

Comparison of Costs and Healing Rates of Two Forms of Compression in Treating Venous Ulcers

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ABSTRACT

The objective of this study was to compare healing rates and costs of treating venous ulcers with traditional Unna boots (UB) or a CircAid Thera-Boot (TB). A multicenter, prospective, randomized parallel-group study was performed in three university medical center vascular surgery clinics and three private medical offices. Patients presented with unilateral venous leg ulcers 5 cm or less in diameter. Patients with severe arterial, metabolic, or neuropathic diseases, and those who would not be expected to heal with conservative treatment, were excluded. Conservative treatment of the leg ulcer consisted of a nonadherent topical dressing and compression with either a traditional Unna's boot or a Thera-Boot. The main outcome measures were the following: time to healing, rate

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(Abstract continued)

of area decrease, rate of percent area decrease, linear healing rate, costs of labor, materials, and overhead. Of 38 enrolled patients seven were withdrawn (five UB, two TB). Three patients were still in treatment when the study was stopped. Eleven UB patients and 17 TB patients completed the study. Healing rates were for UB and TB patients (mean $\pm$ sd) were, respectively: time to healing (weeks) 9.69 ± 3.28 , 7.98 ± 4.41 ($p = 0.41$), area healing rate (cm^2/day) 0.0239 ± 0.0534 , 0.0433 ± 0.0910 ($p = 0.27$), % area healing rate ($\%/ \text{day}$) 1.0493 ± 1.5583 , 2.0357 ± 1.9520 ($p = 0.56$), and linear healing rate (cm/day), 0.0060 ± 0.0092 , 0.0109 ± 0.0125 ($p = 0.27$). Costs for UB and TB (dollars to completion) were, respectively: clinician labor 331.37 ± 255.75 , 201.91 ± 131.17 ($p = 0.09$), materials 160.86 ± 96.86 , 122.79 ± 27.59 ($p = 0.14$), overhead (number of visits) 11.70 ± 6.40 , 6.71 ± 3.77 ($p = 0.02$), and total costs 901.73 ± 576.45 , 559.41 ± 290.75 ($p = 0.05$).

Treatment of venous ulcers with CircAid Thera-Boots is significantly less costly than treatment with traditional Unna's boots. Trends toward faster healing were noted.

Introduction

Venous stasis ulcers are a common problem in adult populations worldwide. Though recent surgical advances have shown benefits in selected patients, the majority of venous ulcers are still treated conservatively.¹⁻³ Compression is acknowledged as the mainstay of nonsurgical treatment; however, no single method has been shown to be superior to all others, in terms of healing efficacy or cost effectiveness, and wide varieties of devices and materials are used.⁴ Many clinicians favor nonelastic compression for treatment in the healing stage.⁵

In the United States the Unna boot is the most commonly used form of nonelastic compression for this disease.⁴ However, application requires skill, the materials are not reusable, and the dressing may lose compression rapidly as edema decreases.⁶ In 1997 CircAid® (CircAid Medical Products, Inc., San Diego, CA) introduced the Thera-Boot™ specifically for the treatment of venous ulcers. It is similar to other CircAid leggings but has fewer bands and is less expensive. The device consists of a series of interlocking, nonelastic bands that encircle the leg and are held in place by hook and loop fasteners and a foot piece made of very low stretch bands. This device is adjustable, thus providing sustained compression, as well as being reusable, and does not require skilled application. These advantages might lead

to faster healing and lower cost of treatment, and this study was done to test these hypotheses.

Methods

A multicenter, prospective, randomized, parallel-group study was conducted. Six centers participated; all obtained appropriate Human Subjects Committee (IRB) approvals. All patients with venous ulcers who met the inclusion criteria and did not have exclusion criteria presenting to the centers between March 1997 and August 1998 were invited to participate.

Study criteria included outpatients 18 years of age or older with a unilateral leg ulcer that was clinically diagnosed as being of venous origin, had documented underlying venous disease by duplex examination, and were willing to participate in the study as evidenced by signing an IRB-approved informed consent document.

