Efficacy of intermittent pneumatic compression in the treatment of oedema comparing calf compression with calf and thigh compression devices

Wie ist die Wirksamkeit der apparativen Kompression bei Beinen mit Ödem unter Anwendung von schenkellangen und wadenlangen Stiefeln im Vergleich?

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ABSTRACT

Introduction In Germany intermittent pneumatic compression (IPC) to treat oedema is applied only by compressing the calf and thigh. Calf devices are available, but their efficacy was never evaluated. This investigation compared the effectivity of IPC devices only applied to the calf versus those applied to the calf and thigh. The results were expressed as leg volume change and oedema related symptoms.

Methods This was a single centre, investigator initiated, randomised study comparing the efficacy of IPC measuring calf and ankle perimeter electronically and by hand as well as the volume (BT 600, Bauerfeind). Pain scores with visual analogue scales from 0 to 10 were used to evaluate the symptoms. Patients with symmetric lipoedema, phleboedema, lymphoedema, oedema attributed to obesity and other medical causes were all included. Investigation consisted of measuring leg perimeters, volumes and pain scores immediately after standing as well as after 5 minutes of standing without moving. This investigation was performed before and after 30 minutes of IPC. Each patient was treated with a calf device (Venenwalker Basic) on one leg and a calf and thigh device (Lymphamat Gradient 300, Bösl) on the other leg after the sides were randomised.

Results Forty-one patients were randomised, 4 men, 37 women, mean age 47.1 years, mean BMI 30.12 kg/m^2 (± 5,42), 21 legs "left long" and 20 legs "right long". Most of the participants had lipoedema (26/41). Both devices achieved a significant volume and perimeter reduction at calf level, no differences were found between both. Pain score were reduced significantly ($p < 0.001$) by 1.31 points after calf and thigh compression and by 1.27 points after calf compression. No significant differences were found in pain reduction between both devices. A slight tendency towards a delay in the increase of calf volume in the standing position after the treatment was shown for both devices.

Discussion Usually most discomfort and complications in case of oedema are found at the calf, where both devices showed the same volume and pain reduction. Possibly intermittent pneumatic compression applied only to the calf would be enough to reduce oedema symptoms in many cases.

ZUSAMMENFASSUNG

Einleitung Zur apparativen intermittierenden Kompression bei Ödemen aller Art sind hierzulande nur schenkellange Geräte, bzw. Hosen üblich. Wadenlange Geräte sind auf dem Markt, aber noch nicht auf ihre Wirksamkeit untersucht. Die Studie vergleicht die Wirksamkeit schenkellanger vs. knielanger Entstauungsstiefel auf Volumenreduktion und Symptome.

Methode Es handelt sich um eine forscher-initiierte, monozentrische, randomisierte Studie mit dem Vergleich der Wirksamkeit anhand Umfangmessungen der Waden (händisch und maschinell), sowie Volumenmessungen (BT 600, Bauerfeind) und Schmerz-Scores. Patienten mit Lipödem, Phlebödem, Lymphödem, Adipositas-bedingtem Ödem und medikamentös/internistischem symmetrischem Ödem wurden aufgenommen, vor der Behandlung im Stehen (nach Hinstellen, sowie nach 5 Minuten) vermessen und befragt (NRS 0–10), 30 Minuten an einem Bein (Seite randomisiert) mit langem Stiefel (Lymphamat Gradient 300, Bösl), an einer Seite mit kurzem Stiefel (Venenwalker Basic) behandelt und danach erneut vermessen und befragt.

Ergebnisse Es wurden 41 Probanden aufgenommen, davon 4 Männer, 37 Frauen, mittleres Alter 47,1 Jahre BMI 30,12 kg/m^2 (± 5,42), 21 Beine „Links lang", 20 Beine „Rechts lang", die meisten Teilnehmer hatten ein Lipödem (26/41). Am Unterschenkel zeigten sich signifikante Verbesserungen der Umfangmaße und Volumina unabhängig von der Wahl des Stiefels, zwischen beiden Geräten waren die Unterschiede nicht signifikant. Die Wadenvolumina nahmen im Stehen zu und wurden durch die Entstauung verringert. Wir fanden eine signifikante Verringerung der Beschwerden im Stehen um 1,31 Punkte bei schenkellangem Stiefel und um 1,27 Punkte bei wadenlangem Stiefel durch die Entstauung ($p < 0,001$) ohne Differenz zwischen beiden Systemen. Es zeigte sich eine Tendenz, dass die Auffüllung des Wadenvolumens und das Verstärken der Beschwerden im Stehen nach der Entstauung langsamer geschieht.

Diskussion Üblicherweise liegen die meisten Beschwerden bei Ödemen (und auch die Komplikationen) in den Waden vor. Der wadenlange Entstauungsstiefel ist dem schenkellangen Stiefel bei der Volumen- und Beschwerdeverringerung nicht unterlegen. Möglicherweise sind bei vielen Indikationen wadenlange Entstauungsstiefel ausreichend.

