Healing rates and cost efficacy of outpatient compression treatment for leg ulcers associated with venous insufficiency

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Objective: **Although newer techniques to promote the healing of leg ulcers associated with chronic venous insufficiency are promising, improved healing rates and cost effectiveness are unproven. We prospectively followed a series of patients who underwent treatment with outpatient compression for venous stasis ulcers without adjuvant techniques to determine healing rates and costs of treatment.**

Methods: **Two hundred fifty-two patients with clinical or duplex scan evidence of chronic venous insufficiency and active leg ulcers underwent treatment with ambulatory compression techniques. The patients were prospectively followed with wound measurements at 1-week to 2-week intervals, and the factors that were associated with delayed healing were determined.**

Results: **Of all the ulcers, 57% were healed at 10 weeks of treatment and 75% were healed at 16 weeks. Ultimately, 96% of the ulcers healed, and only 1 major amputation was necessitated (0.4%). Initial ulcer size and moderate arterial insufficiency (ankle brachial index, 0.5 to 0.8; n = 34) were factors that were independently associated with delayed healing ($P < .01$). Patient age, ulcer duration before treatment, and morbid obesity did not significantly affect healing times. The cost of 10 weeks of outpatient treatment with compression techniques ranged from $1444 to $2711.**

Conclusion: **The treatment of venous stasis ulcers with compression techniques results in reliable, cost-effective healing in most patients. Current adjuvant techniques may prove to be useful but are likely to be cost effective only in a minority of cases, particularly in patients with large initial ulcer size or arterial insufficiency. (J Vasc Surg 1999;30:491-8.)**

Lower extremity ulcers that are associated with venous insufficiency have been estimated to affect 0.2% to 1% of the population in developed countries.[1] Although these ulcers are rarely a cause of amputation, patient debilitation and discomfort are significant. The chronic, recurring nature of these ulcers prohibits many patients from working or enjoying an active lifestyle. The standard therapy for ulcers that are associated with venous insufficiency has emphasized nonoperative techniques, including leg elevation, compression therapy with Unna's paste boot or elastic wraps, and patient education.[2]

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Recently, several techniques have been reported to improve healing rates or to reduce the risk of recurrence for venous leg ulcers. These techniques include subfascial endoscopic perforator surgery (SEPS)[3] and the application of allogeneic cultured human skin construct.[4] Although promising, these techniques are expensive, which raises the question of appropriate patient selection to maximize cost efficacy. This report reviews the factors that are associated with the healing of leg ulcers and the associated costs in a large group of patients to help determine which patients are well served with outpatient compression techniques and who might benefit from adjuvant techniques of treatment.

PATIENTS AND METHODS

Patients who were referred to the University of North Carolina wound care clinic with leg ulcers and clinical or duplex scan evidence of chronic venous insufficiency (CVI) were followed prospectively with the following protocol: all the patients underwent a history and physical examination to

determine causes of ulceration. Patient information, including age, sex, history of diabetes or morbid obesity, ulcer duration before treatment, history of multiple previous ulcers, and peripheral arterial disease, was recorded. The presence of lower extremity edema, hyperpigmentation, and stasis dermatitis in the gaiter region were all necessary to make a clinical diagnosis of CVI. Ulcer location, size, and depth were documented at the initial visit with wound tracings, and planimetry was performed to obtain measurement of ulcer area. At subsequent visits, ulcer size in two maximal dimensions was recorded. When patients were seen with bilateral leg ulcers, each limb was considered separately, and if multiple ulcers were present on a limb, only one ulcer, the largest, was chosen as the index ulcer for measurement and determination of healing time.

Patients with no palpable pedal pulses underwent Doppler scan waveform analysis and segmental pressure measurement to determine the degree of arterial insufficiency (AI). Patients with an ankle brachial index (ABI) of greater than 0.8 were considered to have an adequate arterial supply to heal and comprised the isolated venous insufficiency group (no AI group). Patients with evidence of venous insufficiency and an ABI of 0.5 to 0.8 who were not candidates for revascularization because of medical comorbidity comprised the combined arterial and venous insufficiency group (AI group). Patients with an ABI of less than 0.5 were excluded from the data analysis and were considered for revascularization.

