Randomized clinical trial of three-layer tubular bandaging system for venous leg ulcers

Carolina D. Weller, MEd[1]; Sue M. Evans, PhD[1]; Margaret P. Staples, PhD[2]; Pat Aldons, MBBS, FRACP[3]; John J. McNeil, PhD[4]

1. Centre of Research Excellence in Patient Safety, School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia,
2. Department of Clinical Epidemiology, Cabrini Hospital, Monash University, Melbourne, Victoria, Australia,
3. Private Practice Wound Clinic, The Prince Charles Hospital, Brisbane, Queensland, Australia, and
4. Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

Reprint requests:
Dr. Carolina D. Weller, Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Level 6, The Alfred Centre, 99 Commercial Road, Melbourne Vic. 3004, Australia.
Tel: +61 3 990623;
Fax: +61 3 990576;
Email: carolina.weller@monash.edu

Australian Clinical Trials Registry Number12608000599370
The Web address of clinical trial is: http://www.ANZCTR.org.au/ACTRN12608000599370.aspx

Manuscript received: August 1, 2011
Accepted in final form: July 20, 2012

DOI:10.1111/j.1524-475X.2012.00839.x

ABSTRACT

The safety and efficacy of three-layer (3L) tubular bandaging as a treatment for venous ulcer healing has not been evaluated despite its use in many clinical settings to treat people with venous leg ulcers. We evaluated the safety and efficacy of 3L tubular bandage compared with short-stretch compression bandage to heal venous ulcers in a multicenter, open-label, parallel-group, randomized controlled trial. We randomized 45 patients with venous leg ulcers of up to 20 cm^2 area and an ankle brachial pressure index of >0.8 from hospital outpatient wound clinics in Victoria and Queensland, Australia. We measured time to healing and percentage reduction of wound size from baseline to week 12. Secondary outcomes were proportion of ulcers healed, self-reported compliance of compression bandage, and health-related quality of life, costs, recurrence rates, and adverse events. A total of 27 ulcers healed, the proportion of healed ulcers was higher for the 3L group (17/23 [74%] vs. 10/22 [46%]) ($p = 0.05$). Reported bandage tolerance at all treatment visits was 21 (91%) in 3L group vs. 17 (73%) ($p = 0.10$). There was no difference between the groups in adverse events. Costs were substantially less in 3L group.

Chronic venous ulceration is extremely common and estimates have revealed venous leg ulcers (VLU) occur in approximately 1.5–1.8% of the general population in industrialized countries[1] with prevalence increasing with age, obesity, and diabetes.[2] The natural history of VLUs is often a cycle of healing and recurrence,[3] which has a considerable impact on individual's health, quality of life (QoL), and socioeconomic costs.[4] VLUs are the most common clinical wound problem seen in general practice, and care is largely nurse led. The main treatment for VLU is a firm compression bandage to aid venous return.[5,6]

High compression bandaging (30–40 mmHg) is an effective treatment, healing over 70% of uncomplicated VLUs in 3 months.[7] A systematic review of different compression bandages for venous ulcers concluded that the rate of ulcer healing was increased with compression bandages when compared with no compression. It also found multicomponent systems more effective than single-component systems, and those with elastic bandages were more effective than inelastic systems, but there were no clear differences in the effectiveness of different types of high compression.[8]

Many different types of compression bandages are available, and there is some evidence that nurses have difficultly determining which type to apply.[9,10] Two types of compression bandaging are often used in Australian community and general practice settings: the short-stretch compression bandage system (SS) and the three-layered compression bandaging system (3L).[11] The 3L bandage system is simple to apply, a comfortable alternative to standard compression bandages that need to be applied by a trained operator, are costly, and are hampered by patient nonadherence.[10,12] No studies have been undertaken to assess the effectiveness or cost-effectiveness of the 3L bandage in achieving wound reduction and healing compared with the SS bandage in people with VLUs even though the 3L is one of the most used compression systems. The purpose of this study was to assess the effectiveness, acceptability, and cost of the SS compression bandage compared with the 3L bandage for the treatment of VLUs. We hypothesized there would be no difference in wound size reduction with 3L bandage system when compared with SS.

METHODS

Participants and settings

A multicenter, parallel-group, randomized controlled trial was conducted in four specialist wound clinics. Participants were

recruited between February 2009 and January 2011 from hospital outpatient wound clinics in metropolitan settings in Victoria and Queensland, Australia. Centers were recruited from our known community of key specialist wound clinics.

Eligible participants were aged over 18 years, ambulant, capable of giving informed consent, and of attending weekly clinics. The VLU had to (1) have been be confirmed by clinical assessment; (2) have been present for at least 4 weeks; (3) have an area ≥ 1 and $\leq 20\ cm^2$ as measured by digital planimetry; (4) have an ankle brachial pressure index of ≥ 0.8 mmHg; and (5) be on a leg with an ankle circumference of ≥ 20 to ≤ 30 cm.

