

Prospective, Randomized, Controlled Trial Comparing a New Two-Component Compression System with Inelastic Multicomponent Compression Bandages in the Treatment of Leg Lymphedema

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BACKGROUND New, less-bulky, short-stretch compression bandages could be a valuable alternative in the management of lymphedema of the leg.

OBJECTIVE To compare the effectiveness of a two-component compression (2CC) system in the treatment of leg lymphedema with that of the traditional treatment with conventional inelastic multicomponent compression bandages (IMC).

METHODS Thirty hospitalized patients with moderate to severe unilateral lymphedema (stage II–III) of the leg were included. Patients were divided in two groups; one ($n=15$) received a 2CC, and the other ($n=15$) received IMC. Primary outcome was volume reduction of the affected leg; secondary outcome was loss of interface pressure.

RESULTS Median leg volumes before bandaging were 4,150 mL (2CC) and 4,360 mL (IMC). Median volume reduction after 2 hours was 120 mL (2.9%) with the 2CC system and 80 mL (1.8%) with IMC ($p>.05$). After 24 hours, volume reduction was 8.4% and 4.4% respectively ($p>.05$). Interface pressure dropped significantly within 2 hours of bandage application in both groups.

CONCLUSION Our results indicate that the 2CC system forms a suitable alternative to IMC in the conventional treatment of moderate to severe lymphedema.

This study was supported by a 3M Health Care grant to a foundation.

Compression therapy is a potent treatment in phlebology and lymphology. To compare results and efficacy, it is necessary to use standardized bandaging materials and methods and measuring equipment. In 2006, the International Compression Club (ICC) published recommendations for measurements of interface pressure and stiffness¹ and the classification of bandaging materials by defining four complex central properties of compression bandages: pressure, layers, components, and elastic properties (P-La-C-E).² These recommendations encourage the observance of more evidence-based medicine practices in compression therapy. Taking each factor in turn, pressure is the magnitude of the compression applied by the bandage, layers is the practice of overlapping layers of bandage material

when the bandage is applied, components is the construction of the bandage (single material or composite structure), and elastic denotes the likelihood of the bandage applying a high pressure while the wearer is at rest. The P-La-C-E criteria help in the comparison of compression systems and technologies. The traditionally used compression systems for the conservative treatment of leg lymphedema consist of inelastic multicomponent bandaging materials. A newly developed bandaging material called the two-component compression (2CC, 3M Coban) system was developed and proved effective for the treatment of chronic venous insufficiency. This compression modality has less padding material and incorporates adhesive surfaces. In an ulcer healing study, Moffatt and colleagues³ showed that the 2CC

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TABLE 1. Descriptive Statistics of Patients According to Group (N = 30)

<i>Variable</i>	<i>Two-Component Compression System</i>	<i>Inelastic Multicomponent Compression Bandages</i>
Age, mean \pm standard deviation	54.3 \pm 12.5	48.1 \pm 14.5
Female, <i>n</i> (%)	13 (87)	11 (73)
Affected leg, <i>n</i> (%)		
Left	11 (73)	5 (33)
Right	4 (27)	10 (67)
Type of lymphedema, <i>n</i> (%)		
Primary	6 (40)	7 (47)
Secondary	9 (60)	8 (53)
Duration, years, median (range) (<i>p</i> > .05)	9 (1–46)	15 (2–46)

system exhibited significantly less bandage slippage than a four-component system, promoted wound healing, and achieved favorable health-related quality-of-life values. The material is less bulky, and patients are more mobile. It had been hypothesized that the 2CC system achieves at least equal interface pressures and leg volume reduction, but because these effects had not been studied, we designed a prospective, randomized, controlled trial to compare the 2CC system with traditional inelastic multilayer compression bandages (IMC) in terms of edema reduction interface pressures during the conservative treatment of leg lymphedema under controlled circumstances.

Method

Study Design and Population

This study was conducted as a prospective, randomized, controlled trial at the Lymphedema Department, Nij Smellinghe Hospital, Drachten, The Netherlands, from September 2008 to April 2009. The Medical Ethics Committee of the hospital approved the study, and all patients signed their informed consent. The study was registered under ClinicalTrials.gov identifier NCT00665379.