Patients underwent evaluation of the venous anatomy with duplex ultrasound scanning and a rapid deflation cuff unless contraindicated by obesity or inability to cooperate with the study. With criteria that were established previously, the deep, superficial, and perforator systems were systematically examined for reflux in the standing position.[5] The anatomic pattern of CVI was identified, which allowed comparison with patient outcome. During the time period of this study, the authors did not perform venous surgery on any patients before ulcer healing.

Patients with venous insufficiency alone underwent treatment with one of two forms of compression treatment at the discretion of the attending physician. Unna's paste boot (Medicopaste, Graham-Field, Hauppauge, NY) was applied from the foot to the knee and was covered with an elastic crepe bandage (Coban, 3M, St Paul, Minn). Four-layer, sustained compression wraps (Profore, Smith & Nephew, Largo, Fla) were applied as previously described to achieve 40 mm Hg of sustained compression at the ankle.[6] In all the patients, a primary cover for the ulcer was chosen on the basis of the amount of drainage from the ulcer. At the discretion of the treating physician, the patients who were judged to have more extensive drainage underwent treatment with absorptive foam dressings as a primary cover, such as Sof-foam (Johnson & Johnson Medical Inc, Arlington, Tex) or Allevyn (Smith & Nephew). These foam dressings allowed less frequent changes of the compression wrap or Unna's paste boot. Patients with managable drainage underwent treatment with no primary cover with Unna's paste boot or with the primary layer contained in the Profore kit. Extensive education concerning leg elevation, wound care, and venous disease was performed for each patient. Patients with combined arterial and venous insufficiency (ABI, 0.5 to 0.8) underwent treatment with a three-layer compression wrap, omitting one layer of elastic compression from the four-layer protocol to achieve a reduced level of compression at the ankle (25 to 30 mm Hg, from manufacturer's unpublished data).

The dressings were applied for a maximum of 1 week, with more frequent changes necessitated in patients with excessive ulcer drainage. The patients returned to the clinic for wound examination every 1 to 3 weeks, depending on home health nursing involvement. Home health nursing was used in patients who required dressing changes between clinic visits. Those patients who did not return to the clinic for at least 6 weeks of treatment were considered to be lost to follow-up examination and were excluded from the data analysis. The patients were followed until the ulcers were healed with complete re-epithelialization of the wound. Once the ulcers were healed, the patients were fitted for knee-high compression garments, with 30 to 40 mm Hg of compression at the ankle for patients with venous insufficiency alone and 20 to 30 mm Hg for patients with combined arterial and venous insufficiency. Patient follow-up examination occurred at 6-month intervals after healing to renew compression hose and reinforce education.

The costs that were associated with the treatment of leg ulcers were tabulated on the basis of Medicare reimbursement as follows: physician reimbursement for evaluation and procedures and hospital reimbursement for any blood, vascular laboratory, or other tests were determined by the actual amount reimbursed by Medicare for each charge. The cost of wound dressing materials was based on the amount paid by the hospital for components used in the prescribed dressing. The cost of home health nursing was determined for each patient on

Table I. Patient characteristics

Characteristics	
Average age (years)	61.4 (range, 21 to 91)
Percent male	53%
Average time ulcer present before treatment (months)	7.4
No. of patients with:	
Diabetes	32 (14.1%)
Morbid obesity (>50% above ideal weight)	44 (19.4%)
Arterial insufficiency (ABI, 0.5 to 0.8)	34 (15.0%)

ABI, Ankle brachial index.

Table II. Anatomic distribution of venous reflux in 138 limbs

Reflux site	*No. of limbs*
Deep system reflux alone	60 (43.5%)
Deep and superficial reflux	29 (21.0%)
Deep, perforator, and superficial reflux	9 (6.5%)
Superficial system reflux alone	25 (18.1%)
Superficial and perforator reflux	15 (10.9%)

the basis of the number of home health visits times the usual Medicare allowable per visit of $120 in North Carolina.

