imperative. In costing the bandaging systems utilised, the cost of the MLB is approximately three times more expensive than the 2-layer system. At the time of the study, the total cost of 6 weeks' treatment with the LSB system totaled \$35 and an equivalent treatment period with the MLB system \$114 (these costs do not include dressings). However, the additional cost of the MLB system over the 2-layer system could be outweighed by the advantages highlighted in this study concerning increased patient comfort and reduced complications when using the MLB system.

Although this study is not able to demonstrate a statistically significant difference between the time to healing in the two forms of compression therapy utilised, the study supports the use of MLB compression therapy for reasons of maximising patient comfort, minimising the incidence of inappropriate pressure, and ensuring the efficient use of nursing care time.

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