Participants

The total study population consisted of 30 patients hospitalized for conventional treatment of moderate to severe lymphedema of the leg. This in-clinic study provided better standardization of the study

groups in terms of application of bandages and concomitant mobilization activities. All patients included in this study had undergone various previous ineffective conservative treatments. All patients included had noticeable pitting edema before being hospitalized. The study population was randomized into two groups using a closed envelope procedure; one group was treated with the 2CC system and the other with IMC. Descriptive characteristics of the participants, including type, duration, and etiology of lymphedema, are summarized in Table 1. Patients included in this study all had moderate to severe lymphedema, stage II to III (International Society of Lymphology).⁴ Varicose veins as a concomitant disorder were present in two patients, one in each group.

Bandaging Materials and Techniques

One group was treated using the 2CC system (10 cm \times 3.5 m; Coban 2-Layer Compression System; 3M Health Care, St. Paul, MN) and the other using three-component Trico IMC (BSN Medical GmbH, Hamburg, Germany) consisting of an initial protective layer (Tricofix, BSN medical GmbH) covered with two layers of synthetic cast wadding (Delta-Rol S, BSN medical GmbH). Two layers of IMC (12 cm \times 4 m) bandaging material were applied over the synthetic cast wadding. The characteristics of the bandages are summarized in Table 2. Dedicated and specialized personnel who had undergone in-service training in application techniques applied both bandages from the base of the toes to the knee. In both groups, the initial bandages were removed

TABLE 2. Comparison of Two Materials According to the Pressure, Layers, Components, and Elastic Properties Classification²

	<i>Pressure (mmHg)</i>	<i>Layers</i>	<i>Number of Components</i>	<i>Elastic Properties</i>
Inelastic multicomponent compression bandages	Strong (40–60)	Multiple	3	Nonelastic (high stiffness)
Two-component compression system	Strong (40–60)	Multiple	2	Nonelastic (high stiffness)

after 2 hours, and new bandages were applied for the following 24 hours. After bandage application, all patients were encouraged to move as much as possible. No other therapeutic intervention was performed.

The primary outcome parameters were volume changes achieved by the bandages. We expected to determine the noninferiority of the new bandage system to the established IMC. Changes in subbandage pressure were considered as a secondary outcome.

Leg Volumetry

Leg volume was measured using a water-displacement device consisting of an acrylic container, filled up to 34 cm from the bottom with warm water (30°C).⁵ The lower leg was positioned slowly in the apparatus, with the patient in a standing position. The displaced water was collected and weighed on a precision scale. This method precisely measures the total leg volume, including the volume of the foot and toes.^{5,6} Leg volumetry was performed in both groups before bandage application, 2 hours after removal of the initial bandages, and 24 hours after removal of the secondary bandages.

Measurement of Interface Pressure

Interface pressures were determined in both groups using a pressure transducer (PicoPress, Microlab Elettronica Sas, Roncaglia di Ponte San Nicolò, Italy), which can measure pressures ranging from 0 to 189 mmHg with an accuracy of ± 3 mmHg. Silicone pressure sensors (diameter 5 cm \times 200 μ m, Microlab, Italy) were placed at the transition of

Achilles tendon to calf muscle (location B1), below the bandages (Figure 1), and interface pressure was measured statically and dynamically in real time with the patient in supine and standing positions after bandage application, 2 hours later, after bandage renewal, and before removal after 24 hours. During the dynamic pressure measurements, patients were requested to perform several maximal dorsal flexions before returning the foot to the resting position. Resting pressures were recorded, and the difference between maximum pressure from flexion

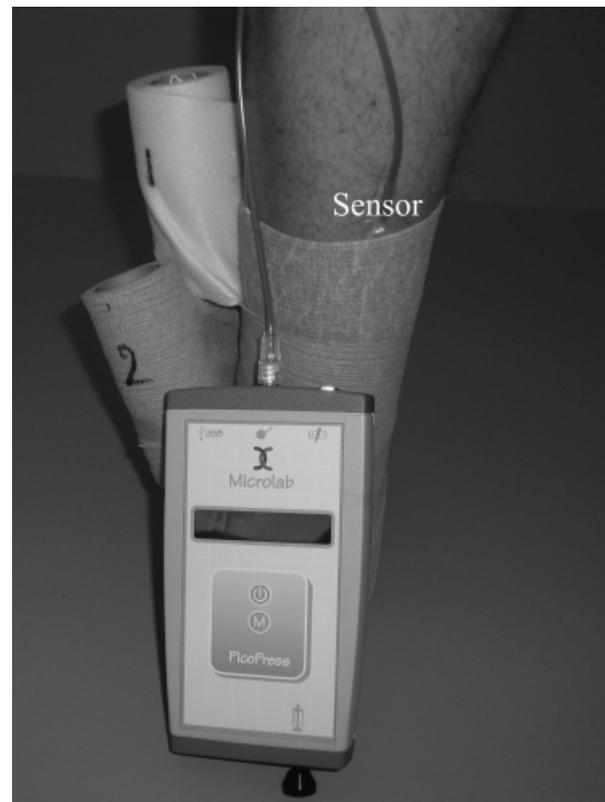


Figure 1. Pressure sensor placement beneath the two-component compression system.

