RESEARCH PAPER

Use of a Novel Two-layer Bandage in the Treatment of Chronic Venous Hypertension

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Abstract Since the development of Unna boot therapies, there has been development in newer technologies for venous compression syndromes and chronic venous hypertension. Chronic lower extremity venous insufficiency results in venous stasis, edema and hypercongestion of the lower extremities. Given the breadth of potential uses, the goal of this study was to retrospectively compile and analyze the clinical application and effectiveness of a 2-layer zinc-impregnated foam Unna boot bandage (Andover Healthcare, Salisbury, MA) in patients with lower extremity swelling with or without wounds treated by a single physician and monitored for 12 weeks post-application in the outpatient setting. In patients with complex comorbidities, the use of this new foam-impregnated multi-layer compression Unna boot shows efficacy in reduction of edema and wound size within 12 weeks. This newer therapy shows extensive promise in the ability to keep patients adherent to treatment regimens with higher rates of success.

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Background

Since the development of Unna boot therapies, there has been little development in new technologies for venous insufficiency syndrome and chronic venous hypertension. Chronic lower extremity venous insufficiency results in venous stasis, edema and hypercongestion of the lower extremities. Given the breadth of potential uses, the goal of this study was to retrospectively compile and analyze the clinical application and effectiveness of a 2-layer zinc-impregnated foam Unna boot bandage (Andover Healthcare, Salisbury, MA) in patients with lower extremity

edema with or without venous ulcers treated by a single physician and monitored for 12 weeks post-application in the outpatient setting.

Chronic venous ulcers are costly in terms of both quality of life and economics. Approximately 6–10% of the world population is afflicted with venous disease.^{1,2} Less than 2% suffer from chronic venous ulcers of the lower extremities.^{2–4} Ruckley in 1997 reported that the prevalence of venous ulcers and venous insufficiency in the United States is similar to that of foot ulcers caused by diabetes mellitus – 5 million people have chronic venous insufficiency and 500,000 patients have chronic venous ulcerations.²

In 2001, Trieman et al reported that venous ulcers have a prevalence of approximately 1% in the United States (approximately 3.4 million persons), with approximately 50% of the patients having an ulcer history of 10 years

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or longer.⁵ Despite standard therapy with compression dressings, only 50–60% of venous ulcers heal completely in 6 months, and the recurrence rate is as high as 70%.^{4,6} The direct and indirect costs associated with the treatment of these ulcers are considerable.⁷ Patients affected with venous ulcers experience a decrease in their overall health-related quality of life, including severe pain, impaired mobility, limited work capacity and negative emotions.^{8,9}

Risk factors for venous disease include family history of venous disease or inherited coagulopathy, employment with requirements for prolonged standing, smoking, obesity, hypertension and/or leg trauma.⁵

Treatment of venous ulcers varies from multiple surgical procedures to the use of various topical agents combined with external pressure support to the legs.⁷ In the United States, the standard compression dressing is the Unna boot, a zinc-oxide-impregnated inelastic dressing, Duke boot with an added elastic bandage or the multiple layer compression dressing.^{4,8,10} Even with good compression therapy, approximately 40–50% of ulcers do not achieve complete closure within 6 months of therapy.^{4,8,9} Because of this low healing rate and a recidivism rate of nearly 70%, multiple wound-healing agents, cytokine growth factors and cell-based devices have been used to determine if closure of venous ulcers can be facilitated without operative intervention.^{1,8–11}

Topical compression therapy provides a means to treat or prevent adverse effects as noted above. Limb compression functions¹ alters the tissue gradient pressure which reduces edema and increases resorption²; increases flow velocity³; reduces orthostatic reflux, residual volume and ambulatory venous pressure; and⁵ improves the muscle pump effectiveness and function.¹²

The use of Unna boot compression over the years has demonstrated increased use in the treatment of venous edema and concomitant treatment of venous leg ulcerations. The standard of Unna boot therapy has been zinc or calamine-impregnated gauze roll dressings that require secondary coverage dressings. Since that time, multi-layer compression bandaging has become more widely used in clinical practice beginning with three or four-layer dressings.¹⁶ Newer two-layer compression therapy systems are used more frequently, thereby increasing the use in outpatient settings and need for better ambulatory-style wraps. However, there is no scientific data that proves this in the literature.

