

Comparison of elastic versus nonelastic compression in bilateral venous ulcers: A randomized trial

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Background: There is controversy regarding the effectiveness of elastic vs nonelastic compression in the healing of venous leg ulcers. To gain insight into this controversy, we randomly compared a four-layer elastic bandage with a nonelastic garment (CircAid) in patients with venous leg ulcers.

Methods: Twenty-four extremities of 12 patients with bilateral leg ulcers were randomized to have a four-layer elastic bandage in 1 extremity and a nonelastic compression garment CircAid in the contralateral limb. The CEAP classification in 22 extremities was C₆ S; E_S; A_{D6,14,15,P18}; P_R; 1 extremity in 2 patients was C₆ S; E_S; A_{D6,14,15,P18}; P_{RO}. There were seven men and five women. Age ranged from 45 to 82 years, with a mean of 61 years. All patients had postthrombotic leg ulcers diagnosed clinically by duplex ultrasonography (n = 8) or by phlebography (n = 4). Every 4 weeks, patients had the ulcer area measured in square centimeters by a computerized scanning method and had the limb girth measured in centimeters at the foot, ankle, and calf. The ankle-brachial index was determined in all cases. Color photographs of the ulcer areas were taken monthly to assess healing progress. All patients were compliant. Results were assessed at 12 weeks. A patient satisfaction sheet was filled out by the patient, who circled one of the following scores: 3, very satisfied; 2, moderately satisfied; and 1, not satisfied. Cox proportional hazards models or paired *t* tests were used for comparison.

Results: The 24 limbs were randomized and divided into 2 groups of 12 each. Group A received CircAid, and group B, a four-layer elastic bandage. Duplex scanning showed a pattern of reflux in 11 limbs of each group. One limb in each group had a pattern of obstruction documented by air plethysmography (n = 2). Phlebography demonstrated the anatomic site in both limbs. The initial ulcer area in group A was 48.98 ± 14.13 cm² and was 50.08 ± 18.30 cm² in group B (*P* = .9285). The ulcer healing rate was significantly faster in group A compared with group B (hazard ratio, 0.56; 95% confidence interval, 0.33-0.96; *P* = .0173). Ulcers with hemodynamic obstruction had a protracted course when compared with the contralateral limbs with reflux. There was no significant difference in girth reduction between groups A and B (hazard ratio, 2.36; 95% confidence interval, 0.30-18.52; *P* = .3580). The ankle-brachial index was normal (≥1.0) in all patients.

Conclusions: In compliant patients, venous leg ulcers randomized to nonelastic compression had a significantly faster healing rate per week than ulcers treated by the conventional four-layer compression system. (*J Vasc Surg* 2005;42:1150-5.)

Chronic venous ulceration affects 10 to 15 million Americans.^{1,2} In the United Kingdom, approximately 70% of leg ulcers are secondary to venous diseases.^{3,4} Although venous disease seldom results in amputation of a leg, it leads to patient discomfort and incapacity. Because of its chronic character, with cyclic intervals of ulceration and healing, there is also a significant health cost drain to consider. In the year 2001, the cost associated with venous leg ulceration in the United States was \$1 billion.⁵⁻⁷ The annual cost for difficult-to-heal ulcers may be up to \$27,500 per patient.⁸ There is no definitive cure for this illness; there are only palliative treatments, such as compression therapy.⁹ This is considered the “gold standard” treatment for venous ulceration.¹⁰

Surgery has proven to be successful treatment in long-term healing of ulcers secondary to primary venous insufficiency. Venous ulcers secondary to postthrombotic etiology pose a more serious challenge. Valvuloplasty/transplantation have been accompanied by only moderate long-term success. Compression should always be an integral part of the surgical treatment. Its efficiency in healing and preventing leg ulceration has been highlighted by several investigators.¹¹⁻¹⁴ Compression controls edema, neutralizes venous hypertension, assists the calf-pump mechanism, increases the velocity of venous return, protects the extremity, and ameliorates the devastating effects of venous hypertension. The most common methods of compression are (1) elastic (compression hosiery), (2) mechanical (intermittent pneumatic compression), and (3) bandages (elastic, short stretch, and nonelastic).¹⁵ The introduction of a nonelastic compression system based on adjustable Velcro bands (CircAid, San Diego, Calif) presented the opportunity to compare the efficacy of a time-honored nonelastic compression provided by the Unna boot with that of a system that is also nonelastic but can be changed and adjusted daily or every other day, thus eliminating smelly secretions. The value of a particular type of compression over another continues to be a subject of