and resting pressure was calculated (Dynamic Stiffness Index, $DSI = P_{flex} - P_{rest}$).^{7,8}

Statistical Analysis

Data collected were analyzed using GraphPad Prism 5.0 (GraphPad Software Inc., San Diego, CA). Variables were expressed as means ± standard deviations or medians (interquartile ranges (IQR)) for skewed data. The Mann-Whitney test was used as a non-parametric test to compare the distributions of the two unmatched groups. Matched pairs (non-Gaussian distribution) were compared using the Wilcoxon test. $P < .05$ was considered to be statistically significant.

Results

Leg Volume Reduction

The median lymphedema leg volume before bandaging did not differ significantly between the two legs and was 4,150 mL for the 2CC group (IQR 3,720–5,450 mL) and 4,360 mL for the IMC group (IQR 3,180–5,870 mL) (Figure 2). After 2 hours, a median volume reduction of 120 mL (IQR 60–185 mL) (–2.9%) was measured in the 2CC group, compared with 80 mL (IQR 30–130 mL) (–1.8%) in the IMC group (not significant). After 24 hours, the median leg volume of the 2CC group was 3,960 mL (IQR 3,310–4,940 mL), with a median

reduction of 350 mL (IQR 130–525 mL) (–8.4%). The median leg volume after 24 hours for the IMC group was 3,800 mL (IQR 3,000–5,290 mL), with a median reduction of 190 mL (IQR 100–580 mL) (–4.4%) ($p > .05$).

Leg Pressure Profile

Figure 3 illustrates the loss in interface pressure while patients were standing after bandage application in both groups. The median initial (T0) standing interface pressures were 54 mmHg (IQR 47–68 mmHg) for the 2CC system and 60 mmHg (IQR 54–64 mmHg) for IMC. During the following 2 hours (T2), interface pressures dropped significantly in both groups, by 18 mmHg (33%) with the 2CC system and 18 mmHg (30%) with IMC ($p < .001$). After 2 hours, bandages were renewed. Median standing interface pressures after bandage renewal (T2*) were 48 mmHg (IQR 42–65 mmHg) for the 2CC system and 49 mmHg (IQR 45–66 mmHg) for IMC. After 24 hours, the median standing interface pressures decreased significantly, to 27 mmHg (IQR 17–35 mmHg) (56%) with the 2CC system and 30 mmHg (IQR 18–34 mmHg) (61%) with IMC ($p < .001$).

Dynamic Stiffness Index

Figure 4 illustrates the change in DSI. Directly after bandage application, the median DSI for 2CC was

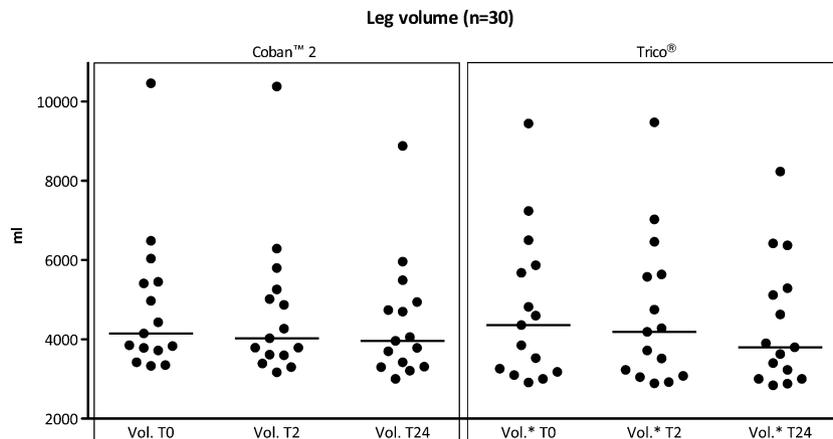


Figure 2. Median leg volume. Volume of the lymphedematous legs before, 2 hours after, and 24 hours after compression bandage application.