Introduction

Devices for intermittent pneumatic compression (IPC) were first described more than 100 years ago, by Murray and Clancy in 1835 and Dr Julius Vogel in 1849 [1]. In the last century these devices underwent considerable technical refinement. The indication for their use is not only to reduce oedema in cases of lymphoedema, lipoedema, varicose veins, and oedema of other origins [2] but also to improve circulation in patients with peripheral arterial disorders [3, 4] and, together with thromboprophylaxis, to reduce oedema following orthopaedic or trauma surgery [5]. Each leg is encased in a boot-like device that is intermittently filled with air from distal to proximal according to pre-set parameters in order to force fluid from the limb, and is then deflated (▶ **Fig. 1**). There are single-chamber systems and two different types of device with multiple chambers: one has several pumps that fill the chambers one after the other, the other is a sequential compression system that applies pressure by inflating the sleeve chambers in sequence from the foot, over the calf, and then the thigh according to the indication, in order to imitate the effects of manual lymphatic drainage. In Germany at present, only devices with foot-calf-high sleeves (sometimes also with hip and abdominal components) are in use for phlebological and lymphological indications. Multi-chamber systems have more rapid success in cases of lymphoedema but there is no difference between multiple- and single-chamber devices in the long term [6]. Depending on the particular device used, the pressure applied ranges from 6 mm Hg to 124 mm Hg [7]; the optimal pressure for phlebological use has been found to be 30–40 mmHg [8]. This pressure is also applied for lymphoedema, with a maximum of 60 mmHg. There are no studies on the optimal pressure in these cases [2], although pressures up to 120 mmHg seem to be superior in a few studies [9]. There are various studies on the duration of treatment, most of which concern the acute phase of drainage and recommend using the device for up to 4–6 hours a day or in the mornings and the evenings, with different phases of compression and release. Inflation varies between 10 and 60 seconds of compression at intervals of 60 to 90 seconds – it is therefore impossible to draw any conclusions on the optimal use of IPC based on the available study data [2].

Foot devices or foot and calf devices can be used for peripheral arterial disease (PAD) and postoperative oedema after orthopaedic surgery [2–5].

Classical indications for IPC in phlebology are:

- Lipoedema: Unknown aetiology, possibly familial with disproportion between trunk and legs [10].
- Lymphoedema: Oedema due to sluggish lymphatic drainage, typically positive Stemmer's sign, and the oedema having a rather doughy consistency.
- Phleboedema: Swelling of the legs due to varicose veins
- Obesity-related oedema: Lymphoedema due to sluggish flow of lymph in the groin and retroperitoneal space [11–13].
- Other causes of oedema: Many drugs and diseases may cause oedema, but it may also be the result of standing or sitting for long periods or restricted movement of the muscles [9].

The treatment for all forms of oedema consists of eliminating the cause as far as possible and using compression therapy (initially with compression bandages and later with compression stockings), combined with manual lymphatic drainage or IPC, depending on the severity of the condition. After the first phase with compression bandages and frequent manual lymphatic drainage (complex decongestive therapy [CDT]), maintenance therapy with compression stockings and lymphatic drainage is required to sustain the results in the long term if the cause of the oedema cannot be treated.

Conventionally, thigh-length compression stockings had always been the variant chosen for varicose veins, deep vein thrombosis, and oedema until it became apparent that knee-length compression stockings were sufficiently effective to prevent skin changes in patients with chronic venous insufficiency (e. g. with varicose veins or after a deep vein thrombosis) [15].

Intermittent pneumatic compression (IPC) therapy for lymphoedema is usually carried out using thigh-length devices with up to 12 chambers or with compression garments. For many years, the increasing calf oedema with lipoedema or obesity-related oedema has also been treated with calf-length devices that can be bought without prescription. Their effectiveness for trauma patients has already been confirmed [4]. However, there has not yet been a direct comparison of the efficacy of the two types of device on chronic oedema and its symptoms or the patient's quality of life. Calf-length devices are easier for patients to use, less cumbersome, and considerably less expensive to purchase.

Aims of the study

To compare the efficacy of thigh-length and calf-length IPC devices on calf volumes and on the patient's symptomatic relief and subjective well-being.

Methods

This was a single-centre, investigator-initiated, randomised study to confirm or reject the hypothesis 'Thigh-length and calf-length IPC devices have a similar effect on calf oedema and its symptoms'. The primary outcome measure was the comparison of the circumference and volume of the calf after using a thigh-length or calf-length IPC device, as measured with a tape measure at the ankle and calf, as well as with the BT 600 (Bauerfeind). The secondary outcome measures were the changes in symptoms measured on a visual analogue scale and the user comfort of the devices as determined by a questionnaire. The Ethics Committee of the Lower Saxony Medical Association did not see any need to give advice on carrying out this study. The patients received a full verbal explanation and an information sheet and gave their written consent.

Patients

Patients were recruited in our practice, either by asking them directly or writing to them after reviewing their medical records. The inclusion criteria were the presence of symmetrical oedema due to one of the following causes: grade I-II lymphoedema; grade I-II lipoedema; phleboedema, obesity-related oedema analogous to grade I-II lymphoedema, and other symmetrical oedema originating from general medical conditions.

