Bandages or Double Stockings for the Initial Therapy of Venous Oedema? A Randomized, Controlled Pilot Study

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WHAT THIS PAPER ADDS

This study could influence future clinical practice as it shows that chronic oedema does not necessarily need a treatment phase with inelastic bandages, which exert strong pressure and require specialised personnel to apply them. According to our results an elastic kit consisting of two superimposed compression stockings is very effective, both for the treatment and maintenance phases. In addition, this treatment modality allows a significant cost saving.

Objective/background: Treatment for leg oedema conventionally starts with compression bandaging followed by elastic stockings once swelling is reduced. The aim was to investigate if a kit consisting of a liner and outer stocking, each exerting 20 mmHg of pressure, would be equally effective in achieving and maintaining volume reduction compared with short-stretch bandaging (2 weeks) followed by a class II (23–33 mmHg) stocking (2 weeks).

Methods: Forty legs (28 patients) with chronic venous oedema were randomised to either short-stretch bandages applied weekly for 2 weeks, followed by an elastic stocking for 2 weeks (group A) or a light stocking ("liner") for 1 week followed by superimposing a second stocking for 3 weeks (group B). Interface pressures and leg volumes were measured weekly.

Results: Despite differences in the pressure (median ± interquartile range) applied (bandage: 67 mmHg [55.7–73.0] vs. liner 24.5 mmHg [21.2–26.5]) volume reduction after 1 week was equal (12.8% [8.7–16.5] and 13.0% [10.4–20.6]). After 2 weeks (group A: 17.8% [10.6–20.0] vs. group B 16.2% [13.0–25.4]) and 4 weeks (group A: 17.3% [9.6–22.8] vs. group B: 17.0% [13.1–24.1]) volume reductions remained identical.

Conclusions: The initial improvement in leg volume (1 week) was independent of the pressure applied and the reduction was maintained by superimposing a second stocking. This offers a simple alternative for managing leg oedema with reduced staffing costs.

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INTRODUCTION

In the management of venous and lymphatic oedema of the extremities usually two phases are distinguished: a therapy phase, consisting of firm bandages to remove oedema, and a maintenance phase, in which elastic compression stockings are used to maintain the result achieved by bandages and to prevent oedema recurrence.[1,2] In a previous study we were able to demonstrate that leg oedema can be treated effectively by elastic compression stockings with moderate pressure[3] provided the stocking size can be readjusted to the reduced leg volume during and at the end of the therapy phase. However, this approach would make such a regimen prohibitive with regard to cost.

The aim of the present study was twofold: first to question the dogma that initial compression pressure needs to be high to reduce leg oedema; and second to investigate if an elastic compression kit consisting of two superimposed elastic compression stockings exerting a total resting pressure of about 40 mmHg could be as effective as a inelastic bandages (IBs) applied weekly to maintain the effect over time without the need of replacement in a very short period of time.

METHODS

Patients

Forty legs of 28 patients (15 men, 13 women aged 70.2 ± 8.5 years; range 44–78 years) affected by chronic

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leg oedema caused by primary and secondary chronic venous disease were randomised to receive two different initial compression treatments, applied for a total of 4 weeks: (a) a strong, IB applied at weekly intervals, followed by adjusted compression stockings for 2 weeks (group A); (b) a liner for the first week followed by superimposition of a second stocking, both of which exerted a pressure of 20 mmHg (group B). The two stockings together make up an elastic kit (EK), which achieves a total pressure of around 40 mmHg (Fig. 1).

Men and women, aged between 18 and 85 years, who had suffered for more than 3 months from chronic oedema due to primary and secondary chronic venous disease (according to the Clinical, Etiological, Anatomical, Pathophysiological [CEAP]classification of venous disease C 3, according to the Venous Clinical Severity Score [VCSS] oedema score 2, restricted to the lower leg[4]) were included in the study.

Patients with skin changes due to venous insufficiency (CEAP C4—C6), lymphoedema, cardiac failure, conditions requiring diuretics, cortisone, Ca^{++} antagonists treatment, and/or with an ankle brachial pressure index below 0.8 were excluded.