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Fig 1. Bilateral postthrombotic venous leg ulcers in 1 of the 12 patients. The areas of several ulcerations in 1 limb were determined by computer scanning and added. One limb was randomized to have elastic and the other to have nonelastic compression systems.

controversy. To gain insight into this controversy, we randomly compared a four-layer elastic bandage with a non-elastic garment (CircAid) in patients with bilateral venous leg ulcers.

PATIENTS AND METHODS

Patients. The study protocol was approved by our institutional review board. Eligible patients were those with bilateral chronic venous leg ulcers (Fig 1), those with no chronic or acute systemic disease, those with no arterial insufficiency as determined by an ankle/brachial index of 1 or higher, and those without impaired mobility secondary to rheumatoid arthritis or similar diseases. All enrolled patients signed an informed consent form.

Twenty-four extremities of 12 patients with postthrombotic bilateral leg ulcers were randomized to apply CircAid to either the left or right extremity and an elastic bandage to the contralateral limb. The CEAP classification in 22 extremities was C₆ S; E_S; A_{D6,14,15,P18}; P_R; 1 extremity in 2 patients was C₆ S; E_S; A_{D 6,14,15,P18}; P_{RO}. There were seven men and five women. Age ranged from 45 to 82 years, with a mean of 61 years. All patients underwent a complete physical examination before treatment to determine their health condition and the etiology of their ulceration.

All patients had a history of deep venous thrombosis, and their extremities showed chronic venous sequelae (edema, pigmentation, lipodermatosclerosis, and ulceration). Three patients had previous pulmonary embolism, one had two Greenfield filters, five had subfascial procedures, and four had previous superficial venous surgery and skin grafts.

Methods. This was a randomized study comparing elastic vs nonelastic compression systems in 24 limbs of patients (n = 12) with bilateral leg ulcers. The 24 extremities were divided into 2 groups. Group A (n = 12) received CircAid, and group B (n = 12) received elastic bandages. Before the compression treatment was applied, every leg ulcer was cleansed with neutral soap and water, and the skin was lubricated with lanolin. Instructions were given to the medical personnel to cleanse the ulcers every 72 hours and reapply compression. No special dressings were used. After cleansing, the ulcers were covered with a fine mesh Vaseline gauze (Aquafor) and a single layer of sterile absorbent gauze. Limbs assigned to CircAid had a 1-cm-thick felt pad cushion applied over the absorbent gauze that was held in place by a surgical cotton stockinette. The nonelastic custom garment was fitted during the first visit and consisted of a series of individually adjustable Velcro bands 5.1 cm wide that extended from the ankle to the knee; these were fastened by woven nylon loops. An elastic anklet (Medi) was applied from the base of the toes to 5 cm above the malleoli.

The four-layer elastic compression system consisted of a layer of fine mesh Vaseline gauze (Aquafor), a layer of absorbent gauze, and a 1-cm-thick felt pad overlapping at least 3 cm of the ulcer area and held in place by a thick gauze bandage (Kerlix). A 15-cm-wide elastic bandage was firmly applied to a comfortable level from the base of the toes to just below the knee. An initial determination of the ulcer area was recorded. Every 4 weeks, the patients had the ulcer area traced over a fine reticular paper and scanned as a digital image by following the method reported by Thalmann et al¹⁶; the leg circumference was also measured in centimeters at the midfoot, ankle, and calf. Data were recorded in the patient's chart by using special sheets. Leg drawings were used to illustrate the size and location of lesions. Color photographs were taken before treatment and every month to monitor the healing-rate progress. A final photograph was taken at the end of the study period. All patients had culture of exudates. Eight patients had duplex scanning of the deep venous system, and four had phlebography. Air plethysmography was performed in two patients. All patients were compliant. At the end of the study period, patients were asked to fill out a patient satisfaction scoring sheet where 3 indicated very satisfied, 2 indicated moderately satisfied, and 1 indicated not satisfied. Results were assessed at 12 weeks when the final area measurement was determined. All available data were entered into a database and statistically analyzed.