Patients were ineligible if they were participating in another clinical trial, had evidence of severe liver disease, cardiac disease, chronic pulmonary disease, clinically suspected deep vein thrombosis, a medical condition likely to require systemic corticosteroids during the study period, were suffering from severe depression or psychiatric illness, or if they had suspected thrombophlebitis. The study was approved by Monash University, Alfred Health, Austin Health, Melbourne Health, and Queensland Health Human Research Ethics committees.

Randomization

Eligibility was assessed and consent obtained by research nurses at each site. Consenting participants were randomly assigned 1 : 1 to one of the two groups via a web-based secure, central independent randomization service (nQuery v7, Statistical Solutions, Saugus, MA). Randomization was stratified by study center and wound size. Where more than one ulcer was present, the largest ulcer was used as the target ulcer and all ulcers treated with allocated treatment. Because of the nature of the interventions, it was not possible to blind either participants or study staff to treatment.

Interventions

Participants randomized to the intervention group received a 3L straight bandage (Tubular-Form, Sutherland Medical, Oakleigh, Vic., Australia) applied in different lengths as outlined in Figure 1. The first layer (long length) extended from the base of the toes to just under knee; the second layer (medium length) from base of toes to above calf pump, and finally, the short third layer from base of toes to mid gaiter. Calf measurement determined the size of bandage in both intervention and control group.

Participants randomized to the control group received standard SS compression therapy consisting of inelastic SS compression bandage (available in 8 cm and 10 cm width, 5 m length Lastolan, Hartmann, Rhodes, NSW, Australia) applied in a figure of eight and tubular retention to keep the inelastic bandage in place. Two layers of standard compression therapy were applied from base of toes to just under the knee. Compression in both groups was applied over a padding layer (Tubular Plus, Sutherland Medical) to protect underlying bony prominences and prevent skin breakdown. The number of rolls applied was determined by limb circumference.

All participants received dressings that the research nurse deemed appropriate at the time of each visit. The dressing choices reflected the normal range of choices available at each center (hydrogel, hydrocolloid, foam, silver dressings, and zinc dressings). Participants attended the study clinic weekly where dressings and bandages for both the intervention and control groups were changed. The bandages were not to be removed in-between visits unless clinically necessary (e.g., slippage, infection, and/or increased exudate). Study protocol only allowed more frequent change if deemed clinically necessary. Any extra bandage changes between weekly treatment visits were documented in case report form. After removal of all dressings and bandages, the ulcer was cleaned with warm tap water and soap-free wash.

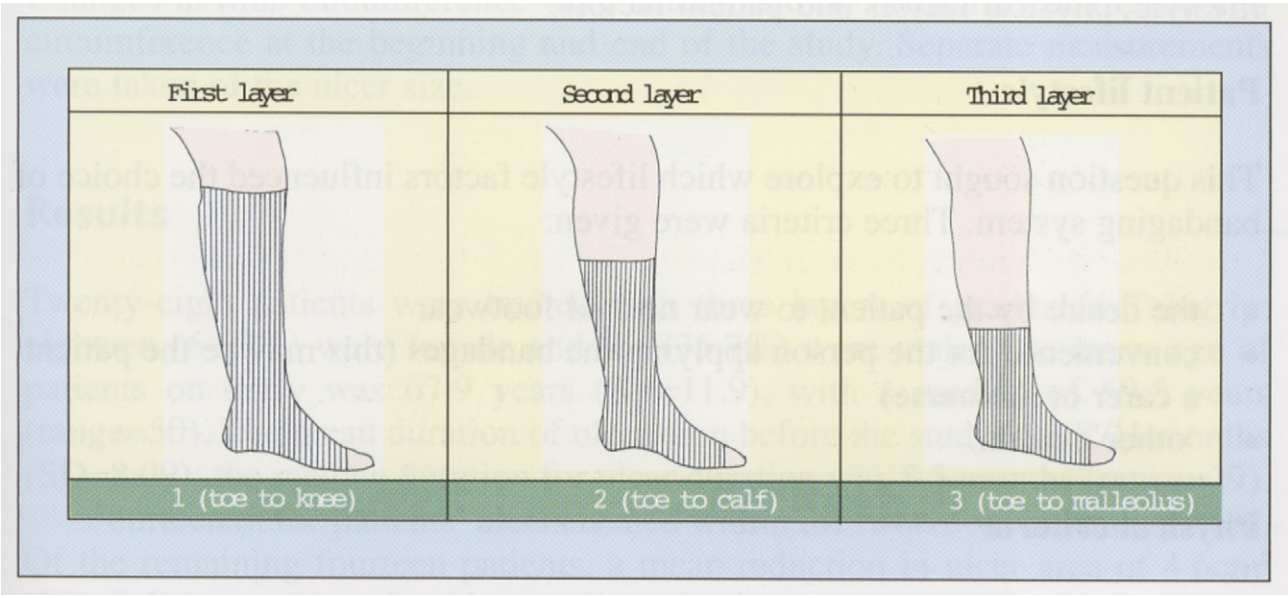

Figure 1. 3L diagrammatic example of intervention bandage from Bale and Harding study.[12]

Nurse training

The nurses applying the bandages were trained in wound tracing using the Visitrak system (Smith & Nephew, Hull, United Kingdom), ulcer digital photography, and application of both 3L and SS bandages. Competency for bandage application was not formally assessed as the nurses applying the bandages all worked in specialist wound clinics.