The venous pathophysiology of oedema was investigated by Duplex scanning (Esaote MyLab 60 with a multifrequency linear probe of 7.5—12.0 MHz; Esaote, Genoa, Italy): 29 legs were affected by superficial venous insufficiency (C3EpAsPr), 5 by deep venous insufficiency (C3EsAdPr), and 6 by both superficial and deep venous insufficiency (C3EpsAsdPr).

Patient characteristics are summarised in Table 1.

All individuals were informed about the investigation and gave their written, informed consent. Ethics committee consent for the study was also obtained.

The primary endpoint of the study was oedema reduction; secondary outcome parameters were the interface pressure of the compression device in the supine and standing position, and the comfort of the compression systems during the day and night.

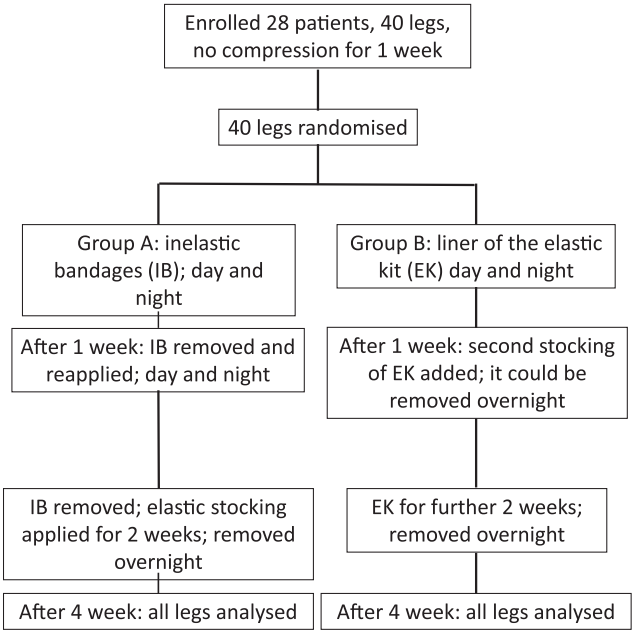


Figure 1. Time sequence of compression devices: group A (bandages) and group B (elastic kits).

Compression

Group A received multilayer, multicomponent, inelastic bandages consisting of a cotton padding layer (Cellona), a short stretch cohesive bandage (Mollelast Haft), and a short stretch nonadhesive bandage (Rosidal K) on the top (Lohmann & Rauscher, Rengsdorf, Germany). The three components were applied in a spiral fashion, with 50% overlap between the layers, from the base of the toes up to 2 cm below the knee. Mollelast Haft and Rosidal K were applied under full stretch to exert a strong-to-very strong pressure according to the International Compression Club classification of compression materials.[5] After 2 weeks 23—32 mmHg knee high compression stockings (Mediven Forte, Bayreuth, Germany) were applied.

Group B began to wear the knee length grey "liner" from the Mediven Ulcer Kit, which exerted a pressure of 20 mmHg, in the first week. The size of the liner was chosen according to leg circumference. After 7 days the second stocking of the kit, a Mediven Plus, one size smaller than the liner fitting to the reduced leg circumference and exerting a pressure of 20 mmHg, was superimposed on the liner, achieving a pressure of about 40 mmHg in the lying position.

Study protocol. One week before starting the study the patients were randomly allocated to treatment by means of IB or EK according to a list randomiser (http://www.random.org/lists/). Venotonic drugs, bandages, or stockings, when used routinely by the patients, were stopped at enrolment, 7 days before baseline oedema assessment (wash-out period), and remained discontinued for the study period, during which the patients were encouraged to maintain their usual lifestyle.

On day 0 leg volume measurements were performed and either inelastic compression bandages or the liner fitting to the individual leg were applied. The interface pressure of the applied compression device was measured at the B1 point after application.

The knee-high bandages and liners were kept on day and night and were removed on day 7, when leg volume was measured and new compression applied. In group A a new IB was applied. Patients in group B put on the elastic stocking of the EK, which was one size smaller compared with the initial fit over the liner. The patients were asked to wear their EK overnight and to remove the outer stocking only if strong pressure caused pain. Interface pressure was measured before removing the old devices and after applying the new compression ones.