The Andover Healthcare 2-Step Unna Boot bandage is a new revolutionary type of Unna boot dressing. The main composition of the boot is a foam bandage with polymer-impregnated zinc or calamine bonded to the material (for clinical purposes, all patients received zinc-impregnated dressings). This foam dressing has the ability to absorb approximately 200 g of exudate, compared to 1.5 g of exudate with traditional gauze Unna boots.

This study will demonstrate retrospectively how this new novel two-layer foam-impregnated compression system can be used efficaciously in the outpatient arena with successful reductions in pain, ulcer size, inflammation and compliance with maintenance compression therapies. The report of this real-world experience will establish new baseline clinical outcomes for a modified foam-impregnated Unna Boot technology that does not exist in the literature. These outcomes described herein are valuable for setting up new treatment expectations for chronic venous insufficiency and chronic venous ulcerations.

Methods

The investigator contracted with Liberty IRB for this study. Liberty IRB ruled that this retrospective review of existing patient records was exempt from IRB review in accordance with 45CFR46.101. The data collected was without identifiers or link to identifiers. Additionally, the investigator who would normally have access to the records as part of the patient's routine clinical care conducted the records review.

A retrospective cohort chart review of a single clinical site was conducted. 60 patients were identified who qualified for the study. Male and female patients were randomly selected without bias to gender. Inclusion criteria consisted of failure of therapy or presence of a chronic venous ulcer of greater than 30 days and subsequent compression bandaging with Andover's 2-Step Unna Boot Bandage from April 2010 through October 2013. Exclusion criteria consisted of any signs of erythema/infection, malignancy in the extremity, uncompensated congestive heart failure, advanced peripheral arterial disease with ABI <0.65, previously treated chronic venous insufficiency controlled with compression garments <3 months duration and osteomyelitis of the foot and/or extremity.

The venous clinical severity scoring scale (VCSS) was utilized to provide a method for serial assessment of chronic venous disease.¹³ Although the usefulness of the original VCSS has been clearly demonstrated,¹⁴ several areas of deficiency have also been noted.¹⁵ The revised VCSS (used in this study) addresses certain ambiguity in clinical descriptors while preserving strength of symptom evaluation.

Prior to use of the Andover 2-Step Unna Boot Bandage, standard methods were used to prepare the patient and wound bed (if necessary) to ensure that wounds were free from debris and necrotic or infected tissue. Such preparation included cleansing of the affected extremity(-ies), sharp or surgical debridement of wound to ensure adequate bleeding at the viable wound edges. Once this process was completed, Andover's 2-Step Unna Boot Bandage was applied en toto per the manufacturer specifications. All wounds were treated similarly in the study, with hydrogel, contact layer, gauze and dry sterile kling dressing. For the first two weeks, the lead investigator routinely used silver antimicrobial dressings to help eliminate bacterial colonization.

Table 1 Patient Characteristics

Gender	Female: 33	Male: 27	
Race	Black: 2	White: 58	
Ethnicity	Hispanic: 1	Non-Hispanic: 59	
Age	Min: 32	Median: 78	Max: 96
BMI	Min: 18.5	Median: 28.6	Max: 56.4
DM	Absent: 40	Present: 20	
CVH	Absent: 6	Present: 54	
VI	Absent: 38	Present: 22	
PVD	Absent: 49	Present: 11	

Patients were assessed weekly with the first assessment occurring at week 0 and culminating at week 12. If patients experienced wound closure with compression therapy and returned to baseline, they were followed until week 12.

Nine venous clinical severity scores (listed in Table 1) were recorded at weeks 0, 8 and 12.