Exclusion criteria included ulcers of nonvenous or mixed etiology and ulcers larger than 5 cm in diameter and patients who, in the physicians' judgment, would not be expected to heal with only conservative treatment, had poor underlying general health, were taking medications known to inhibit wound healing, had had an acute deep venous thrombosis within the last 3 months, had had venous surgery within the last

month, had allergies to study materials, were pregnant, patients who the investigator felt were likely to be noncompliant, and those who the investigator felt could be better treated by methods other than those used in the study.

All patients received initial evaluation and randomization on the first visit. At each visit the ulcers were cleansed and debrided as appropriate and a tracing of the ulcer outline was made on clear film. Time spent with the clinicians and materials used were recorded. Initially, billing was tracked, but the different centers were very disparate.

The topical ulcer dressings in both groups was an impregnated gauze (Adaptic®, Johnson and Johnson Medical, Arlington, TX) covered by a 4 in × 4 in gauze pad (Curity®, The Kendall Company, Mansfield, MA) and held in place by a conforming gauze wrap (Kling, Johnson and Johnson Medical, Arlington, TX). Those in the Unna boot group had a zinc oxide, glycerin, and gelatin impregnated 4 in by 10 yd roller gauze bandage (Medicopaste®, Graham-Field, Hauppauge, NY) applied to the limb from the base of the toes to just below the knee and covered by an elastic Ace type bandage. The Thera-Boot group had the device applied as recommended by the manufacturer, with application of the straps so that they were firm but comfortable. Patients were told to adjust the straps as necessary to maintain this level of compression. They were allowed to remove it for bathing or for dressing changes. Both groups were seen as often as the investigator felt was appropriate until the ulcer had healed, or until 12 weeks had elapsed, whichever was shorter.

Data sheets and ulcer tracings were sent to the study coordinator (WPB) for tabulation and analysis. Costs of treatment were calculated for completed patients based on the following: physician time \$100/hr, nurse time \$35/hr, Thera-Boot \$95 each, Unna boot \$11 each, impregnated gauze \$0.50 each, 4 × 4 gauze pads \$0.04 each, conforming gauze \$0.50 each, elastic bandage \$1.65 each, and overhead at \$35 per visit. From these data, clinician costs, materials cost, overhead costs, and total costs were tabulated.

Healing rates were calculated for enrolled patients as time to healing and, from the ulcer tracings, rate of area decrease, rate of percent area decrease, and linear (also called planimetric) healing rate as described by Gorin et al.⁷ Areas and perimeters for the healing rate calculations were obtained from computerized planimetry of the ulcer tracings by use of Adobe Photoshop (Adobe Systems Inc., Mountain View, CA).

Results are reported as means and standard deviations (sd). Statistics were calculated by use of Student's *t* test by Primer of Biostatistics Software (New York: McGraw-Hill). Data were analyzed on an intention to treat basis. *P* values of 0.05 or less were considered significant.

Results

Thirty-eight patients were enrolled. Nineteen patients were randomized to each of the two groups. Characteristics of each group on enrollment are shown in Table I. There were 28 completed patients, 11 in the Unna boot group and

Table I
Patient and Ulcer Characteristics on Entry

	Age (Years)		Ulcer Size (cm ²)		Duration (Months)	
	Mean	sd	Mean	sd	Mean	sd
Unna boot	63.95	9.73	3.59	3.54	27.42	54.72
Thera-Boot	58.15	9.60	3.28	4.08	12.28	14.54
P value	0.07		0.80		0.24	

17 in the Thera-Boot group. Three patients were in treatment at the time the cost part of the study was halted. There were seven dropouts/withdraws. Reasons for the dropouts/withdraws are shown in Table II. Table III lists the classification of completed patients by CEAP criteria.⁸

Mean time from enrollment to healing in the Unna boot group was 9.69 ± 3.28 weeks and 7.98 ± 4.41 weeks for the Thera-Boot ($p = 0.41$). Other healing rate results are shown in Table IV.