On day 14 compression was removed again, leg volume was measured, and compression reapplied; the patients in the bandage group received elastic stockings that fitted their new leg size and the patients with EK continued with the device. In this last period patients were allowed to remove their compression devices overnight. The pressure of the compression devices was measured before compression removal and after reapplication.

Table 1. Clinical features.

	Age (y)	Sex		Pathophysiology (*n*)			BMI
		Male (*n*)	Female (*n*)	SVI	DVI	SVI + DVI	
Bandage	69.4 ± 9.9	11	9	15	3	2	26.5 ± 2.0
ECS	68.1 ± 9.8	10	10	14	2	4	25.9 ± 2.0

Note. ECS = elastic compression stockings; SVI = superficial venous insufficiency; DVI = deep vein insufficiency; BMI = body mass index.

On day 28 interface pressure was measured before compression removal and leg volume was measured for the last time (Fig. 1).

Measurements. Patients were always seen at the same time of the day in a quiet room, which had a constant temperature of about 22 °C.

Two different methods were used to assess leg oedema.

1. Leg volumetry by water displacement for measuring the total lower leg volume.[6–8]
2. Measurement of leg circumference by tape[9] was taken at the malleolar level and every 4 cm for eight leg segments. Measurement of leg circumference can be used both for assessing the profile of the leg circumference and of its reduction, and for calculating leg volume according to the mathematical formula of the truncated cone ("Kuhnke formula").[9] All the measurement points on the leg were marked at time 0 to allow repetition of the measurements in exactly the same site after 7, 14, and 28 days.

The interface pressure between the compression devices and the skin was measured in supine and standing position by means of Picopress (Microlabitalia, Padua, Italy), which is a pneumatic pressure transducer.[10,11] The pressure probe, measuring 5 cm in diameter and less than 1 mm in thickness, was placed at the B1 point—which is the area of the medial aspect of the leg where the gastrocnemius muscle turns into its tendinous part, 10–15 cm above the medial malleolus[12]—and filled with 2 ml of air during measurement. After measurement at application the probe was disconnected from the measuring device and left in place under the compression systems. It was reconnected, and supine and standing pressure was measured again before the compression devices were removed.

The wearing comfort of the compression device was assessed by using a visual analogue scale (VAS) at day 7 and day 14, both during the day and night (0 = very poor comfort, 10 = optimal comfort).

Statistical analysis

Based on our previous study,[3] which revealed a percent volume reduction with elastic compression stockings of 9.6 ± 4.9% and with bandages of 11.5 ± 3.7% after 2 days, 70–80 patients in each group would be required to obtain a significance level (alpha) of .05 (two-tailed) with a power of 90%.

As the required size of noninferiority trials is usually even larger than that for superiority trials,[12] a large, multicentre study would be necessary to recruit enough patients, which is unrealistic. Therefore, we decided to proceed with a pilot study in which 20 legs in each treatment group were enrolled and randomised to receive either bandages or stockings.

Medians with interquartile ranges (IQRs), and maximal and minimal values are given. For repeated measures analysis of variance was used to compare the volume and pressure changes on the same leg. The nonparametric Mann–Whitney test was used to compare the effects of bandages and stockings. The nonparametric Spearman rank test was used to quantify correlations. Differences with a $p < .05$ were considered statistically significant.

Graphs and statistical evaluations were generated using Graph Pad Prism, version 5 (Graph Pad, San Diego, CA).

RESULTS

Volumetry

Neither group showed any significant difference in regard to age, sex, venous pathology or body mass index, and, in baseline conditions, leg volumetry measured by both water displacement and the Kuhnke formula showed a linear correlation (Pearson's $r = 0.983$).

Both compression systems achieved a significant reduction of total leg volume after 7, 14, and 28 days compared with baseline ($p < .002$) (Fig. 2A and B). By comparing the effects of the different compression devices at weekly intervals no significant difference of the percent reduction of leg volume after 7, 14, and 28 days was seen (Fig. 3).