Outcome measures

The primary outcome measure was the percentage reduction of wound size from baseline to week 12 (end of treatment). Wound size was measured weekly with Visitrak, an acetate wound tracing wound measurement system, and confirmed with digital photographs of target ulcer. The Visitrak system has been shown to provide accurate and reliable measurement of wound area.[13] End of treatment was defined as the visit at which the ulcer healed or week 12, whichever came first. Complete healing was defined as 100% epithelialization or skin closure without drainage.

Secondary outcomes included (absolute) reduction in ulcer size, time to complete healing, proportion of ulcers healed, self-reported compliance, and comfort level of bandage and change in QoL over the study period. At each visit, patients reported the tolerability and comfort of their bandage on a four point scale (1 = very comfortable, 2 = comfortable, 3 = uncomfortable, 4 = very uncomfortable) and compliance with the bandaging (yes/no). General QoL using the short form 36 health survey (SF36)[14] and condition-specific QoL using the Cardiff Wound Impact Scale (CWIS®)[15] were completed at baseline and end of treatment. Healed ulcers were monitored with monthly clinic visits to record recurrence within 3 months of the healed date. Participants whose ulcers had not healed at the 12-week visit were returned to the care of the specialty wound clinic. Adverse events (AEs) were recorded at each treatment visit and classified as related to the study or not related.

Statistical analysis

All analyses were performed on an intention-to-treat basis with a two-sided 0.05 significance level using Stata version 11 (Stata Corp, College Station, TX). A total sample size of 36 participants (18 per group) was required to detect a 30% absolute difference between the groups in the mean percentage reduction in wound size with 80% power at the 5% significance level. To allow for loss-to-follow-up of 20% between baseline and end of treatment, we randomized 23 participants to each arm.[11] Missing data for primary outcome were included in analysis using last observation carried forward. All statistical analyses were specified a priori.

Percent reduction in wound area was defined as 100*(Area1−Area2)/Area1, where Area1 is wound area (in square centimeter) at week 0 and Area2 is wound area at healing or week 12. The mean percent reduction was determined for each group, and between-group mean differences were assessed using *t* tests. Reduction in wound size was measured using log (Area2/Area1). For healed ulcers (Area2 = 0 cm^2), Area2 was the smallest observed wound area prior to healing. Between-group differences were assessed using *t* tests or nonparametric Wilcoxon rank-sum tests as appropriate.

Differences in the proportion of ulcers healed for each group were assessed using logistic regression with a binary measurement of healed or unhealed (no/yes) as the outcome and treatment group as the predictor. Other predictors of healing included in the model were age, sex, body mass index (BMI), ankle circumference, calf circumference, ulcer size, ulcer duration, and smoking status. Variables were reported as having an association if the coefficient was significant at the 5% level.

Time to ulcer healing was investigated using a Kaplan–Meier curve and between-group differences compared using the log-rank test. The time to healing was defined as days from randomization date to date of healing. The censoring date for unhealed ulcers was 3 months after the randomization date. Ulcers recurring within 3 months of healing were recorded and the relative risk (RR) of recurrence calculated.

Compression tolerability was calculated as the percentage of treatment visits with tolerability recorded as "very comfortable" or "comfortable." Similarly, overall compliance was calculated as the proportion of treatment visits at which compliance = yes was recorded. Comparisons were undertaken using Wilcoxon rank-sum tests.

SF36 scores were calculated using a standard algorithm and scores were standardized to the Australian population norms. The mental component summary (MCS) and physical component summary scores are reported for this study. The CWIS scores (well-being, physical symptoms and daily living, social life, QoL) were calculated using methods obtained from the developers.[15]

Overall and treatment-related AEs were compared for the treatment groups and RR calculated using binomial regression. The total costs per group were compared using the Wilcoxon rank-sum test.

RESULTS

A total of 110 people with leg ulcers was screened across four centers; 47 participants were eligible, 2 refused to participate; 45 (95.7%) were randomized: 23 to 3L compression and 22 to SS compression. Figure 2 shows the flow of participants through the trial, and Table 1 summarizes baseline characteristics.

Table 2 shows end of treatment outcomes by treatment group. Figure 3 shows the change in mean ulcer size over the 12-week treatment period by treatment group. The between-group difference in mean absolute ulcer size reduction was 0.6 cm^2 (95% confidence interval (CI) 1.9, 3.2). We found no statistical difference between the treatment groups in percentage reduction in ulcer size or reduction in ulcer size.

