# Efficacy of a Ready-Made Tubular Compression Device Versus Short-Stretch Compression Bandages in the Treatment of Venous Leg Ulc

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V enous leg ulcers are skin disorders of the lower leg that do not heal spontaneously caused by chronic venous insufficiency. They affect at least 0.2 percent of the population in the developed world,1,2 and their prevalence increases considerably with age, affecting about two percent of the population over the age of 80. Treatment of venous ulcers aims to ensure healing of the wound and prevention of recurrence. Compression, either alone or combined with surgery, is considered the principal treatment for venous ulcers and takes priority over local wound treatment. Today, short- and long-stretch bandages constitute the forms of treatment most commonly used in everyday practice.3–8 These bandages are changed every two or three days by medical staff but also by patients themselves or family members. In the latter case, the bandages are often poorly positioned; they may be either too loose, causing slippage, or they may be too tight, causing constriction. This results in impairment of patients' quality of life, poor compliance, and consequently, delayed healing. A new heelless, open-toed tubular elastic compression device (Tubulcus®, Laboratoires Innothéra, Arcueil, France) exerts a clearly defined pressure that remains constant over time.9–11 It can be applied without the need for a qualified fitter, and application is facilitated by a specific positioner.

The purpose of this study was to compare the efficacy and safety of the new tubular compression device with a short-stretch compression bandage for 12 weeks in patients with venous leg ulcers.

The new ready-made knee-length tubular compression device for the treatment of venous ulcers exerts graduated pressure with the highest compression (30–40mmHg) at the ankle, diminishing up the calf, and corresponds, in concern of exerted pressure, to class III compression stockings. It is open toed and has no heel, which permits more flexible placement of the maximal pressure, as opposed to stockings with heels. Due to the fact that it is a tubular, knitted, ready-made device, the appropriate pressure is exerted regardless of fitter's skill. This is in contrast to the application of the correct pressure with bandages, which is possible, especially with bandage systems, but is not easy, and training is required. The test device is composed of 34 percent elastan, 27 percent polyamide, and 27 percent cotton at the inside (it does not contain latex). The device can be reused and laundered at 60° C.

The compression bandage (Rosidal® K, Lohmann & Rauscher International GmbH & Co. KG, Rengsdorf, Germany) is made from 100-percent cotton and has short-stretch properties (about 90%).

Methods

This was an open, randomized, comparative, international multicenter study (France, Germany, Austria, and Switzerland) in two parallel groups. The study was approved by the respective national Ethics Committees and conducted in accordance with the Declaration of Helsinki (Somerset West, 1996) and European Good Clinical Practice.

Patients. Inclusion criteria. Ambulatory male or female patients between the age of 18 and 80 signed an informed consent form and agreed to take part in the study for a maximum of 12 weeks of treatment. Patients included were those with venous leg ulcers present for less than three months with a maximum diameter of 5cm, ankle-brachial pressure index (ABPI) > 0.9, and Doppler ultrasound confirmation of venous reflux (Tables 1 and 2). Only patients not permanently confined to bed and walking for at least one hour per day were included. No special physical therapy or training was performed.

Exclusion criteria. Patients excluded were those with diabetic, arterial, or mixed ulcers, ulcers showing local or systemic clinical signs of infection, decompensated heart failure, cancer, chronic or autoimmune infection, insulin-dependent diabetes or diabetic neuropathy, or clinically significant restricted ankle movement. Use of antibiotics, immunosuppressants, cytotoxic agents, and venoactive drugs was prohibited throughout the duration of the study. All new prescriptions or changes in dosage of existing anti-inflammatory drug prescriptions (steroidal and nonsteroidal) and diuretics were prohibited throughout the duration of the study, as were other treatments, such as sclerotherapy, venous surgery, and skin grafts.

Patients evaluated. Of the 191 patients selected, three were not randomized (1 patient with ABPI < 0.9; two patients aged > 80 years), two were excluded from the intent-to-treat (ITT) population (1 patient was randomized to bandages but did not consent to use them; one patient was lost to follow up), and eight were excluded from the per-protocol (PP) population (7 patients wore their respective compressive treatment for less than 7 days; 1 patient presented with insulin-dependent diabetes). The PP population, which is

preferable for demonstration of noninferiority, comprised 178 patients: 88 in the tubular compression device group (50 in France/Switzerland, 38 in Germany/Austria) and 90 in the bandage group (52 in France/Switzerland, 38 in Germany/Austria).12

Study Design

A treatment period of 12 weeks was considered necessary and adequate to obtain sufficient instances of healing to allow conclusions to be drawn regarding the treatment efficacy. Assignment to treatment was performed by blindfold randomization. Once a patient was eligible, the investigator received the corresponding treatment number (by telephone from an external randomization center) in accordance with a previously prepared center-stratified randomization list. After inclusion and randomization, patients were asked to consult their physicians at least every 7 days ± 1 (intermittent consultations were possible at any time if necessary). Between visits, the respective compression device remained in place day and night. Patients were instructed not to change it themselves. Change in ulcer size was evaluated by physicians drawing an outline of the study ulcer on tracing paper. These tracings were then used to calculate the area and diameter of the ulcers.

