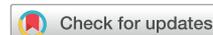


Using bioelectrical impedance analysis to compare the treatment of edema with the Unna's boot and noncompression in individuals with venous ulcers



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Venous insufficiency is related to aging. Edema, pathological evolution of venous insufficiency, favors the appearance of venous ulcers as the main complication. Leg ulcers can be treated with compression, the Unna's boot being one of them, and noncompression therapies (conventional dressing). Bioelectrical impedance analysis accurately measures the patient's body fluids. The objective of this study was to evaluate the edema evolution of the venous ulcer-affected lower limb by means of electric bioimpedance with the use of Unna's boot and noncompressive dressing. Fifteen legs with active ulcers were treated from September 2014 to December 2016. The legs were treated with Unna's boot and noncompression therapies on different days with randomized order of events. Bioimpedance was performed in the morning and afternoon to evaluate the increase in edema over the day. All patients were female with ages ranging from 50 to 76 years (mean age: 63 years). According to bioimpedance, the volume of the legs increased with both types of therapy. However, compression therapy was significantly more effective than noncompression therapy. Bioimpedance confirmed that compression therapy (Unna's boot) gives better results than noncompression therapy in relation to the formation of edema over a day in patients with chronic venous ulcers. (J Vasc Nurs 2018;37:58-63)

Often related to aging,¹ venous insufficiency is characterized by mechanical obstruction (thrombosis) or valve insufficiency, which results in increased pressure and instability between the arterial supply and venous drainage within a limb. The main risk factors include obesity, female gender (number of pregnancies), family history, advanced age, diabetes, hypertension, deep venous throm-

bosis, leg trauma, and smoking.² Difficult-to-heal wounds can develop after the disease is established; these lesions reoccur in up to 66% of cases, categorizing complications of the condition.³

Between 5% and 30% of the adult population is affected by chronic venous insufficiency (CVI), and thus, it is considered a public health concern worldwide with a growing burden in industrialized countries.⁴ At an estimated cost of \$3 billion annually to the health sector, 2.5 million people are affected by CVI every year in the United States alone.⁵ One of the main prevention methods, in addition to maintaining adequate eating habits, is physical activity. Treatment involves elevation of the legs and the correct indication of elastic compression stockings by a qualified health professional.

Venous ulcers affect about 1% of the adult population. They are considered the main complication of CVI and commonly manifest in the lower third (malleolus) of the legs.⁴ Often venous ulcers are difficult to treat and may last for several years.⁶ In the western hemisphere, venous ulcers are a major public health problem and represent 80%–85% of all ulcers, with the remaining being diagnosed as arterial, mixed, or neuropathic.^{7,8}

In Europe, one in every one thousand people have leg ulcers; the disease is more common in the elderly with about twenty of every one thousand individuals being affected when they are over the age of 80 years.⁹

Compressive, topical, drug, or surgical therapy are some treatments for wounds. The choice of the best option depends on the evaluation of a multidisciplinary team that comprises doctors, nurses, and physiotherapists, among others. Compressive therapies include elastic (socks and single or multilayer bandage), inelastic (Unna's boot), and intermittent pneumatic compression.¹⁰

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Compression and noncompression (conventional dressing) therapies can be used to treat leg ulcers. The Unna's boot, one of the types of compressive therapy, is generally made of similar constituents—10% zinc oxide, acacia gum, glycerol, castor oil, and deionized water. The homemade version requires thermal preheating, but the commercial product is purchased ready for use; both are expected to cause compression of 18–24 mmHg.¹¹

According to some studies, the use of Unna's boot provides good results with a cure rate of 40%–60% in three months and 70% within one year.¹² Changing of this dressing varies from twice a week to weekly, being performed by a nurse or doctor, depending on the exudate and edema. The benefits of this dressing are that it interferes little in daily activities and protects the leg from trauma. However, it is contraindicated in cases of mixed ulcers (arterial and venous), erythema,¹¹ bedridden patients, and wheelchair users, as well as when there is inflammation of the lesion.¹³ The conventional dressing is composed of gauze, physiological saline solution (0.9%), and crepe band. Changing of this dressing is performed two to three times a day depending on the amount of exudate.