A total of 27 ulcers healed, the proportion of healed ulcers was higher for the 3L group (17/23 [74%] vs. 10/22 [46%]). A higher proportion of ulcers in the 3L group healed within 12 weeks, but the difference fell short of traditional levels of statistical significance ($p = 0.056$) (Table 2; Figures 4 and 5). Multivariable logistic regression indicated that longer ulcer duration and larger ulcer size at baseline were associated with lower healing rates. For each square centimeter increase in ulcer size at baseline, the likelihood of healing was reduced by 25% ($p = 0.005$), and for each week of ulcer duration, the likelihood of healing was reduced by 19% ($p = 0.02$). No other predictors were significantly associated with healing. After adjusting for baseline ulcer size and duration, the odds ratio for healing was 0.2 (95% CI 0.03, 1.3). Figure 4 shows

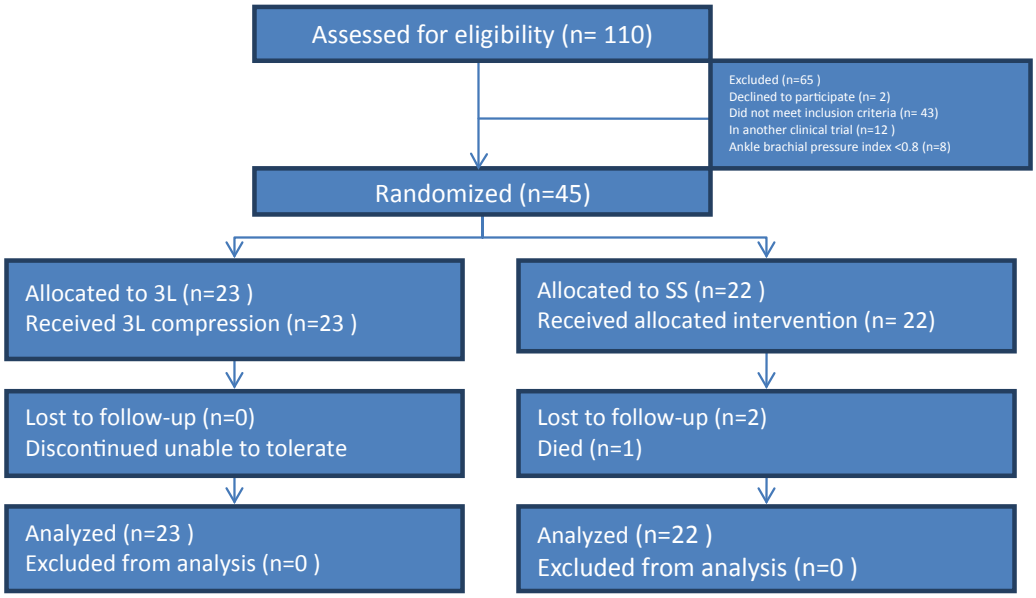

Figure 2. Flow of participants through trial.

the Kaplan–Meier estimates for proportion of healed ulcers by treatment group There was no difference in time to healing (log-rank test $p = 0.18$). Both groups reported high levels of compliance and tolerability for the bandages and there were no significant between-group differences (Table 2). Of the 27 wounds that healed, there were six recurrences and all occurred within 5 weeks of healing. A higher proportion of the 3L group recurred, but due to the relatively small number of recurrences, the difference was not significant. The RR for recurrence in the 3L group compared with the SS group was 1.2 (95% CI 0.3, 5.3).

Table 3 shows the differences in QoL scores between baseline and end of treatment and the mean between-group differences. All mean SF36 QoL scores improved between baseline and end of treatment. While there were no significant differences between the 3L and SS groups in mean changes for any of QoL measures, participants whose ulcer had healed had higher mean change in MCS scores (9.6, standard deviation [SD] = 10.8, $n = 20$) than those with unhealed ulcers (–2.2, SD = 13.8, $n = 9$) ($p = 0.02$). Change from CWIS baseline mean difference was similar for well-being and physical symptoms and daily living. The social life scores were lower for SS, and QoL scores were lower for the 3L group, although this was not statistically significant.

There were 12 AEs in 12 participants (Table 2) and no difference between groups in AE rates (RR = 1.33, 95% CI 0.49, 3.60). Four AEs were related to the study: cellulitis and pain at wound site for two participants in 3L group and

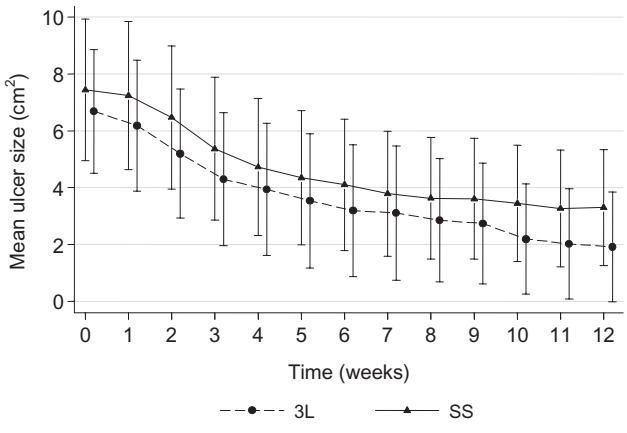

Figure 3. Mean change in ulcer size over 12-week treatment period by treatment group (bars indicate 95% confidence intervals).