Statistical analysis. The primary outcome was ulcer area reduction or healing rate (square centimeters per week):

Healing rate = (initial ulcer area – final ulcer area) / (number of weeks taken to heal completely or at 12 weeks)

Secondary outcomes were the limb circumference reduction rate (centimeters per week) and patient satisfaction scores. Patient satisfaction was scored as follows: 3, very satisfied; 2, moderately satisfied; and 1, not satisfied. To compare the two matched groups (A vs B), hazard ratios by

Table I. Comparison of groups A and B

<i>Ulcer area reduction</i>	<i>HR for CircAid (group A)</i>	<i>HR for group B</i>	<i>95% CI for HR</i>	<i>P value</i>
Area reduction rate (cm ² /wk)	0.56	1 (reference)	0.33-0.96	.0173*
Limb circumference reduction rate (cm/wk)	2.36	1	0.30-18.52	.3580

Hazard ratios (HRs) are shown with 95% confidence intervals (CIs; n = 12). The P value of the Cox proportional hazards model was used for comparison of group A vs group B (as a reference).

*Significant at the 5% significance level. Note: independence between groups A and B was assumed.

Table II. Comparison of groups A and B

<i>Outcome</i>	<i>CircAid (group A)</i>	<i>Control (group B)</i>	<i>95% CI of the difference (A - B)</i>	<i>P value</i>
Initial ulcer area (cm ²)	48.98 ± 14.13	50.08 ± 18.30	-27.25 to 25.07	.9285
Ulcer area reduction rate (cm ² /wk)	2.93 ± 0.60	2.30 ± 0.70	0.05 to 1.21	.0369
Initial limb circumference (cm)	35.59 ± 2.42	35.59 ± 2.56	-2.17 to 2.17	1.0000
Limb circumference reduction rate (cm/wk)	0.32 ± 0.14	0.15 ± 0.18	-0.08 to 0.42	.1606
Patient satisfaction score	2.92 ± 0.08	2.58 ± 0.15	-0.08 to 0.75	.1039

Data are mean ± SE with 95% confidence intervals (CIs) for the difference between group A and group B (n = 12). The P value of the paired t test was used for comparison of groups A and B.

Table III. Comparison of elastic versus nonelastic compression in bilateral venous ulcers

<i>Patient No.</i>	<i>Group A ulcer area (cm²)</i>		<i>Group B ulcer area (cm²)</i>		<i>Group A study period (wk)</i>	<i>Group B study period (wk)</i>
	<i>Initial</i>	<i>Final</i>	<i>Initial</i>	<i>Final</i>		
1	25.0	10.0	19.3	13.2	12	12
2	44.0	24.0	24.0	10.2	12	12
3	25.7	15.4	37.2	28.3	12	12
4	18.0	0.0	10.2	0.0	8*	8*
5	174.0	82.3	108.0	35.8	12	12
6	108.4	35.8	220	130.4	12	12
7	18.3	0.0	5.2	0.0	8*	4*
8	16.3	0.0	10.6	0.0	6*	8*
9	68.4	30.2	56.4	37.2	12	12
10	61.7	10.4	90.7	30.4	12	12
11	6.7	0.0	3.2	0.0	4*	4*
12	21.2	5.8	16.1	11.3	12	12

Group A, Nonelastic; group B, elastic.

*Healed.

using the Cox proportional hazards model were used for ulcer area and limb circumference reduction rates, and the paired t test was used for the other outcomes. Statistical software (SUDAAN 9.01 and PC SAS 9.1 [SAS Institute, Cary, NC]) was used for computations. The significance level of a statistical test was set at 5% (Tables I and II).