Edema is a sign of physiological alterations indicating the presence of fluid in the tissues due to pathological changes. The most common causes of edema are heart failure, injuries to the lymphatic system, venous insufficiency, and severe hypoproteinemia.¹⁴

The evaluation of edema is of extreme importance to understand its etiology and determine the plan of care. It is usually performed clinically by pressing the index finger on a prominent bone (tibial region or internal malleolus) for a few seconds or by measurements of the circumference of the limb, which are not very objective because of the empiricism and possibility of human error, not precise, but are commonly characterized qualitatively.

Bioelectrical impedance analysis is a safe and effective noninvasive test with direct segmental measurement technology. By placing electrodes on the hands and feet,¹⁵ this technique measures the resistance offered by the body to the passage of electric current,¹⁶ thereby evaluating water balance and nutritional status in detail. The phase angle analyzes functionality by measuring the resistance of the cell membrane.¹⁷ Thus, the data obtained provide information about the body composition, the amount of fluids, protein, minerals, and fat mass,¹⁸ detailing the amount of water in the extracellular space and total body water, an adequate indicator of water balance.

The hypothesis raised in this study was that according to bioimpedance, the Unna's boot (compression) is a clinically better and more effective method to control leg edema than conventional dressing (noncompression) in a population of individuals with venous lesions.

The main objective of this study was to evaluate the edema evolution of the venous ulcer-affected lower limb by means of electric bioimpedance with the use of the Unna's boot and the noncompressive dressing.

MATERIALS AND METHODS

This randomized crossover study used bioimpedance to evaluate variations in edema of patients with chronic venous ulcers who used an Unna's boot and conventional dressing on two different moments.

Patients aged 18 years or older with leg ulcers and a history and physical examination compatible with chronic venous disease were enrolled in this study. Exclusion criteria were a history suggestive of chronic arterial disease, active infections, and joint immobility.

Of the 11 patients who met the inclusion criteria, four of them had wounds in both the limbs, totaling 15 legs evaluated. The transference of the participants to a private clinic (Godoy's) was necessary due to the unavailability of the bioimpedance examination in the public health network. There, they underwent a physical examination and bioelectrical impedance analysis. The patients were submitted to 4 evaluations at different moments of the injured limbs, totaling 60 results that were compared and analyzed. All the participants used the Unna's boot and the conventional dressing in equivalent amount of times to be compared, and these patients worked as their own control. The research was performed from September 2014 to December 2016.

The study protocol was approved by the Ethics Committee of FA-MERP, through the Certificate of Presentation for Ethical Appreciation: 32785714700005415, and after signing an informed consent form, all patients were interviewed, examined, and weighed (kg) and their edema was assessed using the InBodyS10 bioimpedance device.

The order of events considering the use of Unna's boot and traditional dressing was randomly assigned by chance and drawing a number from an envelope determined the type of dressing to be used until the next evaluation. The recommended exchange of dressing was adapted to the study for skin exposure and electrode placement to perform bioimpedance evaluation. Care was taken to start the evaluation immediately after removal of the dressing so as not to compromise the result. The dressings were used during the entire day, with bioimpedance assessments being performed between 7 and 8 o'clock AM and between 4 and 5 o'clock PM. During the research, the dressing exchanges took place in the Godoy's clinic by the nurse. After the research evaluation, patients carried on with the original medical prescriptions of the public health units.

Statistical analysis was performed using the paired *t*-test, with an alpha error of 5% (*P* value < .05) being considered statistically significant.

RESULTS

In total, 58 patients who used the Unna's boot and attended the public health units were invited to participate in the study. The final sample consisted of 15 legs of 11 individuals, with ages ranging from 50 to 76 years (mean age: 63 years; standard deviation [–SD]: =7.5 years), who met the inclusion criteria. All the patients were female.

Table 1 shows the volumetric variations evaluated by bioimpedance with the patient using the Unna's boot or conventional dressing.

A significant mean increase of 0.371 L (SD: 0.163) in the volume of edema was found between the morning and afternoon in patients using conventional dressing (*P* value = .0001) (Figure 1).

When patients did not use compression therapy (Unna's boot), the largest difference in volume between the morning and afternoon evaluations was 0.7 L (12%) and the smallest was 0.13 L (2%). Among patients who used the Unna's boot, there was a significant difference between the morning and afternoon volumes of edema (paired *t*-test; *P* value = .0006) with a mean difference of 0.163 (SD = 0.033) (Figure 2). With the use of Unna's boot, the largest difference in volume was 0.38 L (7%); for two patients, there was no change in the volume of the edema during the day.