Data analysis. The following risk factors were analyzed for association with ulcer healing with multivariate discriminate analysis with the StatView statistical analysis software package (Abacus Concepts, Berkeley, Calif): patient age, sex, diabetes, morbid obesity, initial ulcer size, AI, ulcer duration before treatment, ulcer location, site of venous reflux, and type of compression. The healing times for individual factors were compared with Kaplan-Meier method curves and the log-rank test, with a P value of less than .05 necessary for statistical significance in all cases.[7]

RESULTS

Study population. Two hundred twenty-seven patients with 264 ulcerated limbs that were associated with venous insufficiency underwent evaluation from July 1995 to July 1998. Ten patients were lost to examination before 6 weeks of therapy and were excluded, which left 252 ulcers in 217 patients for analysis. Thirty-five patients had bilateral leg ulcers. The patient characteristics are summarized in Table I.

The average ulcer size was 24.6 ± 63.2 cm^2 (range, 1 to 600 cm^2). At initial examination, 91 ulcers (36.1%) measured less than 5 cm^2, 94 ulcers (37.3%) were 5 to 20 cm^2, and 67 ulcers (26.6%) were greater than 20 cm^2 in size. One hundred thirty-eight limbs in 116 patients underwent venous duplex scan studies for reflux, with the distribution of disease listed in Table II. Deep reflux was shown in 71% of the limbs. The remaining 29% of the limbs had superficial or superficial and perforator incompetence, which could potentially be corrected with superficial vein removal and SEPS if necessary. Overall, 56.5% of the limbs had superficial reflux, and 17.4% were found to have incompetent perforator veins.

Healing rates. Sixty-nine percent of the patients underwent treatment with four-layer compression bandages, 13% underwent treatment with three-layer compression bandages for combined arterial and venous insufficiency, and 18% underwent treatment with Unna's paste boots. Time to healing in the entire population of 252 leg ulcers on the basis of life-table analysis is illustrated in Fig 1. Fifty-seven percent of the ulcers were healed at 10 weeks, and 75% were healed at 16 weeks of treatment. At 1 year, 96% of all the ulcers were healed, and only one major amputation was necessitated (0.4%). Of the 10 unhealed ulcers, seven were significantly improved, two were unchanged, and one worsened in a patient with combined arterial and venous insufficiency and necesssitated amputation. This patient was considered for arterial revascularization but was not a surgical candidate because of severe medical comorbidity. Fifteen patients were hospitalized during the study period for leg ulcer–related complications, including infection, uncontrolled edema, or both.

Risk factor analysis. With multivariate analysis, the only factors to independently effect healing time were initial ulcer size ($P < .001$) and AI ($P < .01$). When the effect of the site of reflux on healing was examined, the patients with superficial or superficial and perforator incompetence had ulcers that were found to heal in 8.2 ± 5.8 weeks as compared with 13.7 ± 8.8 weeks for patients with deep venous incompetence alone. This difference was not significant when corrected for initial ulcer size ($P = .09$).

The effect of initial ulcer size on time of healing is illustrated in Fig 2. Ulcers that were less than 5 cm^2 at initial presentation healed significantly faster (77% at 10 weeks) than ulcers measuring 5 to 20 cm^2 (61% at 10 weeks; $P < .025$, with log-rank test). Ulcers that were larger than 20 cm^2 at presentation were associated with significantly delayed healing ($P < .001$, as compared with both other groups), with only 22% healed at 10 weeks. Although 89% of the large ulcers eventually healed, 21 weeks of treatment were necessary to heal 50%, and many ulcers needed required treatment for more than 9 months.