In addition, demographic and medical history information was obtained. This included age, gender, race, ethnicity, BMI and five disease variables containing 65 ICD9 codes. For each patient, the ICD9 codes were collapsed into four variables: diabetes mellitus (DM) if any of the codes were ≥ 250 and < 260 , venous insufficiency (VI) if any of the codes = 459.81, chronic venous hypertension (CVH) if any of the codes ≥ 459.3 and < 459.4 and peripheral vascular disease (PVD) if any of the codes = 443.9.

Statistical Methods

Exploratory data analysis included numerical summaries and plots of the data to visually assess the relationship of clinical severity scores with time.

Frequency tables and chi-square tests of association between each of the severity scores and time provided a more formal analysis of the change in clinical severity with time.

In order to incorporate the impact of demographic and medical history information in the analysis of change over time, generalized linear mixed models (GLMM's) were employed. Covariates included gender, age, BMI, DM (diabetes mellitus), VI (venous insufficiency), CVH (chronic venous hypertension) and PVD (peripheral vascular disease). Because most patients were white and non-hispanic, race and ethnicity were not included as covariates.

Results

Table 1 summarizes patient characteristics. Age ranges from 32 to 96 with a median of 78. 33 are female and 27 are male. Almost all (57) are white non-Hispanic. BMI ranges from 18.5 to 56.4 with a median of 28.6. Diabetes is present in 20 patients (33%), CVH is present in 54 (90%), VI is present in 22 (37%) and PVD is present in 11 (18%).

Plots showing the relationship of each of the venous severity scores with time for each patient are shown in Figure 1. Here the data have been jittered, that is, a small amount of random noise has been added to each score and time value so that individual trajectories may be distinguished. For some severity scores, patterns over time are quite uniform. For instance, for all individuals, pain remains steady between weeks 0 and 8 and then declines. For other measures, patterns vary among individuals. For instance, for some individuals, active ulcer size increases between time 0 and time 8 and then decreases. For other individuals there is a steady decrease over time.

Figure 1 Plots.

Frequency tables and the p -values for chi-square tests of association of each of the severity scores with time are shown in Table 2. By this criterion, varicose veins increase with time, skin pigmentation and active ulcer duration show no relationship with time and the remaining severity scores decrease with time.

Generalized linear mixed models (GLMM's) provide control for the effects of covariates and differences among individual subjects. Because the outcome variable (severity score at each time point) is not normally distributed, ordinary regression models cannot be employed. One type of GLMM, the ordered logit (cumulative link) model commonly used to model rankings did not fit the data well. Poisson models (used most often to model count data) provided more satisfactory results. Predictors included time

and time squared (to accommodate any possible non-linear relationship with time) and also covariates: gender, age, BMI, DM (diabetes mellitus), VI (venous insufficiency), CVH (chronic venous hypertension) and PVD (peripheral vascular disease). Incorporating a random effect for each patient allowed control for differences among individuals.

Results from these models are shown in Table 3. For pain, the negative and highly significant coefficients for time and time squared indicate that pain decreases significantly over time. The negative coefficient for gender indicates that males are less likely to report pain than females. For varicose veins, the positive and highly significant coefficient for time indicates that varicose veins increase with time. Varicose veins are also positively associated with age and BMI. Venous edema decreases

Table 2 Counts of Then Numbers of Observations With Each Severity Score at Each Time Point