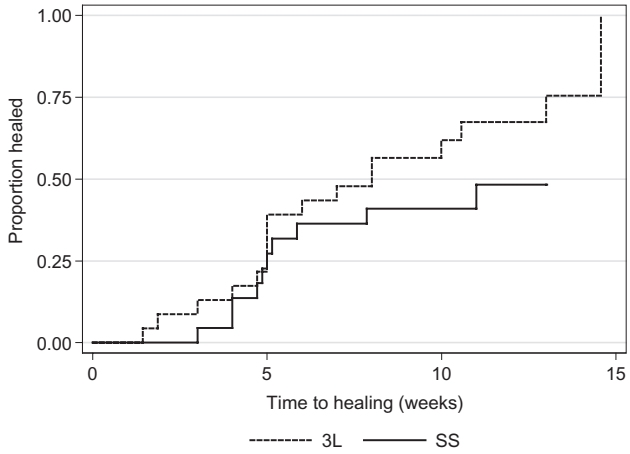

Figure 4. Kaplan–Meier estimates for the proportion of healed ulcers over time by treatment group.

Table 1. Demographic and clinical characteristics of 45 participants who were randomized to three-layer and short-stretch compression at baseline assessment

	Three-layer bandage ($n = 23$)	Short-stretch bandage ($n = 22$)
Age in years, mean (SD)	71.0 (14.6)	79.3 (9.2)
Male gender, *n* (%)	14 (58)	9 (43)
Caucasian ethnicity, *n* (%)	23 (96)	20 (95)
BMI groups, *n* (%)		
<20	1 (4)	2 (10)
20–24	3 (13)	3 (15)
24–29	3 (13)	6 (30)
30+	16 (70)	9 (45)
Risk status, *n* (%)		
Never smoked	11 (48)	14 (64)
Former smoker (≤10 years ago)	2 (9)	4 (18)
Former smoker (>10 years ago)	7 (30)	4 (18)
Current smoker	3 (13)	0 (0)
Normal range of ankle mobility *n* (%)		
Full range	18 (78)	20 (91)
Reduced	5 (28)	2 (9)
Ankle circumference (cm^2)		
Median (range)	24 (21, 30)	24 (20, 29)
Mean (SD)	24.0 (2.3)	23.9 (2.8)
Calf circumference (cm^2)		
Median (range)	38 (32, 51)	36 (27, 50)
Mean (SD)	38.5 (4.5)	37.3 (7.2)
Ankle brachial pressure index		
Median (range)	1.1 (0.9, 1.6)	1.2 (0.8, 1.3)
Mean (SD)	1.2 (0.18)	1.1 (0.15)
Ulcer location (R : L)	9 : 14	13 : 9
Ulcer area (cm^2)		
Median (range)	5 (1.2, 19.8)	7 (1.2, 19.0)
Mean (SD)	6.7 (5.3)	7.4 (6.0)
Ulcer duration (months)	5.8 (5.6)	9.5 (10.0)
Margolis index[22]		
(0) ulcer size ≤5 cm^2 and ≤6 months, *n* (%)	8 (35)	8 (36)
(1) ulcer size >5 cm^2 or >6 months, *n* (%)	10 (43)	6 (27)
(2) ulcer size >5 cm^2 and >6 months, *n* (%)	5 (22)	8 (36)

infection at wound site and pain at wound site for two in the SS group. The RR of a study-related AE was 1.05 (95% CI 0.16, 6.79).

Costs per healed ulcer per bandage group were calculated using nurse costs for the time required to apply the bandage plus the cost of the bandages. We used a nursing rate $46 per hour. Nurses documented treatment time including bandage application time for the 3L bandage was approximately 30 minutes. The 3L tubular bandage was replaced weekly at an average cost of $2 per week resulting in a cost per visit for the 3L group of $25. The SS group including treatment and bandage application was reported by nurses to take approximately 1 hour per visit. If necessary, the SS was replaced more frequently than weekly. SS bandages can be washed and two sets were allocated to each participant at the start of the treatment period: one in use and one being laundered. In some instances, some patients were unable to launder bandages so another set was allocated for treatment. The cost for the SS was $66 per patient irrespective of number of visits. The cost per week for the SS group was $46 with the bandage costs added to the cost of the baseline (week 0) giving a week 0 cost of $112. We calculated the mean group costs for each week from the cost per participant and the number of participants presenting each week in the two groups. Total cost per participant was obtained by summing the individual weekly patient costs. Those with incomplete treatment follow-up