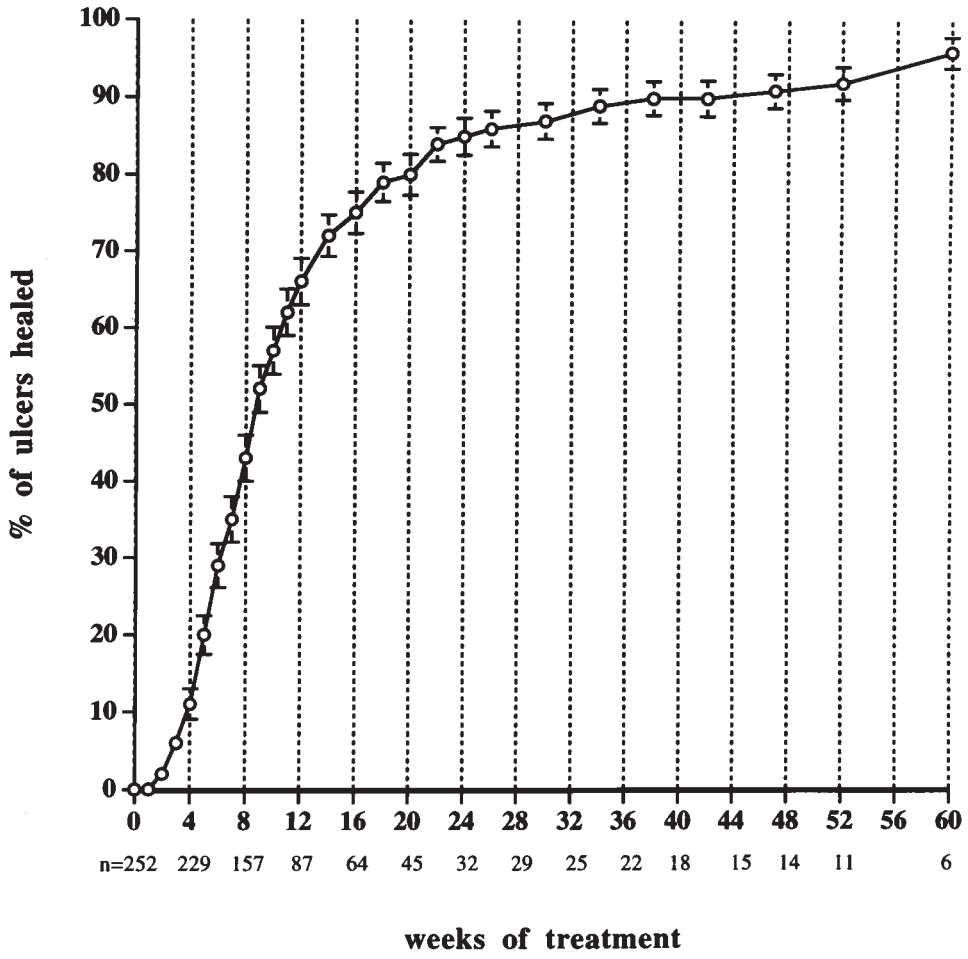

Fig 1. Life-table analysis for time to healing for all 252 ulcers.

The effect of AI on ulcer healing time is illustrated in Fig 3. In the no AI group, 63% of the ulcers healed after 10 weeks of treatment as compared with only 25% of the ulcers in the AI group ($P < .005$, with log-rank test). Eighty-five percent of the ulcers in the AI group were eventually healed with three-layer compression dressings, with 19 weeks of treatment necessary to heal 50% of the ulcers.

Ulcer recurrence. After ulcer healing, follow-up examination was obtained in 202 ulcerated limbs. In these limbs, the ulcer recurrence rate with life-table method was 21% ± 3.7% at 12 months, 29% ± 5.8% at 24 months, and 38% ± 10.5% at 36 months.