Severity Score	0	1	2	3
Pain ($p < 0.001$)				
Week 0	4	31	15	10
Week 8	4	31	15	10
Week 12	35	15	10	0
Varicose veins ($p < 0.001$)				
Week 0	13	29	17	1
Week 8	4	16	36	4
Week 12	4	16	36	4
Venous edema ($p < 0.001$)				
Week 0	4	16	36	4
Week 8	11	30	18	1
Week 12	41	18	1	0
Skin pigmentation ($p = 0.154$)				
Week 0	11	30	18	1
Week 8	4	25	29	2
Week 12	4	25	29	2
Inflammation ($p < 0.001$)				
Week 0	4	25	29	2
Week 8	11	33	16	0
Week 12	44	16	0	0
Induration ($p < 0.001$)				
Week 0	11	33	16	0
Week 8	26	30	1	3
Week 12	56	1	3	0
Number active ulcers ($p < 0.001$)				
Week 0	26	30	1	3
Week 8	27	20	10	3
Week 12	51	7	0	2
Active ulcer duration ($p = 0.646$)				
Week 0	27	20	10	3
Week 8	29	13	16	2
Week 12	29	13	16	2
Active ulcer size ($p < 0.001$)				
Week 0	29	13	16	2
Week 8	20	18	20	2
Week 12	38	20	2	0

p values for a chi-square test of association are shown. A p -value < 0.05 indicates that the null hypothesis of no association can be rejected. Varicose veins increase with time, skin pigmentation and active ulcer duration show no relationship with time and the remaining severity scores decrease with time.

Table 3 Results of Generalized Linear Mixed Models Investigating the Relationship of Each of the Severity Scores With Time

	Time	Time Squared	Gender	Age	BMI	DM	CVH	VI	PVD
Pain	HS(−)	HS(−)	S(−)		B(−)				
Varicose veins	HS(+)			HS(+)	S(+)			HS(+)	
Venous edema	HS(−)	HS(−)		S(+)				HS(+)	
Skin pigmentation							S(+)	B(+)	
Inflammation	HS(−)	HS(−)		B(+)		B(+)			
Induration	HS(−)	HS(−)		HS(+)			B(+)		
Number active ulcers	HS(−)	HS(−)	B(+)	HS(+)			B(+)		
Active ulcer duration				S(+)					
Active ulcer size	HS(−)	HS(−)		S(+)	S(+)				

Demographic and medical history variables were included as covariates. HS means highly significant ($p < 0.01$), S means significant ($p \leq 0.05$ and ≥ 0.01) and B means borderline ($p > 0.05$ and < 0.1). The symbol in parenthesis is the sign of the coefficient. For pain, the coefficient for gender is negative meaning that males are less likely to have pain. For number of active ulcers, the coefficient for gender is positive (with borderline significance) meaning that males are more likely to have active ulcers.

with time and is positively associated with age. Skin pigmentation shows no relationship with time, but is positively related to CVH and VI. Inflammation declines with time, but is positively associated with age and DM. Induration and number of active ulcers decrease with time and are positively associated with age and CVH. The positive coefficient for gender indicates that the number of active ulcers is higher among males. Active ulcer duration shows no relationship with time, but is positively associated with age. Active ulcer size decreases with time and is positively associated with age and BMI. Of the covariates, age is often associated with these clinical severity measures. BMI and VI frequently are important. PVD was not significant in any of the models.

Conclusions

Overall, six of the venous severity measures (pain, venous edema, inflammation, induration, number of active ulcers and active ulcer size) decline with time. The plots in [Figure 1](#) indicate that there are strong individual differences in the patterns of change over time. Further analyses may elucidate the reasons for these differences.

Due to the nature of this single-site center, single investigator study, further research is needed with randomized-controlled trials with a larger sample of patients to verify the VCSS scoring results encountered here in this study. While there was bias from a single investigator, the author was careful with regard to moderating the scoring system to account for objectivity.

In patients with complex comorbidities, the use of this new foam-impregnated multi-layer compression Unna boot shows efficacy in reduction of edema and wound size within 12 weeks. This novel therapy shows extensive promise in the ability to keep patients adherent to treatment regimens with higher rates of success than without compression therapies. With only a few multi-layer dressings on the market, it is imperative that qualified health

professionals choose the proper therapy for patients with chronic venous pathologies. Appropriate selection and use of Andover's 2-Step Unna Boot Bandage system will optimize a wound environment, reduce edema and control the venous flow. As with all multi-layer compression systems, this should be used in conjunction with standards of care and addressing the local and systemic factors that affect wound healing.

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