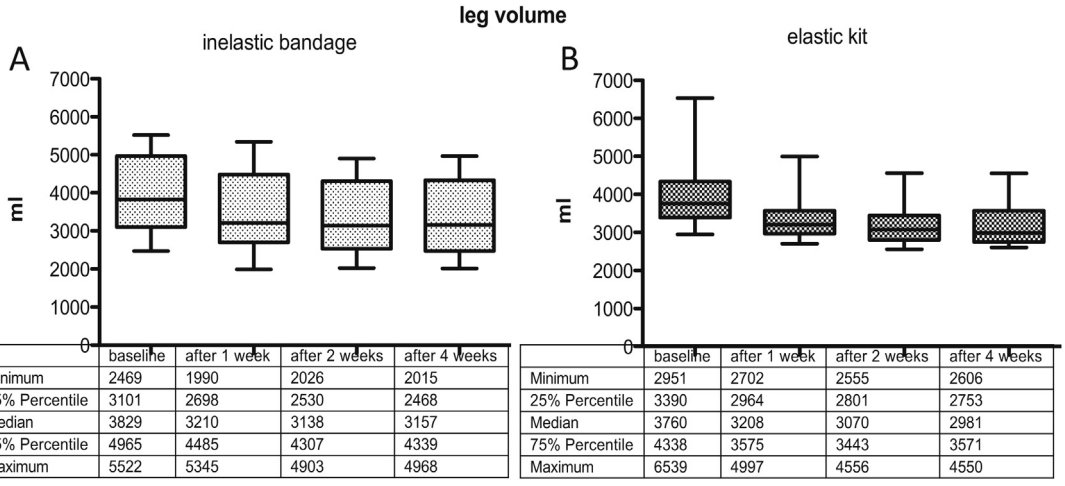
After the first 2 weeks of treatment with bandages, elastic stockings were able to maintain the volume reduction: leg volumetry increased minimally, but not significantly, from 14 to 28 days.

The changes in leg circumferences after 2 weeks were compared to assess at which level of the leg the applied compression devices was most effective (Fig. 4).

Considering the calf area as the gastrocnemius muscle location, starting 10–15 cm above malleoli, the reduction of leg circumference was maximal at ankle level and progressively less so moving towards the calf, both with IB (median reduction was 13.23% at ankle level and 4.00% at calf level) and EK (median reduction was 14.50% at ankle level and 4.24% at calf level). In the gaiter area between the malleoli and the calf (4 and 8 cm above the ankle) the graduated stockings were significantly more effective ($p < .05$) than the bandages.

Interface pressure

After application the interface pressure was much higher with IB compared with the liner, both in supine (median values 67 mmHg, IQR 55.7–73, vs. 25 mmHg, IQR 21.2–26.5) and standing position (87.5 mmHg, IQR 72.5–92.5, vs.



	baseline	after 1 week	after 2 weeks	after 4 weeks
Minimum	2469	1990	2026	2015
25% Percentile	3101	2698	2530	2468
Median	3829	3210	3138	3157
75% Percentile	4965	4485	4307	4339
Maximum	5522	5345	4903	4968

	baseline	after 1 week	after 2 weeks	after 4 weeks
Minimum	2951	2702	2555	2606
25% Percentile	3390	2964	2801	2753
Median	3760	3208	3070	2981
75% Percentile	4338	3575	3443	3571
Maximum	6539	4997	4556	4550

Figure 2. Water displacement volumetry overtime in the bandage (A) and elastic kit (B) groups.

26, IQR 25.2—28.7) ($p < .001$) (Fig. 5); 7 days later the supine pressure of IB was about the same as the liner (21.5 mmHg, IQR 18.5—24.0, vs. 19.0 mmHg, IQR 17.0—22.7) (n.s.), while the standing pressure remained higher with IB (34.5 mmHg, IQR 30—43.5, vs. 21.0 mmHg, IQR 18.0—24.5) ($p < .05$). In the second week the pressure of bandages at application was significantly higher than that of EK both in supine (61.5 mmHg, IQR 54.2—69.5, vs. 40.0 mmHg, IQR 38—44.5) and in standing position (79.5 mmHg, IQR 70.5—93, vs. 44 mmHg, IQR 40.2—47.9); 1 week later, before removal, the pressure of IB dropped to 25.5 mmHg (IQR 22.2—29.0) in supine position, but was still 40.5 mmHg (IQR 39.0—46.2) in the standing position. Elastic kits maintained their pressure more effectively (37.0 mmHg, IQR 32—38, and 39.5 mmHg, IQR 35—42, respectively, in supine and standing position) exerting a higher supine pressure and about the same standing pressure compared with the bandage (Fig. 5). In the third and fourth weeks the patients in the IB group were changed to elastic stockings exerting a lower pressure compared with EK, both in supine and in standing position, and at application (supine 29.0 mmHg, IQR 26.2—30.0, vs. 36.0 mmHg, IQR 32.2—38.7) (standing 31 mmHg, IQR 29.2—32.7, vs. 41.0 mmHg, IQR 35.2—42.0 mmHg) and removal (supine: 25.5 mmHg, IQR 22.2—27.0, vs. 33 mmHg, IQR 30.0—35.0; standing: 27.0 mmHg, IQR 25.0—29.5, vs. 36.0 mmHg, IQR 33.0—37.7) of compression.