RESULTS

The ankle/brachial index was normal (≥ 1.0) in all patients. At the end of the 12-week observation period, four ulcers in group A and four in group B had healed completely. None of the ulcers had symptoms or signs of infection (pain, inflammation, redness, and so on).

As observed in Table III, the ulcer healing rate was faster in group A than in group B (hazard ratio, 0.56; 95% confidence interval, 0.33-0.96; $P = .0173$). No significant

difference was found in the limb circumference reduction rate between groups. None of the demographic factors (age or sex) was associated with reduction rates. No significant differences were found in patient satisfaction scores, initial ulcer areas, or initial limb circumferences (Table I).

There were 12 extremities with both medial and lateral perimalleolar ulcers. The remaining 12 extremities had ulcers over the medial aspect only. The patients had had recurrent ulceration for more than 10 years, and at the time of enrollment, patients had had active ulcers for 1 to 6 years. Phlebography showed femoral vein obstruction in one limb and partially recanalized ilioacaval obstruction in another; duplex scanning revealed a hemodynamic pattern of reflux in the remaining 22 extremities. The two ulcerated limbs with hemodynamic venous obstruction had a protracted course when compared with the contralateral limb

with hemodynamic reflux. The girth reduction rate (centimeters per week) was greater in group A than in group B during the initial 4 weeks of treatment. However, at the end of the study period, there was no significant girth difference between groups.

DISCUSSION

There is continuous controversy regarding the effectiveness of elastic vs nonelastic compression in the management of chronic venous insufficiency, particularly in the healing of venous leg ulcers.^{13,14} The Unna boot has been by far the most commonly used nonelastic compression. Its success in noncompliant patients has been confirmed in some reports. However, the apparent advantage that it cannot be removed by the noncompliant patient becomes its main disadvantage when the oozing ulceration becomes foul-smelling and the patient begs to have it removed. In this study, we documented the effectiveness of nonelastic compression as compared with a four-layer elastic compression system in the healing process of bilateral venous leg ulcers of the same hemodynamic etiology. This comparison is not unique in the literature.^{12,15,17} Previous investigators have compared elastic vs nonelastic or short-stretch compression systems in the management of leg ulcers of the extremities, and their results have been conflicting. In a randomized study of 40 patients with leg ulcers, Danielsen et al¹⁸ compared long-stretch vs short-stretch compression bandages and found better healing rates at 12 months in the group with long-stretch bandages (81% vs 31%). Similar results were reported by Iglesias et al,¹⁹ who randomized 387 patients with venous leg ulcers to a four-layer elastic bandage or a short-stretch bandage. The primary end point was complete healing of all ulcers, and the secondary end point was healing at 12 and 24 weeks. Most ulcers (82%) were 10 cm² or larger. At the end of the study period, there was no significant difference in the healing rate between the two systems. One important difference between this study and ours is that the initial size of the ulcer area in our groups was significantly larger. The initial ulcer area in group A was 48.98 ± 14.13 cm² and was 50.08 ± 18.30 cm² in group B ($P = .9285$). Large ulcers take longer to heal. Another important and positive aspect of our study is that we randomized limbs with bilateral postthrombotic venous ulcers by using one limb of the same patient as a control (Fig 2). The ulcer-healing process was carefully monitored by color photography, and ulcer size was assessed by a computerized scanning method, which is particularly accurate in multiple ulcerations of different shapes and sizes.

A possible criticism is that the primary end point of our study was not complete healing of the ulcer. However, the rate of healing of ulcers of the same etiology located in the limbs of the same patient with good arterial inflow by using a set period of time for the study (12 weeks) is a valid parameter to evaluate both systems of compression. Both systems, the elastic and nonelastic, have as a basis the documented beneficial effects of compression.²⁰⁻²² Even though there were only two limbs, an observation worthy of note was the protracted healing rate of ulcers of the limbs



Fig 2. Patients were randomized to have non-elastic bandage (CircAid) in 1 extremity and a four-layer elastic in the contralateral. In this patient, CircAid is on the right lower limb.

with hemodynamic obstruction as compared with the contralateral limb with venous reflux as the main hemodynamic etiology of the ulceration. These patients had a pattern of obstruction by air plethysmography. One limb had femoropopliteal venous obstruction, and the other had obstruction and partial recanalization of the ilioacaval segment (Fig 3). In addition, this patient had a Greenfield filter placed after an episode of pulmonary embolism.