Cost efficacy. The average cost for 10 weeks of outpatient treatment with the outlined protocol was $2198 ± $445, ranging from $1444 to $2711. In patients who did not require home health nursing visits, physician reimbursement comprised 48% of the total cost, peripheral vascular and other laboratory testing comprised 19%, and wound dressing materials comprised 33%. In patients who required home health nursing (56% of the patients), physician reimbursement comprised 24% of the total cost, laboratory tests comprised 14%, and home health reimbursement comprised 62%. The factors that were most closely associated with increased treatment costs were ulcer size and the amount of ulcer drainage. Patients with larger, heavily draining ulcers initially required dressing changes two to three times per week, which necessitated increased home health use, resulting in a significantly increased cost per week of treatment. The cost to heal ulcers less than 5 cm^2 averaged $1327, ulcers 5 to 20 cm^2 averaged $1978, and ulcers more than 20 cm^2 averaged $5289.

DISCUSSION

The standard treatment for lower extremity ulcers that are associated with venous insufficiency has

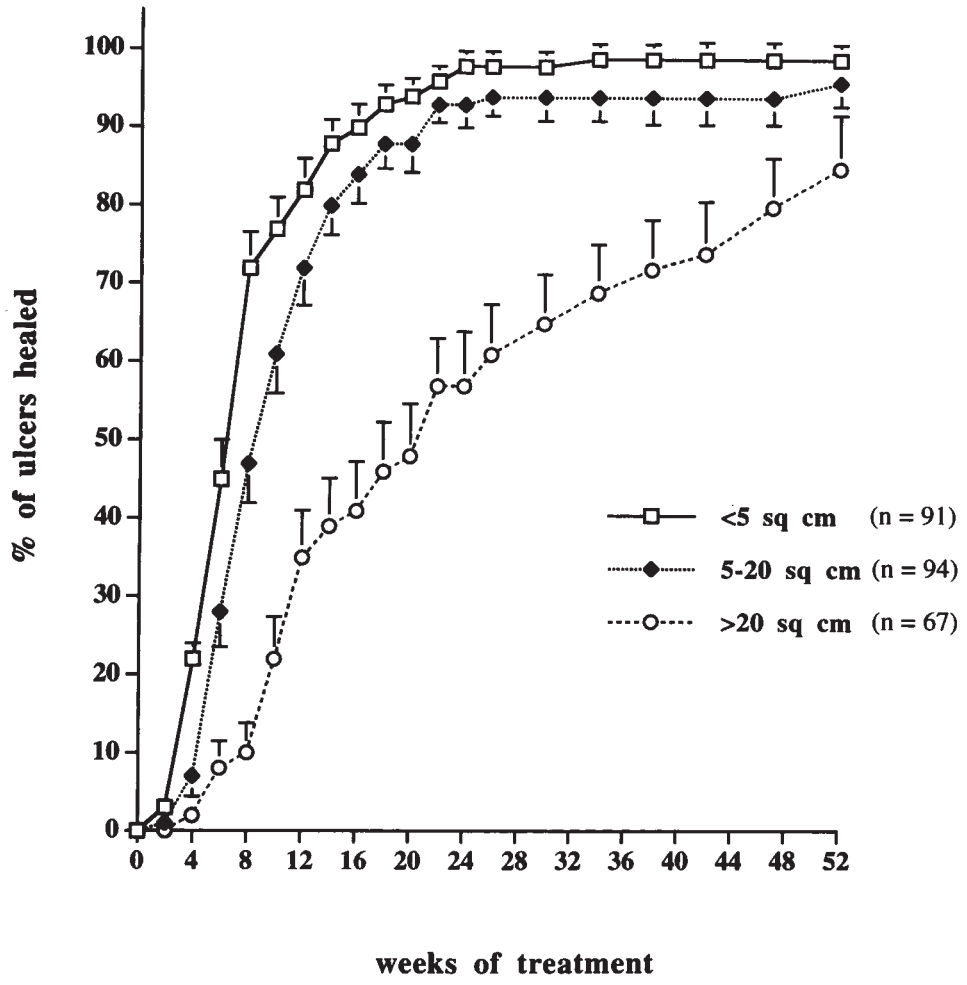

Fig 2. Life-table analysis for time to healing for ulcers on basis of initial size. All curves are significantly different with log-rank testing with $P < .025$.