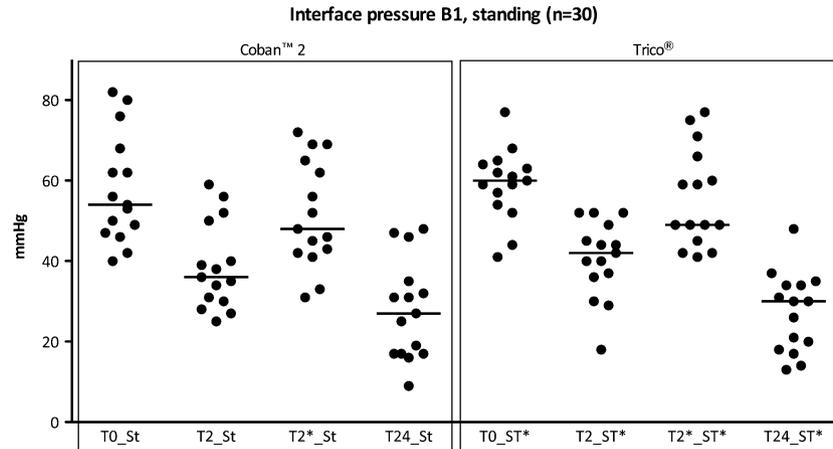


Figure 3. Median standing interface pressure profile. Pressure loss within 2 hours (T2) is significant for both bandage types ($p < .001$). After bandage renewal (T2*), pressure loss was 56% (-21 mmHg) for the two-component compression system and 61% (-19 mmHg) for inelastic multicomponent compression bandages ($p < .001$).

25 mmHg (IQR 5–35). For IMC bandages, the median DSI was 12 mmHg (IQR 1–19). After 24 hours, the median DSI decreased to 9 mmHg (IQR 4–27) for the 2CC system and 7 mmHg (IQR 1–22) and for IMC (no significant differences between the groups).

Discussion

Although compression bandages may appear to be a simple medical device, their effectiveness depends on the selection of appropriate materials and the

application methods used. The differences between the materials used in this analysis include the method of application, the number of layers, and the amount and structure of the components used.

Studies of volume reduction achieved by compression in leg lymphedema are rare. In 2008, Damstra and colleagues⁹ showed that inelastic, multilayer, multicomponent compression bandages lead to an immediate reduction of lymphedematous leg volume, with some correlation between the drop in

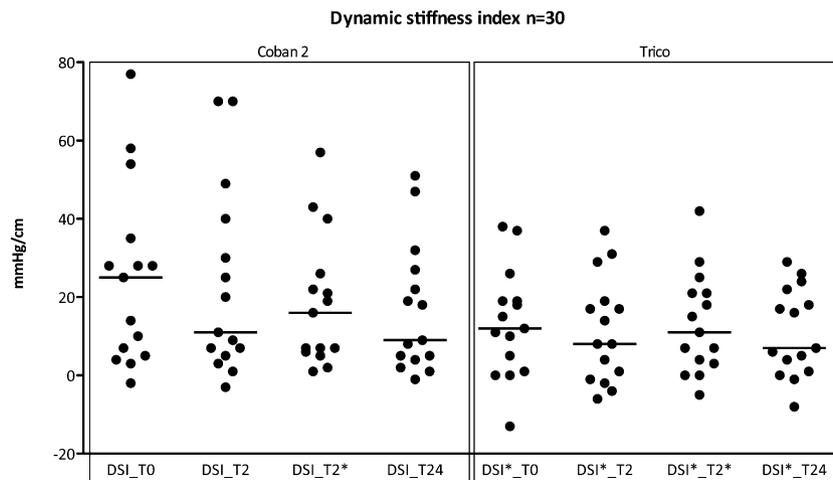


Figure 4. Median dynamic stiffness indices (DSIs). The DSI of the two-component compression (2CC) system was greater than those of inelastic multicomponent compression bandages (IMC) at each measurement. The difference was 12 mmHg at T0 and 11 mmHg at T2. The mean 2CC DSI was 5 mmHg greater than for IMC after bandage renewal and 6 mmHg greater after 24 hours (no significant differences between the groups).

interface pressure and the reduction in volume. The presented data show a significant pressure drop of over two-thirds of the initial applied interface pressure within 2 hours after bandage application. During that period, a slight reduction in volume was achieved.