TABLE 1

VOLUME (IN LITERS) OF LOWER LIMBS OF PATIENTS WITH LEG ULCERS USING UNNA’S BOOTS AND CONVENTIONAL DRESSINGS EVALUATED BY BIOELECTRICAL IMPEDANCE ANALYSIS IN THE MORNING (7–8 AM) AND AFTERNOON (4–5 PM)

<i>Conventional dressing</i>			<i>Unna’s boot</i>		
<i>Morning (7–8 AM)</i>	<i>Afternoon (4–5 PM)</i>	<i>Difference</i>	<i>Morning (7–8 AM)</i>	<i>Afternoon (4–5 PM)</i>	<i>Difference</i>
8.33	8.71	0.38	8.32	8.44	0.12
9.38	9.89	0.51	9.11	9.17	0.06
6.57	6.87	0.30	7.20	7.20	0.00
4.57	4.70	0.13	4.93	4.95	0.02
5.17	5.55	0.38	5.11	5.32	0.21
8.46	8.74	0.28	7.59	7.95	0.36
5.17	5.53	0.36	5.32	5.70	0.38
4.10	4.43	0.33	4.22	4.34	0.12
7.48	8.05	0.57	7.24	7.31	0.07
5.28	5.58	0.30	5.46	5.69	0.23
5.02	5.15	0.13	5.02	5.11	0.09
7.00	7.70	0.70	6.65	6.97	0.32
6.70	7.31	0.61	6.67	6.85	0.18
6.68	6.97	0.29	7.42	7.45	0.03
6.57	6.87	0.30	7.20	7.20	0.00

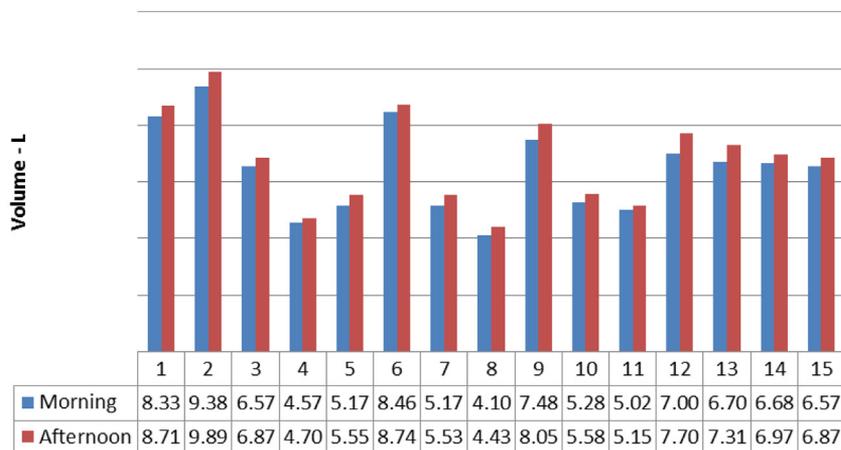
Paired *t*-test *P* value = .0001.

When comparing the volume of limbs with ulcers before treatment in the morning, there was no significant difference between patients using the Unna’s boot or those using conventional dressing (paired *t*-test: *P* value = .55) (Figure 3). Comparing the Unna’s boot and conventional dressing, the difference in volume of the edema was higher when the Unna’s boot was not used (paired *t*-test: *P* value = .001) (Figure 4).

DISCUSSION

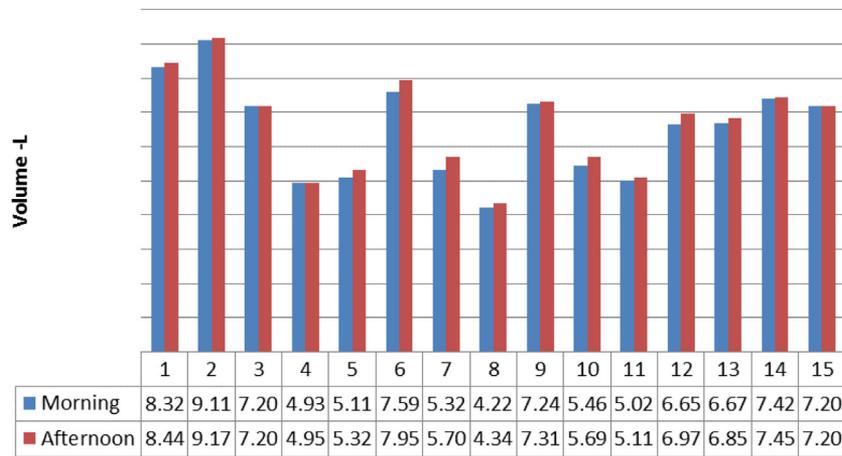
The authors of the literature studied the main aspects related to the use of compressive therapy, especially that of the Unna’s boot, which was emphasized by its effectiveness in reducing edema compared with conventional dressing.