Table 2. End of treatment outcomes by treatment group

	3L ($n = 23$)	SS ($n = 22$)	p-value
Percentage reduction in ulcer size, mean (SD)	82.4 (32.4)	70.1 (37.5)	0.23 (t test)
Median (range)	100 (–11, 100)	89 (–8, 100)	
Reduction in size*	2.0 (1.4)	1.7 (1.5)	0.52 (Wilcoxon)
Number healed at or before 12 weeks, n (%)	17 (74)	10 (46)	0.056 (z test)
% of treatment visits with tolerability = Very comfortable/Comfortable†, mean (SD)	95 (21)	89 (29)	0.13 (Wilcoxon)
Reported tolerance at all treatment visits, n (%)	21 (91)	16 (73)	0.10 (chi-square)
% of treatment visits with compliance = Yes, mean (SD)	96 (9)	98 (5)	0.74 (Wilcoxon)
Reported100% bandage compliance, n (%)	19 (79)	17 (81)	0.65 (chi-square)
Adverse events n (%)	7 (58)	5 (42)	0.56 (chi-square)
Quality of life SF36 score, mean (SD)			
PCS	34.8 (9.8)	34.4 (7.5)	
MCS	54.1 (9.0)	55.6 (10.1)	
Quality of life CWIS, mean (SD)	($n = 12$)	($n = 13$)	
Well-being	65.5 (20.3)	55.8 (22.6)	
Physical symptoms and daily living	86.1 (14.6)	72.3 (20.1)	
Social life	88.1 (9.5)	79.3 (22.9)	
Quality of life	79.2 (13.9)	85.0 (14.5)	

*Assessed using log(Area2/Area1), where Area1 = size of ulcer at baseline, Area2 = ulcer size at end of treatment. If ulcer healed, Area2 = minimum size recorded prior to healing.
†The zero values for compression tolerability indicate that some people reported "Uncomfortable" at all treatment visits.

were assumed not to have healed by 12 weeks and were given the maximum cost for the allocated bandage.

Costs per ulcer healed per treatment group are shown in Figure 5. The median total cost over the treatment period for the 3L group was \$200 (range \$25, \$300) and for the SS group was \$618 (range \$158, \$618; Wilcoxon rank-sum test $p = 0.0001$).

DISCUSSION

In this study comparing conventional SS compression bandages with a 3L compression bandages over a 12-week period, we found no significant differences between the two in wound size reduction, general or condition-specific QoL, compliance, recurrence, or AEs.

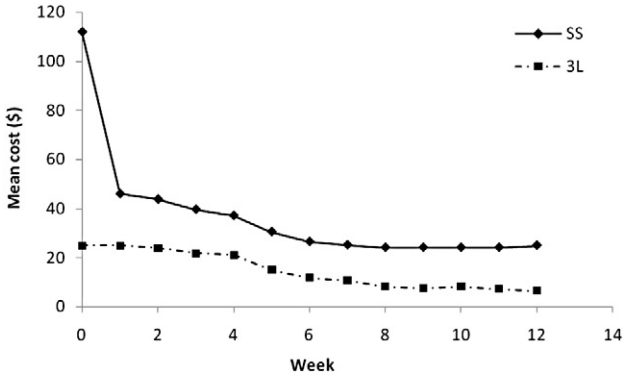

Figure 5. Costs per group for treatment period (bandage costs and nursing time).

The SS group was slighter older although range of ankle mobility was matched for both groups regardless of age difference between groups. The BMI (30+) was greater in 3L group, which may affect healing potential. The Margolis index (MI) was similar in both groups for ulcer size ≤ 5 cm^2 and ≤ 6 months duration. The MI of ≤ 5 cm^2 or ≤ 6 months duration was slightly greater in the 3L group, although there were three more participants in the SS group with an MI score of 2 (≥ 5 cm^2 and ≥ 6 months duration), which may have influenced healing rates.

There was limited evidence that 3L compression changed weekly improved VLU healing compared with the SS group. While the difference failed to reach nominal significance, this finding suggests that it appears to be an effective and safe compression treatment for people with VLU. It is also significantly less expensive and does not require the same level of expertise to apply as other compression bandages.

As recommended by Partsch et al. that future trials should measure sub-bandage pressures (SBP) of compression in vivo prior to undertaking a clinical trial,[16] we measured the difference between mean interface SBP of 3L and SS in a previous in vivo study[17] and found SBP varied according to different activities (lying, standing, exercising, and rest) but the mean difference between 3L and SS was consistently at least 13 mmHg higher in the SS group. Stiffness was 7.3 mmHg higher in SS (95% CI 5.1, 9.5). The estimated difference in amplitude of SBP between the bandages during exercise was 15.5 mmHg (95% CI 12.2, 18.9). It is worthy to note the in vivo SBP was measured immediately after bandage application. It is known that SS bandages lose pressure over time and this can

Table 3. Change from baseline to end of treatment in quality of life scores

	3L	SS	Mean difference (95% CI)*	*p*-value
SF 36 scores	(*n* = 13)	(*n* = 16)		
PCS score	4.5 (7.2)	3.6 (8.7)	0.9 (–5.2, 7.1)	0.76
MCS score	4.6 (7.2)	6.9 (16.2)	–2.2 (–12.2, 7.8)	0.65
CWIS scores	(*n* = 12)	(*n* = 12)		
Well-being	17.6 (26.0)	17.0 (25.0)	0.6 (–24.0, 22.2)	0.96
Physical symptoms and daily living	18.9 (19.9)	16.7 (26.1)	2.3 (–17.4, 21.9)	0.81
Social life	9.8 (23.1)	4.5 (19.1)	5.3 (–13.3, 23.8)	0.56
Quality of life	3.7 (11.5)	14.5 (20.5)	–10.8 (–25.1, 3.5)	0.13

*Positive values favor the 3L group.