The multilayer compression systems usually recommended for the management of lymphedema causes problems for patients and for clinicians.¹⁰ Some well-known problems include inconsistency in application techniques, resulting in inconsistent pressures, variable results, and bulkiness, which can impede patients from wearing normal footwear and clothing, leading to a low level of adherence and the potential risk of falling. Another problem can be slippage and bunching, leading to uneven distribution of compression, which can result in discomfort at night and the potential for skin breakdown. During use of multilayer compression systems, patients often report experiencing “bulkiness” of the applied materials, especially during mobilization. Bulkiness is caused by the material itself and the use of large amounts of the padding material traditionally used during lymphedema treatment. Recently, a new two-component compression system has been developed and marketed as the 2CC system for use in the context of compression therapy for chronic venous insufficiency. The product is packaged in a kit form and contains two latex-free roll bandages. After application, the two layers bond tightly to form one single, stiff, stable layer with no internal movement. The inner “comfort” layer is polyurethane foam laminated to a cohesive bandage. The foam side provides a cushion over bony prominences and a mechanical grip of the skin when compressed. Large amounts of padding material are not necessary to ensure effective pressure distribution or patient comfort. The cohesive outer side provides a surface to which the second compression layer bonds tightly. It is believed that the skin-gripping properties of the inner comfort layer and the cohesive bonding properties of both layers provide for a more stable compression system. A study conducted by Moffatt and colleagues¹¹ in patients with venous leg ulcers

showed that this 2CC system with greater patient comfort was as effective as traditional IMC, leading to better quality of life for the patient. During the course of this study, no untoward effects of either compression system were noticed or reported by the participants. Even though this study did not include questionnaires regarding comfort, all participants treated with the 2CC system reported enhanced mobility and comfort during walking than with previously worn compression systems.

The efficacy of the 2CC system has not been compared with that of conventional treatment before. Our results indicate that the volume reduction achieved using the 2CC system during a 24-hour period matches that achieved with IMC.

With regard to stiffness as assessed by DSI, the 2CC system achieved greater values at all time points measured in our study. The DSI yielded negative values at several individual time points. The static standing dorsal flexions the participants were asked to perform during this study could explain this in part. Furthermore, for accurate DSI calculation, circumference measurements at the B1 location should be recorded in real time during walking, which was not performed in this study. Previous research has indicated that higher DSIs result in higher interface pressure pulses during mobilization of ambulant patients with lymphedema,⁸ which in turn results in more-effective distribution and mobilization of edema, especially during mobilization.

Redistribution of edema fluid to the upper part of the leg is plausible, although abnormal congestion of edema around the knee was not observed. Nevertheless, this possibility cannot be excluded because we focused on lower leg volume. The issue of edema redistribution was not the focus of this study.

A weakness of our study is the relatively low sample size. To achieve a power higher than 80% with 95% reliability, we calculated that a sample size of 741 for a 10% difference in volume reduction between the two study groups and 119 for a 20% reduction was

necessary, but from a practical point of view and with regard to our research question, these numbers were not realistic.

In terms of cost efficiency, the 2CC system is more expensive than the classic short stretch bandaging system (ratio 2.4:1). To achieve cost effectiveness, the number of bandage changes over time can be lowered when using the 2CC system while still providing adequate interface pressure. This can be an extra advantage because, in daily practice, most patients are treated on an ambulatory basis in which bandage change is less frequent and practical aspects such as better mobility and the use of normal shoes are of more significance.

Therefore, when early stages of lymphedema with a large pitting component (stages I–III) are treated, and frequent bandage changes are necessary during the first week of treatment, initial usage of IMC bandages is more cost effective. After the initial usage of IMC bandages, a conversion to the 2CC system results in less frequent bandage changes, adding to patient comfort.

Conclusion

This study shows that, for compression therapy of leg lymphedema, a newly developed two-layer system is as effective in reducing volume as conventional inelastic short-stretch bandaging. There is no significant difference between systems in pressure or volume loss after 24 hours. The two-component system provides greater subbandage pressure for every centimeter of circumference than conventional short stretch bandages. This property potentially enhances the efficiency of long-term compression therapy during the conventional treatment of lymphedema.

Acknowledgments D-A.A Lamprou was the lead author. R.J. Damstra, in cooperation with H. Partsch, designed the study. R.J. Damstra and H. Partsch were helpful in revising and editing the text. We

thank Elske Wijbenga, Annet Bosma, and Nicole Wittevrongel, nurse practitioners in the Department of Dermatology, for performing pressure and volume measurements and applying the short stretch bandages.

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