Mean time spent by physicians with patients to completion was 2.63 ± 2.00 hours for an Unna

Table II

Reasons Patients Were Withdrawn Before Completion

Unna Boot, 5 Patients	Thera-Boot™, 2 Patients
"Allergy" to Unna boot	Enrolled with exclusion criteria (low ABI)
"weeping dermatitis"	Not healing, referred for surgery
Patient left town	
Enrolled with exclusion criteria (immunosuppression)	
Ulcer size increasing—referred for surgery	

ABI = ankle-brachial index.

Table III

CEAP Classification of Completed Patients

Classification	Unna Boot, n = 11		Thera-Boot, n = 17	
	Number	Percent	Number	Percent
C ₆	11	100	17	100
E _p	5	45	11	65
E _s	6	55	6	35
A _s	7	64	11	65
A _d	10	91	10	59
A _p	5	45	9	53
P _r	10	91	15	88
P _o	4	36	5	29

CEAP = clinical state, etiology, anatomic distribution, pathophysiology.

Table IV
Healing Rates

	Area Healing Rate cm ² /day		% Area Healing Rate %/day		Linear Healing Rate cm/day	
	Mean	sd	Mean	sd	Mean	sd
Unna boot	0.0239	0.0534	1.0493	1.5583	0.0060	0.0092
Thera-Boot	0.0433	0.0910	2.0357	1.9520	0.0109	0.0125
P value	0.27		0.56		0.27	

Table V
Cost Results per Completed Patient

	Clinician Costs \$		Materials \$		Overhead No. of Visits		Total Costs* \$	
	Mean	sd	Mean	sd	Mean	sd	Mean	sd
Unna boot	331.37	255.75	160.86	96.86	11.70	6.40	901.73	576.45
Thera-Boot	201.91	131.17	122.79	27.59	6.71	3.77	559.41	290.75
P value	0.09		0.14		0.02		0.05	

*Total costs are clinician plus materials plus number of visits at \$35 per visit.

boot patient and 1.46 ± 0.81 for a Thera-Boot patient ($p = 0.04$). For nurses the times were 1.95 ± 1.60 hours for Unna boot and 1.58 ± 1.43 hours for Thera-Boot ($p = 0.53$). Other cost results are shown in Table V.

Discussion

We have documented in a randomized, prospective fashion the healing rates and costs of treatment of healing venous ulcers in two groups in

which the only variable was the method of compression, either a traditional Unna boot or the CircAid Thera-Boot. There was no practical method of blinding this study. The topical dressing of the ulcer itself, an impregnated gauze, was chosen to be a simple nonadherent covering for the wound. Despite some studies that have shown benefit of one topical dressing over another, there is no consensus that any single one is clearly superior.^{9,10} Our study was structured to avoid any assertions that healing rates might be attributed to the topical dressing and not the method of compression. Small venous ulcers, less

than 5 cm in diameter, were selected for the study in order that reasonable healing rates by both methods of compression would be compared within a reasonable time frame.

The two study groups had similar underlying venous disease. In the Unna boot arm of the study four patients had chronic deep venous obstructions and all but one had deep venous reflux. The Thera-Boot group had five subjects with chronic deep obstructions and all but two had deep reflux. As can be seen in Table I the Unna boot group tended to be slightly older, had larger ulcers, and had the ulcers longer prior to study entry, though none of these parameters was statistically significant and the differences were unlikely to be clinically significant with regard to rates of healing according to Skene et al.¹¹ The difference in ulcer duration was largely due to one patient randomized to treatment with Unna boots who reported an ulcer duration of 18 years. This was not a completed patient, however.