PCS, physical component summary score; MCS, mental component summary score.

cause bandage slippage in some instances. The 3L bandage delivered lower SBP than SS in the in vivo study yet still showed potential for improved healing in this clinical trial.

To our knowledge, there are no clinical trials of the 3L system even though it is a commonly used compression system in Australia. A systematic review of 39 randomized controlled trials of compression bandaging found no clear evidence favoring tubular compression over other compression bandages but better healing outcomes were evident when an elastic component was included in the compression system.[7] Two evaluations[18,19] of tubular compression (stocking system) vs. SS compression bandages have provided conflicting results. One study[19] found better outcomes for healing and recurrence for the tubular device, while the other found no difference between groups. This finding may be due to different types of tubular compression and the number of layers used. The elastic bandages/stockings used in both studies differed from the 3L bandage system evaluated in this report.

A previous non-comparative study treated 28 patients who were unable to tolerate standard compression with three layers of graduated Tubigrip (tubular bandage; Medshop Australia, Preston, Australia) as an alternative to therapeutic compression. They reported 50% of the group healed in the 12-week treatment period with a mean reduction in ulcer area of 4.6 cm^2.[12] The authors concluded the 3L system be used in patients with difficulty tolerating other compression. Our RCT results showed a greater proportion healed at or before the 12-week treatment period (74%), and the mean percent reduction in ulcer area was more than 10% greater in the 3L group when compared with standard compression. From our previous in vivo SBP study,[17] we know that the SBP of 3L is 15 mmHg less than SS when lying, standing, exercising, and resting.

The strengths of our study include in vivo SBP measurement of both 3L and SS[17] prior to the study as recommended by international experts,[16,20,21] although it must be acknowledged that a future study to measure SBP after application and before removal of compression would be useful. The RCT study was designed using Consolidated Standards of Reporting Trials (CONSORT) criteria to ensure potential risk of bias was minimized. Our study had wide inclusion criteria to increase the generalizability and applicability of our findings. We used best available standard treatment, had low loss-to-follow-up, and collected and reported QoL data and ulcer recurrence follow-up.

There are a number of limitations to this study that should be considered when interpreting findings: (1) the study was small and powered only to detect a 30% absolute difference between the groups in the mean percentage reduction in wound size; (2) follow-up timeframe was only 3 months and it would be useful to have a longer follow-up for target ulcer recurrence; and (3) bias due to non-blinding of wound size measurement is a limitation, although in compression bandaging studies this is difficult to avoid. We attempted to minimize the effect of non-blinding by ensuring that wound size was measured using an objective measure.

Here we report the first randomized controlled trial comparing 3L bandage for wound healing. We found 3L bandages can heal VLUs and the finding is worth further exploration particularly in view of minimal cost per ulcer healed for the 3L bandage and because it can be applied with relative ease compared with SS. Further work is required to explore whether 3L bandage should be adopted as main stay treatment for VLUs in the community. This study should be replicated on a larger sample size and with a longer follow-up for recurrence and better QoL response rate. The potential impact of early adoption of weekly 3L bandages by community and general practice nurses may have benefits, with significant cost savings in terms of reduced bandage costs, reduced time nurses spent bandaging, and improved healing. Greater investment is required to monitor outcomes at a population level on patients who present with VLUs and to ensure that practice is in line with established evidence-based practice guidelines.

ACKNOWLEDGMENTS

We thank the patients who took part in the trial, the research nurses and principal investigators at each site. We thank Dr Pat Aldons and Ms Liz Jenkins from Prince Charles Hospital in Brisbane for coordinating the site. We thank associate professor Damien Jolley for earlier statistical advice. We thank associate professor Christopher Reid for earlier study design advice and for review of final manuscript. We thank Wound Healing Research Unit, Cardiff University, for use of CWIS instrument. We thank Elizabeth Mudge for CWIS advice and guidance.

Contributors: CDW designed and coordinated the study, conducted the clinical and economic analysis with MS, drafted the manuscript, and edited and approved the final

draft. SME contributed to the study design, oversaw the conduct of the analysis and edited the paper. MS conducted the clinical and economic analysis and edited the manuscript. PA contributed to coordination of the Queensland site with Elizabeth Jenkins and commented on final manuscript. JM contributed to the study design and coordination and commented on final manuscript.

Competing interests: All authors have completed the Unified Competing interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from corresponding author) and have no competing interests.