Correlation interface pressure/volume reduction after the first week

In the IB group the volume decrease showed a tendency to have an inverse correlation above pressures of 40 mmHg: with higher pressure, leg volume decrease was progressively reduced. In the liner group volume decrease showed a trend toward a positive correlation with the interface pressure up to a pressure of 30 mmHg. Neither correlations were statistically significant (Fig. 6).

Patient comfort

Comfort was good with both devices. The liner of the EK was well tolerated both during the day and the night. The VAS score was in the same range for both compression regimens, with average scores of 8.5 during the day and 9 during night with the liner (IQR 8—9 and 9—9 respectively), and 9 during both the day and night with IBs (IQR 8.2—9.0 and 9—10 respectively). These scores did not change after 1 week.

In the second week, the pressure exerted by the EK was not tolerated during the night by 15 (75%) patients (median VAS 6.3, IQR 5.0—7.1); these patients removed the outer stocking during the night and reapplied it themselves or with the help of a family member every morning before getting out of bed.

There was no crossover of patients as no patients did not tolerate their compression treatment.

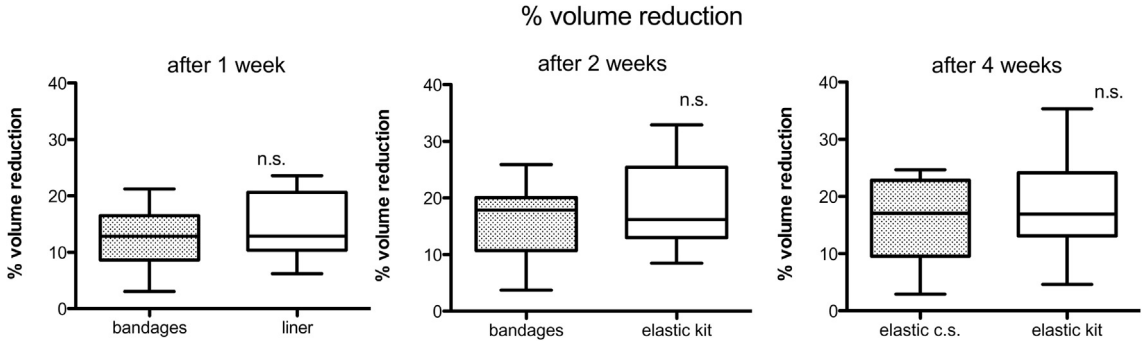
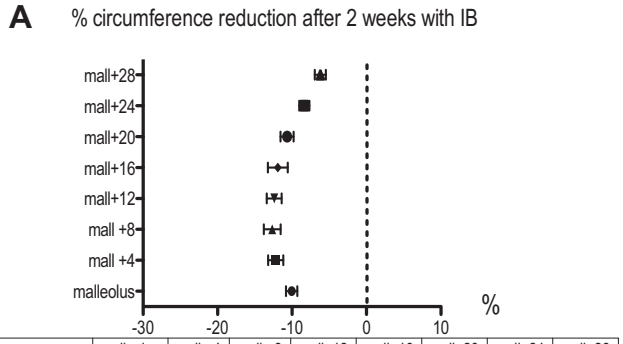
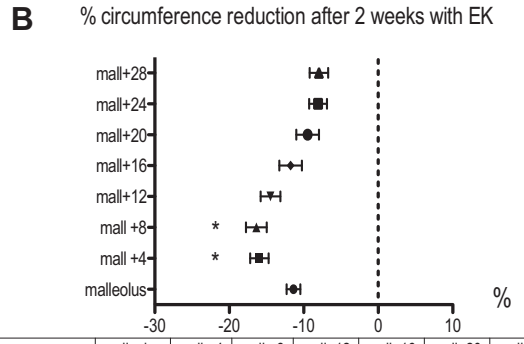