The healing rate measurements, time to healing, rates of decrease in area, and percentage area decrease, as well as the linear healing rate all showed trends to faster healing with the Thera-Boot. However, statistical significance was not reached, owing to the small study size and large standard deviations. Both the Unna boot and Thera-Boot are nonelastic compression devices. Nonelastic compression has been shown to facilitate significant improvement in deep venous hemodynamics compared to elastic compression.¹²⁻¹⁴ It is also dynamic: the actual level of compression varies with patient limb position and state of muscle contraction. The Unna boot, once applied, however, is not adjustable. Because the edema, which most chronic venous insufficiency patients exhibit, usually decreases significantly with nonelastic compression, Unna boots lose compression rapidly. Compression has been reported to fall from an initial ankle pressure of 35 mm Hg to 10 mm Hg at 24 hours.⁶ In contrast, the Thera-Boot can be adjusted as frequently as necessary by the patient to maintain compression. This is probably the major reason for the observed healing trends, though the ability to cleanse the ulcer and apply fresh dressings between clinic visits might have also played a role.

It is difficult to compare area healing rates in this study with other reported data, owing to the influence of initial ulcer size. However, the linear healing rate that corrects for such differences in this study was a mean of 0.0060 cm/day (0.042

cm/wk) in the Unna boot group and 0.0109 (0.0763 cm/wk) in the Thera-Boot treatment arm. These healing rates are somewhat faster than those previously reported for Unna boots. Cordts et al⁹ reported a rate of 0.020 cm/wk for a 12-week treatment course. That study had significantly larger ulcers at entry (means 9.1 vs 3.6 cm²). The larger ulcers may represent more severe underlying disease. Tallman et al¹⁵ have reported a range of 0.02 to 0.04 cm/wk for patients treated with Unna boots. In that study all subjects were older than 62 years and the patients were followed up for up to 6 months. No previously reported healing rates for the Thera-Boot exist.

In the cost analysis part of the study physician costs of \$100/hr were calculated as being the approximate hourly cost for a physician whose salary and benefits were \$140,000 per year if he/she saw patients 30 hours per week for 48 weeks a year. Nursing costs were based on salary/benefits of approximately \$50,000 per year and similar patient contact hours. Material costs were the actual costs to the study sponsor for the study materials (from Titus/General Medical, San Diego, CA) except for the Thera-Boots, which the sponsor manufactures. Their cost was calculated as the retail price for one legging. The clinic costs of \$35 per visit was chosen because it is the average overhead cost per patient visit of vascular surgery clinics at the University of California San Diego Medical Center (range \$22 to \$55). This value was derived by dividing total overhead costs, not including professional services or billable materials, by the number of patients seen in a clinic. It is sometimes referred to as what it costs to have a patient "walk in the door."

There was significantly less time spent by physicians with patients, and trends to lower nursing time and total clinician costs in treating patients with Thera-Boots as opposed to Unna boots. This advantage was due to the combination of less time per visit, because the clinician did not have to do the wrapping necessary with an Unna boot, and fewer clinic visits, partially due to faster healing, but mainly due to the fact that patients, being able to change their own dressings, did not have to be seen as often. Virtually all Unna boot patients were seen on a weekly basis. However, approximately half of the patients treated with a Thera-Boot were seen on a biweekly basis after the first few weeks if they were showing healing progress. The trends in

lower clinician costs and material costs and significantly lower overhead resulted in significantly lower total costs of treating a venous ulcer for 12 weeks, or less if it healed within this time, with the Thera-Boot. If patients had been treated for periods longer than 12 weeks it is reasonable to speculate that cost differences would be even greater owing to the weekly costs of Unna boot materials and clinician time spent in removal and application.

This study has determined the actual costs of treating venous ulcers conservatively in outpatients by tracking labor, materials, and overhead costs. These costs provide data that clinics, capitated programs, insurers, or individual practitioners might use to estimate true costs of treatment by these two methods of compression. Reimbursement from third parties was not tracked. Other studies have reported cost data; however, no direct comparisons can be made owing to the methods of calculation and what costs were and were not included. Some studies mix inpatient and outpatient costs, others include home visits by nurses, and most do not count overhead costs.^{10,16-20}

A consensus document has stated that the desirable properties of a dressing for venous leg ulcers are that it be "inexpensive, conserve the utilization of skilled professional care, and encour-

age a supervised program of self-treatment."³ This study has shown that the Thera-Boot conforms to these recommendations and when compared to the traditional Unna boot shows trends to faster healing and significantly lower costs.

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