emphasized the use of outpatient compression methods, elevation, and patient education. Various forms of compression therapy have been used throughout history for the treatment of venous leg ulcers, but no randomized trial has been performed that compared it with wound care without compression. Because compression has become the standard of care, it is unlikely that such a study will be performed given the ethical problems of the control group. With ambulatory elastic compression hose, Mayberry et al[8] achieved healing at a mean time of 5.3 months. Compliance with the treatment protocol was identified as the primary factor relating to time of healing and recurrent ulceration. Erickson et al[9] reported similar results in the treatment of 99 ulcers with Unna's paste boot or ambulatory compression hose. Median time to healing was 3.4 months, and normal venous refill time and patient compliance were associated with faster healing. Recurrent ulceration occurred in 57% of patients. Other factors that have been associated with delayed ulcer healing have been increased age, larger initial ulcer size,[10] popliteal vein reflux,[11] and poor response to the initial 2 weeks of compression treatment.[12]

Recent developments for the treatment of lower extremity ulcers that are associated with venous insufficiency include SEPS and the application of allogeneic cultured human skin construct. SEPS has been reported to accelerate the healing rate of venous leg ulcers and to possibly reduce the incidence of recurrence.[13,14] Cultured human skin construct was found, in a multicenter randomized trial, to accelerate the healing rate of larger ulcers and those present for extended periods of time.[4] However, these tech-