Different to the present study, one Brazilian study reported more men (67%) than women with venous ulcers.¹⁹ However, another



Paired *t*-test: *p*-value = 0.0001

Figure 1. Leg volumes of patients with ulcers in the morning and afternoon upon using conventional dressings.



Paired t-test: p-value = 0.0001

Figure 2. Leg volumes of patients with ulcers in the morning and afternoon upon using compression (Unna’s boot).

retrospective cohort study had a predominance of women probably because women are more predisposed to varicose veins (associated with age and body mass index) and hormonal changes.^{20,21}

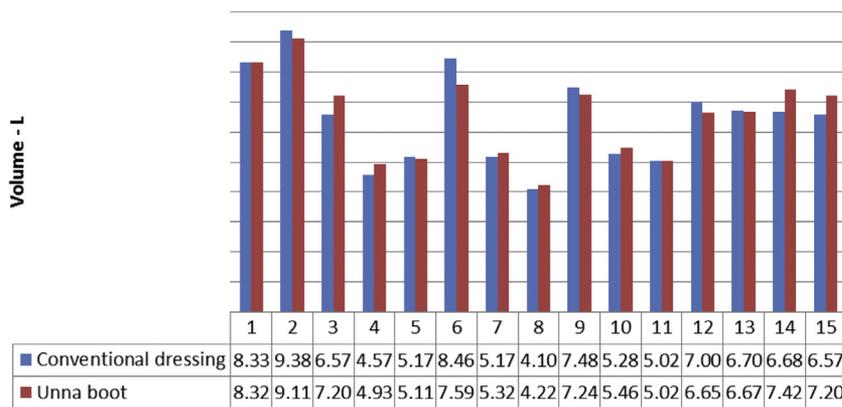
In relation to age, as life expectancy is prolonged, the number of elderly people increases²²; these subjects are prone to ulcers due to malfunctioning of the vascular system. In this study, the mean age of the patients was 63 years (range: 50–76 years), which is similar to the age reported by other publications.^{23–25}

The main anatomical location described in this study was the ulcer in the malleolar region, as described in the literature.¹³ It can be seen that legs with ulcers undergo a significant volume change during the day; in the morning, the edema is mild, but the volume increases by the end of the day. This can be explained by the fact that the person lies down at night, and thus, there is no effect of gravity on the vascular circulation. During the day, on the other hand, subjects remain upright to perform their daily activities, and the venous insufficiency is further aggravated by the pressure of gravity on the blood vessels, thereby increasing fluid retention (edema) in the legs.

Using bioelectrical impedance analysis, the present study showed that the use of compression therapy (Unna’s boot) was more efficient in preventing edema than noncompression

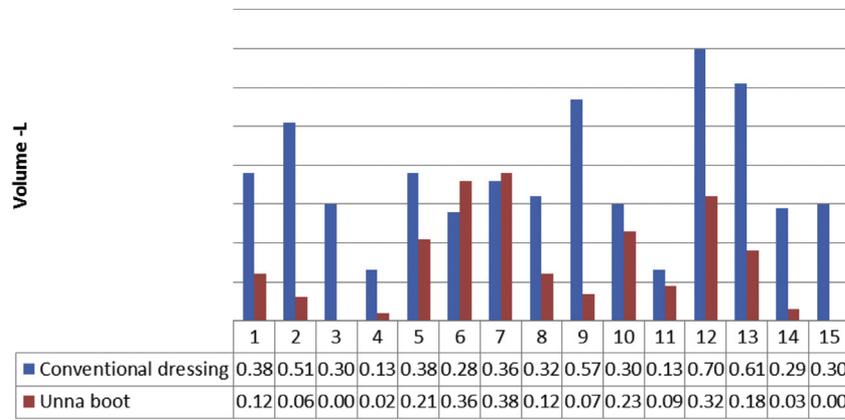
therapy (conventional dressing) in the treatment of venous ulcers. From the analysis found in the journals, the improvement of scientific knowledge about compression therapies with presentation of their benefits in general was observed. However, these techniques must be permanently studied, disseminated, and compared with the objective of constant advances in the treatment of patients with venous ulcer. Still, the efficacy of such techniques is closely related to professionals’ training, multidisciplinary involvement, cooperation, and patient adherence.