Local treatment. Local treatment was standardized in the trial protocol and was the same for all patients: manual debridement and cleansing of the ulcer with physiological saline and application of an absorbent, sterile, nonadherent gauze (Vlivin®, Lohmann & Rauscher) not containing any active pharmaceutical substance. No topical medication other than nonirritant protective substances was permitted for lesions to the surrounding skin (e.g., eczema, weeping, erythema, etc).

Application. Application of the compression devices was performed solely by the experienced investigator or experienced and well trained medical staff, never by patients themselves or family members. After local treatment and occlusion of the ulcer, the compression device was applied with the patient lying and the leg outstretched.

Test device. First, device size was determined for each patient according to the circumferences of the leg measured at the ankle and the largest part of the calf. (At the time of the study, 3 sizes—S, M, and L—were available. There are now 5 sizes available.) The first step to put on the compression device is the placement of the positioner on the lower leg (over the local dressing). Then the device is slipped over the positioner up to the desired position. The positioner is then removed by pulling it down by the handle toward the opening in the foot section. As the positioner is gliding on itself and not on the local dressing, there is no danger that the dressing moves down when pulling off the device (Figure 1).

The bandages were applied following the manufacturer's instructions, i.e., with patient in the recumbent position and the foot in dorsal flexion (Figure 2). Only one bandage was used.

Time to healing. Time to healing was calculated as the number of days between inclusion and the date at which complete healing was recorded (Table 3).

Statistical methods. The primary variable for evaluation of efficacy was complete healing of the ulcer during the study. The number of patients required was calculated on the basis of the following hypotheses: level of noninferiority ?=15 percent, percentage number of cases of complete wound healing=65 percent, ?=5 percent, and ß=20 percent. For the primary variable, noninferiority was evaluated by comparison of the 90-percent confidence interval for the difference in percentage healing between the treatments with the noninferiority limit of 15 percent.13 The secondary variable of time to healing was assessed by comparing changes in healing-free survival curves using a Cox model, and change in healing was assessed by comparing healing at the endpoint using Wilcoxon's test. The endpoint used was either Day 84 of treatment (12 weeks) or the day on which complete healing was observed. Given the nature of the comparison (noninferiority), the preferred population for analysis was the PP population.12

Results

There were no differences between the two treatment groups regarding demographic data, clinical examination results (including Doppler ultrasound), or history of the ulcer (the maximum duration of ulcers was limited in the inclusion criteria to 3 months).

In the compression device group, the ulcer was situated at the right leg in 39.7 percent of the patients and at the left leg in 60.2 percent; it was located at the inner malleolus in 68.2 percent, in the lateral malleolus in 18.2 percent, and located otherwise in 13.6 percent. In the bandage group, it was located at the right leg in 45.6 percent and in the left leg in 54.4 percent; it was situated in the inner malleolus in 66.7 percent, in the lateral malleolus in 20.0 percent, and located otherwise in 13.3 percent of the patients.

The length and area of ulcers at inclusion were comparable between the two groups as was time since onset of the ulcer, which was limited to a maximum of three months by the inclusion criteria (Table 2).

Complete healing was achieved in 58 percent in the tubular compression device group and in 56.7 percent in the bandage group (Table 4). The difference between the two treatment groups was –1.3 percent and the 90-percent confidence interval (–13.5–10.9%) was within the limits of noninferiority. These results show that the efficacy of the tubular compression device was not inferior to that of bandages regarding complete healing, with neither treatment showing superior efficacy to the other.

There was no difference between the two treatment groups (p=0.80) regarding time to complete healing (median 42 days). Nevertheless, in the remaining patients with incomplete healing, a decrease was

recorded in the surface area of the ulcer. The percentage of patients without complete healing but with reduced ulcer size was slightly higher in the compression device group (67.6% versus 59.0% in the bandage group) (Table 5).