Figure 3. Percent volume reduction with bandages and elastic stockings after 1, 2, and 4 weeks. *Note.* n.s. = not significant.





	malleolus	mall +4	mall +8	mall+12	mall+16	mall+20	mall+24	mall+28
Minimum	-16.67	-20.31	-25.64	-20.00	-24.49	-16.28	-14.29	-14.86
25% Percentile	-12.50	-15.92	-15.14	-15.17	-16.21	-13.81	-10.55	-7.793
Median	-10.57	-11.93	-11.21	-12.77	-10.91	-11.39	-9.110	-5.910
75% Percentile	-6.920	-8.318	-8.888	-10.07	-7.665	-6.765	-5.765	-3.525
Maximum	-3.850	-4.350	-4.760	-5.000	-2.440	-4.650	-3.330	-1.230

	malleolus	mall +4	mall +8	mall+12	mall+16	mall+20	mall+24	mall+28
Minimum	-18.52	-30.77	-32.56	-26.53	-26.92	-23.26	-18.18	-22.22
25% Percentile	-14.94	-20.95	-20.28	-17.63	-16.15	-15.46	-10.77	-9.738
Median	-10.53	-14.44	-15.27	-13.35	-10.51	-8.270	-7.345	-7.195
75% Percentile	-8.798	-12.13	-11.11	-11.20	-8.160	-4.483	-3.340	-4.820
Maximum	-1.920	-8.700	-8.000	-3.450	0.0	0.0	0.0	-1.350

Figure 4. Percent circumference reduction at different leg levels after 2 weeks with inelastic bandages (B) (A) and the elastic kit (EK) (B). Difference in the gaiter area is significant ($p < .05$).

DISCUSSION

In our study compression reduced leg oedema significantly, as evaluated by both water displacement and by the truncated cone formula. These two methods to assess leg volume showed an excellent correlation (Pearson's $r = 0.98$; 95% confidence interval: 0.96—0.99) confirming for the leg what has been previously demonstrated for the arm.[13,14]

The most surprising result of the present study was the impressive oedema reduction achieved by a liner stocking (median pressure 24 mmHg) in the initial treatment phase which, after wearing for 1 week, did not differ from that produced by a strong bandage applied with a pressure of 67 mmHg. In fact, in the first week the volume reduction was about 13% with both compression devices. This leg volume reduction increased to 16.2% in the second week when the complete EK was used and was only slightly, but not significantly, less than the effect of IB at 17.8%.

The interesting question of whether a liner could be sufficient, at least for a certain time period, to reduce oedema can only be answered by future studies.

Limb volume reduction is the deciding outcome when assessing the effectiveness of compression devices in the treatment of oedema.[15] Leg volumetry by water displacement is considered the gold standard technique with good