Funding: CDW was funded by Monash University Postgraduate Scholarship and Nurses Memorial Centre Scholarship to conduct the study. Sutherland Medical provided Tubular-Form bandages but had no role in data collection, statistical analysis, or writing of this manuscript or the decision to submit for publication. All other authors declare no support from any organization for the submitted work.

Ethics approval: The study was approved by Monash University Standing Committee on Ethics in Research Involving Humans and local site ethics research committees.

REFERENCES

1. Graham ID, Harrison MB, Nelson EA, Lorimer K, Fisher A. Prevalence of lower-limb ulceration: a systematic review of prevalence studies. *Adv Skin Wound Care* 2003; 16: 305–16.
2. Australian Institute of Health and Welfare. *Diabetes prevalence in Australia: an assessment of national data sources*. Canberra: AIHW, 2009.
3. Moffatt C, Martin R, Smithdale R. *Leg ulcer management*. Oxford: Blackwell Publishing, 2007.
4. Gottrup F, Apelqvist J, Price P. Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *J Wound Care* 2010; 19: 237–68.
5. Grey JE, Harding KG, Enoch S. Venous and arterial leg ulcers. *BMJ* 2006; 332: 347–50.
6. Iglesias C, Nelson EA, Cullum NA, Torgerson DJ. VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers. *Health Technol Assess* 2004; 8: iii, 1–105.
7. O'Meara S, Cullum NA, Nelson EA. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2009; (1): CD000265.
8. Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2000; (3): CD000265.
9. Barrett S, Cassidy I, Graham MM. National survey of Irish community nurses leg ulcer management practices and knowledge. *J Wound Care* 2009; 18: 181–2, 184, 186 passim.
10. Annells M, O'Neill J, Flowers C. Compression bandaging for venous leg ulcers: the essentialness of a willing patient. *J Clin Nurs* 2008; 17: 350–9.
11. Weller CD, Evans S, Reid CM, Wolfe R, McNeil J. Protocol for a pilot randomised controlled clinical trial to compare the effectiveness of a graduated three layer straight tubular bandaging system when compared to a standard short stretch compression bandaging system in the management of people with venous ulceration: 3VSS2008. *Trials* 2010; 11: 26.
12. Bale S, Harding KG. Managing patients unable to tolerate therapeutic compression. *Br J Nurs* 2003; 12 (19 Suppl.): S4–13.
13. Etris MB, Pribble J, LaBrecque J. Evaluation of two wound measurement methods in a multi-center, controlled study. *Ostomy Wound Manage* 1994; 40: 44–8.
14. *SF-36v2™ Health Survey 1992, Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated*. All rights reserved. In: Trust S-iartoMO, editor. All rights reserved SF-36® is a registered trademark of Medical Outcomes Trust IQOLA SF-36v2 Standard, Australia (English), 2003.
15. Price P, Harding K. Cardiff wound impact schedule: the development of a condition-specific questionnaire to assess health-related quality of life in patients with chronic wounds of the lower limb. *Int Wound J* 2004; 1: 10–7.
16. Partsch H, Clark M, Bassez S, Benigni JP, Becker F, Blazek V, Caprini J, Cornu-Thénard A, Hafner J, Flour M, Jünger M, Moffatt C, Neumann M. Measurement of lower leg compression in vivo: recommendations for the performance of measurements of interface pressure and stiffness: consensus statement. *Dermatol Surg* 2006; 32: 224–32; discussion 33.
17. Weller C, Jolley D, Wolfe R, Myers K, McNeil J. Effect of elasticity on sub-bandage pressure of three layer tubular compression bandages in healthy volunteers: a randomised controlled trial. *J Wound Care* 2010; 19: 417–23.
18. Junger M, Wollina U, Kohnen R, Rabe E. Efficacy and tolerability of an ulcer compression stocking for therapy of chronic venous ulcer compared with a below-knee compression bandage: results from a prospective, randomized, multicentre trial. *Curr Med Res Opin* 2004; 20: 1613–23.
19. Milic DJ, Zivic SS, Bogdanovic DC, Perisic ZD, Milosevic ZD, Jankovic RJ, Visnjic AM, Jovanovic BM. A randomized trial of the Tubulcus multilayer bandaging system in the treatment of extensive venous ulcers. *J Vasc Surg* 2007; 46: 750–5.
20. Partsch H, Clark M, Mosti G, Steinlechner E, Schuren J, Abel M, Benigni JP, Coleridge-Smith P, Cornu-Thénard A, Flour M, Hutchinson J, Gamble J, Issberner K, Juenger M, Moffatt C, Neumann HA, Rabe E, Uhl JF, Zimmet S. Classification of compression bandages: practical aspects. *Dermatol Surg* 2008; 34: 600–9.
21. Partsch H, Partsch B, Braun W. Interface pressure and stiffness of ready made compression stockings: comparison of in vivo and in vitro measurements. *J Vasc Surg* 2006; 44: 809–14.
22. Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? *Am J Med* 2000; 109: 15–9.