Although other compression techniques may prove to be more efficient than the Unna’s boot by adding more technology, the boot still stands out as a traditional low-cost dressing that reduces venous hypertension and edema and favors the treatment of venous ulcers. The multilayer bandage is a gold standard technique in developed countries and has been widely used, but the Unna’s boot has also been used as an option for treatment of venous injuries. The Unna’s boot may not be the best choice because it requires a higher healing time than the multilayer bandage, but it meets the expectation with a high rate of treatment effectiveness, even if compared with the simple dressing and single- and two-layer bandages.



Paired t-test: p-value = 0.0001

Figure 3. Bioelectrical impedance analysis comparing initial (morning) volumes of legs with ulcers between the two treatment methods.



Paired t-test: p-value = 0.0001

Figure 4. Bioelectrical impedance analysis comparing differences in edema volumes of lower limbs with ulcers treated using the Unna’s boot and conventional dressings.

The information obtained in the scientific literature has highlighted the effectiveness of the Unna’s boot by showing that for its efficiency, the therapy requires wide dissemination in scientific circles, new research, and continuous and ongoing training of nursing professionals and physicians to increase confidence in its indication and handling. More assertive investments in health are needed both in public and private sectors, given the challenges faced in vascular injuries care. Success in the treatment of venous ulcers is multifactorial and depends on correct indication, professional evaluation, follow-up with wound measurement, association between therapies and products, rest, correct elevation of limbs, no manipulation of the patient, adhesion, and correct wound cleaning. In terms of cost-benefit, the Unna’s boot is a great choice as a form of compression therapy because it is affordable, available in the Brazilian public health system, and requires low technology. Its benefits and efficiency overlap the possible discomforts.

To the best of our knowledge, no studies have been published which use bioelectrical impedance analysis to compare the effects of compression (Unna’s boot) and noncompression (conventional dressing) therapies on the evolution of edema related to venous ulcers.

The literature has shown that the use of the Unna’s boot is more common in Latin America, with socks and bandages being more widely applied in Europe and the United States, and may be related to cost and access.

Among the main limitations of the study were refusals, small number of participants, suspension of use (allergy side effect or adverse), medical discharge, hospitalizations, and not following the evaluations. Other studies reported the same difficulties.^{13,20} Elastic or inelastic compression therapy is recommended to treat venous ulcers,²⁶ reinforced by the authors of the Cochrane database in 2012 that there is an increase in healing rates compared to no compression,²³ as compression increases the healing rate compared with noncompression.²² Compressive technologies using different materials have been produced since historical times²⁷; these technologies have undergone constant evolution since the physician William Harvey described venous stasis in 1628.²⁸

These products are aimed at promoting various benefits, such as venous return, reduced pain, and prevention and treatment of edema, as well as amelioration of venous hypertension.²⁰ Even

though several studies in the area showed that the use of compressive therapy improves venous circulation,²⁹ two studies have reported a low rate of indication of this therapy by professionals,^{19,29} which is possibly related to the lack of knowledge, difficulty of access to the technique, or preference to indicate another therapy. It is observed that venous ulcer treatment is usually long and results in many physical, functional, emotional, and financial problems for patients,¹¹ besides the extra expenses to health institutions causing a significant socioeconomic impact.

The choice of dressing depends on the patient’s evaluation and characteristics of the injury. There are many coverage options in the market and studies that have tested the application of the different therapies used in the world. It is noted that each region tends to use a particular technique, and this choice is based on the cost-benefit and availability of the product; the trend is strongly related to socioeconomic aspects of a territory.³⁰

The Unna’s boot can cause, in addition to allergy, discomfort during walking and resting because it does not use elastomeric fibers and does not change shape as the leg volume changes. However, it works as a “physical barrier” protecting the region from possible trauma,¹³ preventing new wounds and worsening of the lesion. It is important to emphasize the responsibility of the patient to avoid recurring lesions after cure²⁵ because many recurrences may be related to nonadherence to preventive measures; several authors have attributed this to the absence of the use of compression stockings and monitoring by angiologists after treatment.^{13,19}

CONCLUSION

Bioelectrical impedance analysis showed that compression therapy (Unna’s boot) more effectively prevented edema during the day than noncompression therapy (conventional dressing) in patients with chronic venous ulcers.

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