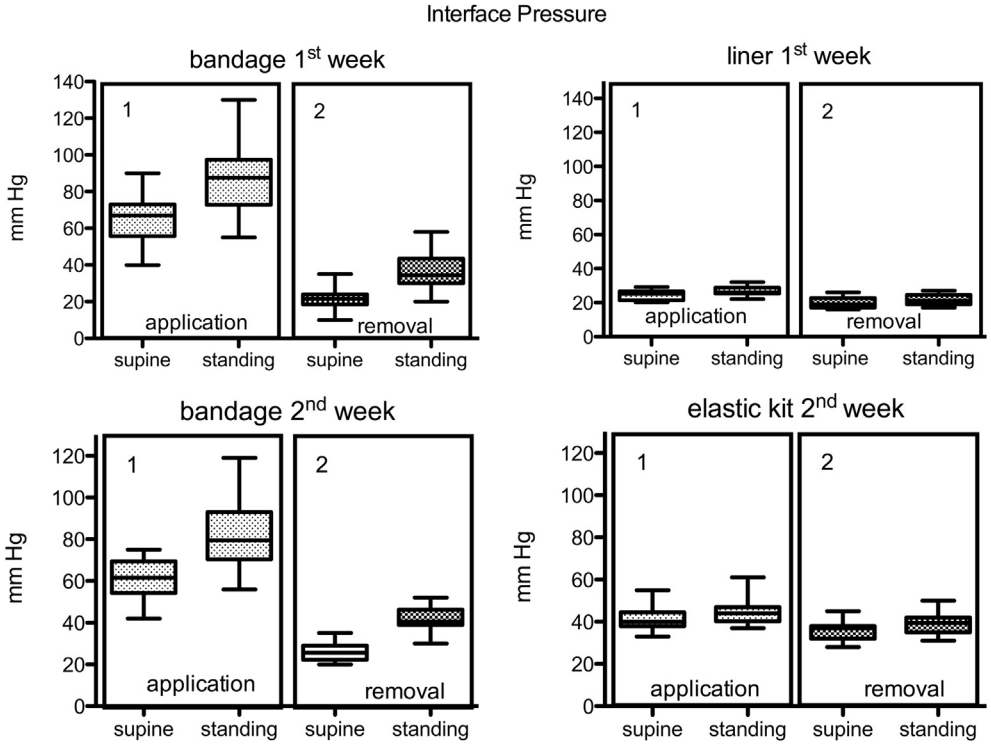


Figure 5. Interface pressure with different compression devices in supine and standing position at application and removal at first visit and after 2 weeks.

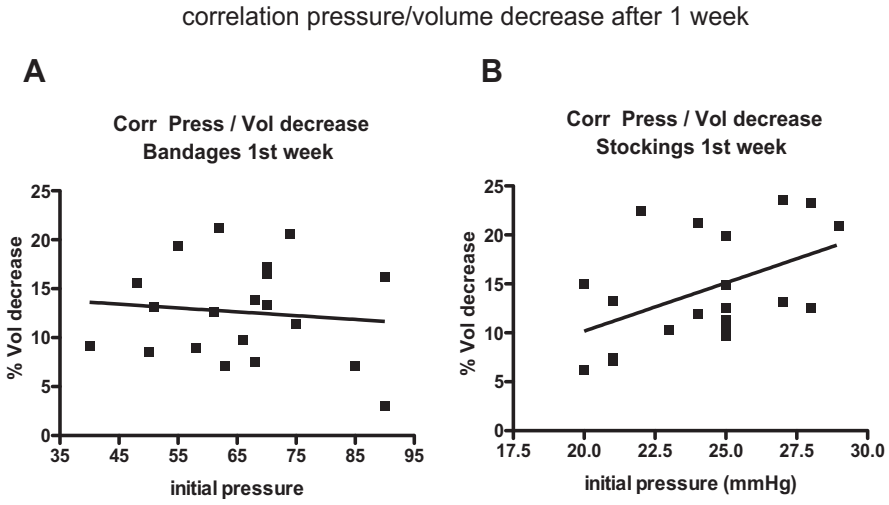


Figure 6. Correlation between interface pressure and percent volume decrease after 1 week with inelastic bandages (A) and elastic kit (B).

accuracy and reproducibility.[6,7] Circumference measurement by tape showed good reproducibility.[8,13] Measuring the leg circumference every 4 cm makes assessment of the leg volume profile possible. Furthermore, leg volume can be calculated by the mathematical formula of a truncated cone,[9] which shows an excellent correlation with water displacement volumetry.[13,14]

The correlation between the pressure exerted by compression devices and oedema reduction was positive in group B up to a compression pressure of 30 mmHg. In group A the beneficial effect of compression was progressively smaller when the compression pressure exceeded 55 mmHg (Fig. 6). This is an agreement with previous dose—response findings, which demonstrated that higher pressures will not necessarily result in more volume reduction.[3,18]

These correlations need to be considered with caution because the given pressures represent only a snapshot relating to the time immediately after application. In particular, the patients with IB showed a drop in pressure immediately after application, which resulted in a supine pressure range after 1 week in the same order as the pressure from a liner, while the standing pressure remained slightly higher. In the second week the supine pressure of the EK was even higher than that of IBs, while the standing pressure remained about the same (Fig. 6). It may be assumed that bandages that are renewed daily or every 2 days to maintain higher pressures would be more efficient, but this needs to be investigated in future studies.