Kaplan-Meier estimates. The Kaplan-Meier estimates showed a higher probability of failure to heal in the bandage group but with no statistically significant difference between the two curves (p=0.41) (Figure 3).

In order to demonstrate the effects of initial ulcer area, time to healing was studied in two sub-populations: patients with small ulcers (area <165mm2) and patients with larger ulcers (area ≥165mm2). Cox's model showed that baseline ulcer area had a significant effect on time to healing (p=0.002). In contrast, patients' age and time of onset of ulcer were not significant prognostic factors for healing time (p=0.35 and p=0.82) in this study.

The results for the ITT population were comparable with those for the PP population.

Compliance. Calculation of compliance was based on the number of days compression devices were worn in relation to the number of days of participation in the study. Compliance was very good: 96.8 percent in the compression device group and 96.4 percent in the bandage group with no significant difference (p=0.42) between the two groups. Compliance was the same for patients achieving both complete and incomplete healing.

Tolerability. The tolerability evaluation was carried out in the tolerability population (93 patients in each group). As reflected by the high compliance rate, compression treatment was generally well tolerated in both groups. However, understandably, the constant high pressure exerted by the tubular compression device gave rise to complaints (pain in lower limb and/or sensation of tightness) in 12 patients either on the day after the first application or one or two weeks later. Consequently, a larger size of the compression device was used on all 12 patients who completed the study. In 7 of those 12 patients (58%), the ulcer healed completely. No such problems occurred in the bandage group, since pressure could be varied by modifying bandaging.

## Discussion

Presently, it is generally recognized that compression treatment of the venous ulcer is necessary to reverse the effects of venous hypertension.33 External compression is mainly applied by using bandages. Great efforts were undertaken in the last few years to overcome problems related to the uncertainty of the exact pressures that should be applied on the leg with bandages. Many clinical studies investigated different compression systems and measured pressure beneath the bandages. Today, one considers that high pressure (about 40mmHg at the ankle) is more effective than low pressure, and it should be stable over time and graduated.33,34 However, there are no clear differences of efficacy between the different types of high compression.35

Published healing rates of venous ulcers obtained with compression therapy vary widely from 40 to 90 percent.14–29 These variations may be due to the numerous factors affecting time to healing. Scoring systems have consequently been developed to better calculate and compare different ulcer sizes and healing times. Skene, et al.,19 developed a prognostic index to calculate healing time for venous ulcers and found that the latter variable depends upon ulcer size, duration, patient age, and history of deep venous thrombosis. For an index of 4 to 4.5 (ulcer size of 1.7 to 4.9cm, duration of 2 to 21 months, patient aged 52 to 86 years with a previous history of deep venous thrombosis), the anticipated healing rate is 54 to 69 percent with a healing time of between 40 and 70 days. Application of this index to the present study reveals excellent healing rates and healing times for both treatment groups, corresponding to the anticipated values. The healing rate in this study is comparable with that obtained using three- or four-layer elastic compression4,24–26 with only slightly lower or higher percentages of healing. Additionally, further healing may be expected in those patients already showing improvement during the observation period.28

The change of the size of the tubular compression device to a larger size (reducing exerted pressure) in 12 patients during the study was necessary due to patient complaints. After the change, the patients tolerated the device, and all finished the study. Having in mind that the pressure exerted by the compression device is rather high, ranging between 30 and 40mmHg at the ankle, and that in 58 percent of the patients the ulcer healed during the study after changing the size, one can assume that the pressure was still sufficient. Application of high pressure is shown to be most efficacious to treat venous ulcers, but it is not always tolerated by the patients. Physicians have to manage the balance between therapeutic effect and compliance, which is known to play a major role in efficacy.36

The healing rate for bandaging observed during the present study was probably higher than that seen during normal practice due to the fact that all investigators were specialists, resulting in reduction of problems associated with application of bandages (insufficient pressure or nongraduated pressure). Another reason is the fact that only relatively small ulcers of short standing were included in the study. In addition, noncompliance has been shown to be the main reason for poor healing and recurrence of ulcers.29–32 In the present study, compliance was consistently higher than that observed in standard practice. However, a controlled study, such as the one described here, cannot address questions associated with general problems in daily practice. This was not the study objective.

## Conclusion

The results of the study showed comparable efficacy of the tubular compression device and short-stretch bandages in compression therapy for venous ulcers. A ready-made tubular compression device exerts well defined pressure independently of the fitter (often the actual patient) that remains stable over time, thereby avoiding known problems associated with compression bandages in current use (poor fitting and poor compliance). Practical questions, such as compliance in daily practice, should be addressed in future studies, although a completely different approach will be needed.

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