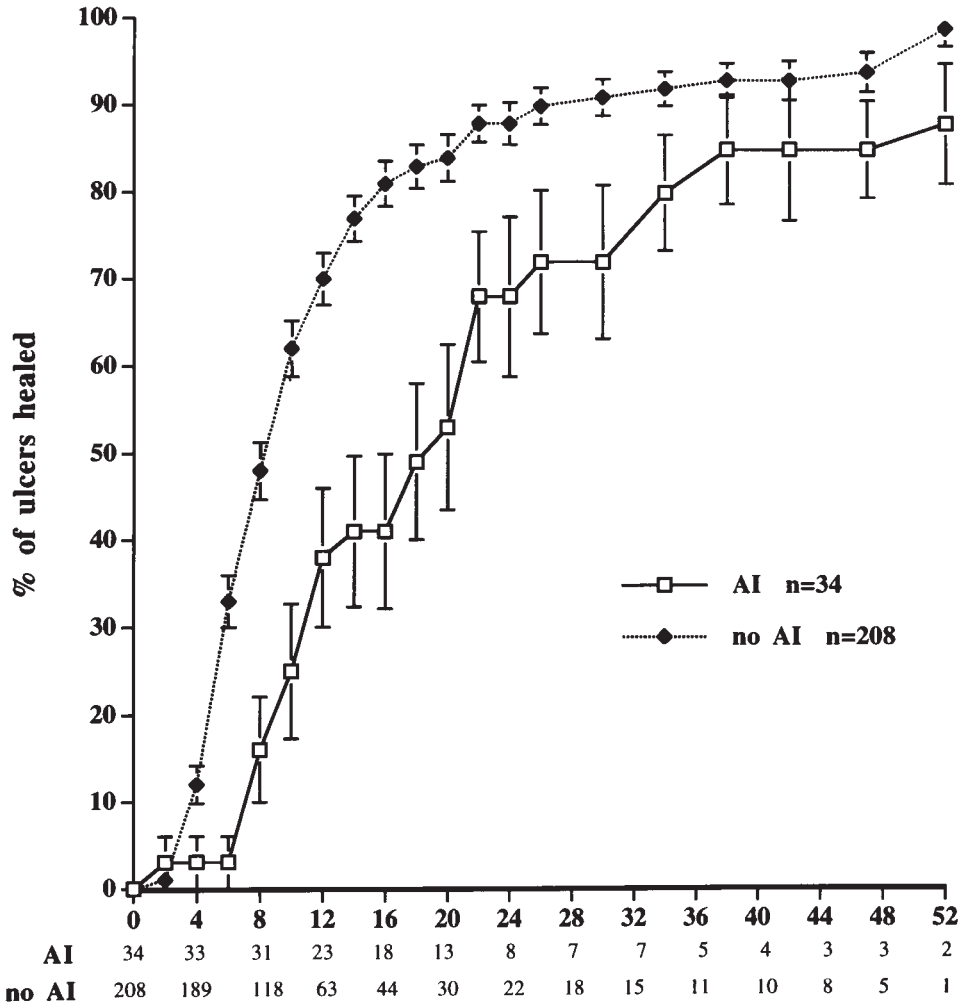

Fig 3. Life-table analysis for time to healing for ulcers with arterial insufficiency *(AI)* compared with ulcers without arterial insufficiency *(no AI)*. Curves are significantly different with log-rank testing ($P < .005$).

niques are associated with disadvantages. In the prospective randomized trial, Falanga et al[4] used an average of 3.4 applications of human skin construct per ulcer in the treatment arm. At more than $1000 per application, this adds significant cost to ulcer care. Although SEPS is a relatively low-risk procedure, the North American registry reported complications, including superficial thrombophlebitis, wound infection, and saphenous neuralgia, in a small number of patients.[3]

In this report, we present the results of the ambulatory compression treatment of a large series of patients with ulcers that were associated with venous insufficiency. We hope to identify the patients who would not be expected to heal in a reasonable period of time with this protocol. The potential benefits of ambulatory compression methods include their wide applicability, minimal risk, and cost efficacy. However, compression treatment does not address the cause of ulceration, and recurrence is frequent, depending on patient compliance with chronic use of compression stockings.

Although no clear differences have been proven for different compression systems,[2] we use four-layer compression bandaging in most patients because we believe edema is better managed and patient comfort is increased. We found that 96% of ulcers that were associated with venous insufficiency were healed within 1 year and that 50% of ulcers of less than 20 cm^2 in size with normal arterial supply were healed with 7 weeks of treatment at an average cost of less than $2000. We suggest that, unless other

techniques provide marked acceleration of healing, smaller ulcers without AI are best treated with ambulatory compression protocols.

Larger ulcers and those with AI were associated with significantly delayed healing. It is in these groups that significant savings in healing time and cost are possible with adjuvant techniques. Clearly, patients with significant AI should be considered for revascularization if possible. When revascularization is not possible, the results of this study suggest that most patients can be healed with modified compression to apply a reduced pressure at the ankle. Although cultured human skin construct was reported to improve healing rates, the cost of this treatment is high (>$1000 for one 7 × 7–cm piece) and markedly increases in larger ulcers because more product is necessitated. Healing rates for venous ulcers after SEPS have not been prospectively compared with healing rates for ulcers without SEPS. In the subset of patients that we studied with duplex ultrasound scanning, 17.4% were found to have perforator reflux and were potential candidates for SEPS.

Given the high incidence of recurrent ulceration after ulcer healing in this and other reports, techniques that reduce or correct venous reflux and associated hypertension may provide significant benefit to these patients. Scriven et al[15] reported that saphenous vein disconnection improved venous function and healed venous ulcers without compression bandaging in 16 patients with saphenous reflux alone. It is not yet clear whether SEPS procedures will result in a reduced incidence of ulcer recurrence. Sparks et al[13] reported no ulcer recurrence after SEPS at an average follow-up period of 8.6 months, but Glovizki et al[16] reported the incidence of new or recurrent ulceration to be 16% at 12 months and 28% at 24 months of follow-up.[16] We believe that a prospective trial that randomizes patients to compression therapy with or without SEPS in patients with incompetent perforator veins would help clarify the role of SEPS. We currently perform this procedure in patients with recurrent ulceration who have incompetent perforators and a competent deep venous system. Superficial venous stripping is performed at the same time as SEPS when indicated.