The segmental volume reduction appeared to follow the local pressures exerted by the compression device. This could be demonstrated at least for the stockings, which achieved a more pronounced effect over the gaiter area than proximally (Fig. 5).

The reported results have some practical and economical implications. In our daily practice compression hosiery is usually prescribed after decongestion of the extremity by bandages because new, smaller-sized stockings would need to be prescribed after some days and adjusted to leg volume reduction. In contrast, a new, pragmatic approach could be discussed: starting with a light liner of an EK for the first week allows the patient to become accustomed to compression. This seems important, particularly in patients with no previous experience of compression.

After 1 week the second stocking of the kit adjusted to the reduced leg size may be superimposed on the liner and worn to maintain the effect. The pressure exerted by this EK remains in an effective range for increasing the effect of the liner in oedema reduction. Based on the presented results one option would be that the companies provide a kit consisting of a liner and a stocking, which could be one size smaller.

An alternative would be to use a very tightly fitted kit from the start of treatment, taking into consideration that the low pressure liner has a considerable tolerance, and that the second stocking will snugly fit after 1 week and may then be worn for several months. In both cases the chance of maintaining the same EK allows considerable cost savings and makes the treatment cost-effective. Such concepts need to be ascertained by adequate clinical investigations.

Another advantage of an EK is its potential use in patients with an associated arterial impairment. It has been shown with inelastic material that a pressure not exceeding.

40 mmHg increased arterial flow in patients with an ankle pressure higher than 70—80 mmHg.[19]

Why do compression devices exerting a low pressure have a similar effectiveness to IBs exerting a very strong pressure?

Compression counteracts oedema mainly by reducing filtration from capillaries into the interstitial space and by improving lymphatic drainage. External compression, thereby increasing the tissue pressure, will reduce capillary filtration, sometimes even very low pressure may be enough to obtain this effect. In fact, while a pressure of about 60—80 mmHg is necessary at ankle level to compress the veins in the upright position, a low pressure—ranging from 1 to 10 mmHg—is enough to counteract the pressure in the subcutaneous tissue.[20,21]

It has been shown, in regard to lymph drainage, that at leg level a pressure of 40 mmHg is most effective in increasing the intralymphatic pressure and evoking spontaneous lymph vessel contractions. Higher pressures do not achieve additional effectiveness.[3,18] Therefore, owing to

these mechanisms, strong pressure is not required to treat oedema—low or moderate pressure is effective enough. High stiffness of non-elastic bandages is needed more for venous compression in case of reflux, working especially during ambulation. In this situation oedema reduction is a secondary effect.

Both compression devices were well tolerated. The patients complained about some tightness at bandage application, but did well after some hours and were able to tolerate the IB during day and night for the entire treatment period. The good tolerability of IBs exerting a high pressure at application is not surprising as these bandages lose pressure in the supine position very quickly, mainly as a result of oedema reduction.[22] Typically, the initial sensation of tightness disappears in a few hours. Patient tolerability of application of the liner from the EK was very high during both day and night. In applying the second stocking over the liner patients reported good tolerance during the day, but some pain during the night. This resulted in 15 out of 20 patients removing the second stocking. The pain experienced during the night with elastic stockings can be explained by the lack of pressure fall under the elastic material, which causes a feeling of permanent constriction, particularly in the supine position.

CONCLUSIONS

In patients with venous leg oedema, a compression pressure of around 20 mmHg exerted by a liner leads to comparable oedema reduction as that achieved by an IB applied with a pressure of around 60 mmHg when both systems are worn day and night for 1 week. Oedema reduction is maintained by applying a second stocking over the liner. Using the same kit also the maintenance phase could allow for a considerable cost saving.

This kit is well tolerated during the day, but it is advisable to remove the outer stocking overnight.

CONFLICT OF INTEREST

None.

FUNDING

None.

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