However, other investigators have reported better compression and better healing rates of venous leg ulcers with the nonelastic or short-stretch compression systems than with the elastic compression bandages. Partsch et al^{15,23} compared the efficacy of elastic long-stretch vs non-elastic short-stretch bandages in 21 patients with hemodynamic venous reflux. Using air plethysmography and compression bandages and applying the same pressures (30 mm Hg), he reported the highest reduction of venous volume and venous filling index in the nonelastic compression system as compared with the elastic. He concluded that with the same bandage pressure, inelastic material is more



Fig 3. Effects of hemodynamic obstruction on ulcer healing. Patient with bilateral postthrombotic venous ulcers. The right limb had a pattern of hemodynamic venous reflux documented by duplex scanning. The left limb had a pattern of hemodynamic venous obstruction documented by phlebography and air plethysmography. Both ulcer areas were initially similar. Healing in the right limb occurred readily under a four-layer compression elastic system. As observed, healing on the obstructed limb treated by nonelastic system was protracted.

effective at reducing deep venous reflux than the elastic long-stretch bandages. Similar conclusions were reached by Spence and Cashall²⁴ and Bergan and Sparks.²⁵ In separate communications, these investigators reported that the continuous sustained pressure provided by the nonelastic or short-stretch compression systems documented by air plethysmography was similar to that provided by the elastic bandages or stockings in the standing or walking positions and that it was able to better control tissue edema. In the recumbent position, the nonelastic compression diminishes its compression and allows better tissue perfusion. However, in the recumbent position and at rest, the elastic compression system maintain its high pressure. This implies that elastic compression applied over a long time in the recumbent position may be deleterious for the microcirculation and may jeopardize tissue viability, a conclusion drawn also by Murthy et al.²⁶

Depending on the ulcer size, ulcer healing rates under compression therapy have been reported to range from 40% to 70% over 3 months and from 50% to 80% over 6 months.^{27,28} In our study, four ulcers in each group had healed completely before the 12-week observation period. However, these had a small initial surface area. The larger ulcers did not heal completely within the 12-week period of observation. Skene et al²⁹ developed a prognostic index to calculate the healing time for venous ulcers. They found that the healing time for ulcers depends on patient age, duration of active ulcer, ulcer size, and history of deep venous thrombosis. It seems clear to us that in addition to those risk factors, the patient's age, degree of mobility, obesity, and compliance; sufficient arterial supply; and the bandager's skill and application technique are the most important factors that determine the rate of healing of a

venous ulcer. In our patients, as had been reported by Mayberry et al,³⁰ compression was selected after surgery for perforator division and other forms of venous surgery had failed to prevent ulcer recurrence. The nonelastic compression provided by the series of adjustable Velcro bands in the CircAid allows it to be tailored as limb swelling decreases and to be adjusted during the day if necessary. It provides sustained ambulatory compression during the day and decreases the pressure during the recumbent position. In addition, it is a good alternative for patients who are unable to wear 35 to 45 mm Hg pressure elastic stockings because of weakness or arthritis or those who are unable to tolerate the Unna boot.

In conclusion, even though it is accepted that compression is the "gold standard" form of treatment for chronic venous insufficiency with ulceration, there is still a great deal of controversy regarding the best method for applying compression. In this limited study of bilateral leg ulcers of the same etiology, we found that the nonelastic compression provided by CircAid was superior to that provided by the four-layer compression system, as reflected by a faster healing rate. The advantage of our study is that each patient's leg served as its own control. We conclude that methods of compression should be compared whenever possible in patients with similar hemodynamic venous pathologic characteristics and by using standardized methods of investigation to avoid variables that may alter the results.

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