The trend towards slower healing in patients with deep venous insufficiency is interesting. Given the limited number of patients studied, the lack of a significant difference may represent a type II error. Other studies have identified global reflux and popliteal vein reflux as associated with delayed healing.[9,11]

Duration of ulceration before treatment did not independently correlate with healing time. This is likely because size was the predominant factor. Neglected ulcers were usually larger by the time of presentation for treatment. If an ulcer was not treated appropriately for a prolonged time but remained small, the patient typically healed rapidly after compression therapy was applied. In this study, we did not address the relationship between ulcer healing in the initial 2 weeks of treatment and time of healing.

In conclusion, ambulatory compression treatment remains a reliable, cost-effective method of treatment for patients with ulcers associated with venous insufficiency, particularly those with smaller, well-vascularized ulcers. With protocols such as the one outlined previously, most ulcers are healed within 10 weeks of therapy at a reasonable cost. Larger ulcers and those associated with AI (31% of the ulcers in this study) often experience delayed healing and may benefit significantly from adjuvant healing techniques, such as human skin construct and arterial revascularization when possible. Recurrence rates after healing were high despite persistent efforts at chronic limb compression and patient education, which emphasizes the need to further define whether corrective venous surgery, such as SEPS or superficial venous stripping when possible, will reduce the risk of ulcer recurrence.

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DISCUSSION

Dr F. Noel Parent III (Norfolk, Va). The essence of this anecdotal series of venous ulcers treated with compression wrapping on an outpatient basis confirms that almost all ulcers will heal with an Unna's paste boot or a compression wrap if given enough time. The majority of ulcers heal within 4 months, and the cost for this treatment regimen is reasonable. Only large initial ulcer size and moderate arterial insufficiency were independently associated with a longer healing time. It is in this group of difficult-to-treat ulcers that the authors suggest those adjuvant surgical therapies, such as SEPS and human skin equivalent, which may be more cost effective than prolonged Unna's paste boot treatment.

The desired outcome is ulcer healing without recurrence. Compression therapy is well known to achieve ulcer healing. However, unless the underlying venous hemodynamics can be improved upon, recurrent ulcers are the rule. Stated in the presentation and manuscript but absent from your abstract is a recurrence rate of 25.6% at 12 months and 36.5% at 30-month follow-up. And I think it is obvious that any cost savings will quickly evaporate if long-term ulcer control is not achieved.

In this series, superficial venous reflux was found in 56.5% of cases, but there is no mention of any surgical treatment for it. Some studies have shown that reflux in the superficial venous system may overload the capacitance of the venous system, resulting in deep venous reflux. After superficial vein stripping, the venous capacitance is restored to normal and the deep and perforator vein reflux may resolve. My only criticism would be of giving up compression boot therapy for SEPS or human skin equivalent before treating any superficial vein reflux by vein stripping.

That leaves me with three simple questions. Do the duplex ultrasound scan data about the deep, superficial, and perforator veins guide your therapy? How do you prefer to treat recurrent ulcers? And what do you think should be done to prevent ulcer recurrence?

Thank you.

Dr William A. Marston. Thank you very much, Dr Parent, and I think those are important questions. Our point is not to suggest that surgery to anatomically correct superficial or perforator lesions, if possible, should not be done. We fully agree with that. After ulcer healing in patients with superficial or perforator incompetence, we attempted to correct these systems if the patient would agree to surgery. If the patient had deep venous insufficiency alone, we have been more reluctant to do that type of surgery, except for young patients who had chronically recurring ulcers. Then, we would attempt to do a venous valve transplantation or, if possible, correction. But that is relatively rare in our population. We use the duplex ultrasound scan data to guide that process by mapping all three systems for the sites of reflux.

I think the main point of our presentation here, though, is that if you use a religious program of compression therapy, you can get the ulcers healed initially, and then your job is preventing recurrence. It does not change the high recurrence rate and it does not lessen the importance of that job, which is truly the important thing in the long run for the patients.

When considering the utility of SEPS, the crux of the matter is whether it will reduce the ulcer recurrence rate, and I do not think we know that yet. Superficial venous surgery has been shown in some studies to reduce recurrence rates, so we are a real proponent of that as well.

Thank you.