The exclusion criteria were regular treatment with manual lymphatic drainage, age below 18 or above 80, pregnancy, severe medical conditions, orthopaedic problems that would make it difficult for the patient to get up quickly or stand for some time, participation in another study, difficulty understanding German (questionnaire), and being unwilling to give consent.

Data Collection

All investigations were carried out between 14.00 and 18.00 hrs. Patients were asked not to wear compression stockings on the day of the investigation and, if possible, not for a few days previously.

The following steps were carried out on the day of the investigation:

1. Diagnosis and ultrasound findings in the leg veins (reflux in the deep or superficial veins, reflux above or below knee if appropriate), as well as the age of the patient were recorded from the medical records, and the patient's height and weight were measured.
2. Patient questionnaire on the severity of the symptoms due to swelling, the duration of the swelling, whether they wore any compression, and if so the type of compression used.
3. Patient were asked about the following symptoms in the previous week, considering the left and right legs separately: sensation of pressure, tension, pain, muscle cramps, itching, tingling, dragging sensation, burning, feeling of heaviness, swelling, stabbing pain, sensation of warmth, tiredness of the legs, and any other symptoms.
4. Scoring of the overall symptoms in each leg in the previous week, considering the calf and thigh separately. Symptoms were rated on a five-point Likert scale from 'none at all' to 'very severe'.
5. Subjects were then asked to lie down and rest with the legs raised on a 50 cm-high foam cushion for 2 minutes.
6. The legs were measured electronically with the Bodytronic 600 (Bauerfeind) The patient had to stand there for about 7 minutes without moving.
7. Volumes of the lower leg and thigh were measured electronically, immediately after standing in position in the apparatus and again after 5–6 minutes.
8. During the first and second measurements, each taking about one minute, patients were asked to rate any leg pain with a numerical rating scale (NRS) on a scale of 0–10 for each leg, considering the thigh and calf of each leg separately ('NRS standing, before' 1 and 2, from which the mean was calculated 'Mean standing, before').
9. After the first electronic measurement, the ankle and upper calf circumferences were measured manually (B measurement, D measurement).
10. Random allocation into either the 'Right long' or the 'Left long' group demined which leg would be treated in the thigh-length device. The contralateral leg would be placed in the short device.
11. Subjects lay on a comfortable couch for putting the device on. In accordance with the randomisation, one leg was encased in the long device and the short device was applied to the other.
12. By means of a questionnaire, patients were then asked how they felt lying down, considering the calf and thigh of the right and left legs separately ('NRS lying, before'). During the 30 minutes' treatment, subjects were not allowed to get up. They could have a glass of water (200 mL) if they wanted but no other drinks, especially not those with a diuretic effect. They could read, listen to music or relax in any other way. If the subject had to get up for any reason during these 30 minutes, the study had to be abandoned for the day and repeated another time if the patient was willing (this did not, in fact, happen).
13. Shortly before the end of the IPC, patients were asked for the second time how they felt lying down ('NRS lying, during').
14. At the end of the IPC treatment, the measurement sequence was repeated in the same order as before treatment (electronically, manually, electronically) with the same questions posed at the beginning and end of the 5-minute standing phase ('NRS standing, before' 1 and 2, from which the mean was calculated 'Mean, standing, before').
15. At the end of the investigation, patients were asked if one of the two devices seemed to be more effective and whether they would recommend either of the devices.

▶ **Fig. 1** Photos of the sleeves used in the study. **a** Thigh-length 6-chamber device (Lymphamat Gradient 300, from Bösl); **b** Calf-length device (Venenwalker Basic from Globalmind; Source: Globalmind consumer electronics GmbH).

▶ **Tab. 1** Demographic data of the 41 study patients.

	Mean	Median	Standard deviation	Minimum	Maximum
Age (years)	47.10	48	12.64	21	75
Height (cm)	167.63	167	5.28	160	187
Weight (kg)	84.53	83	15.49	52	120
BMI (kg/cm^2)	30.12	30.85	5.42	17.4	40.7

Devices

The thigh-long device was a 6-chamber system: the Lymphamat Gradient 300 from Bösl (▶ **Fig. 1b**), set to a pressure of 40 mm Hg. The short device was a Venenwalker Basic (▶ **Fig. 1a**), a two-chamber system (boot with foot-sole chamber and calf chamber) from GlobalMind, set to 40 mm Hg.

Statistics

No comparative data were available for calculating a power analysis. Based on the effects of compression stockings on leg volume, it was estimated that an analysis would be feasible after 40–60 subjects. It was therefore planned to recruit 40–60 subjects with the option of terminating the study after including 40.

The study had a 'double paired' design in which values before treatment were compared with those afterwards and the results from the leg treated with the short device compared with those from the leg treated with the long device. In addition, the effect of treatment was operationalised as the difference between the measurements made before and after IPC. The results were presented as means and standard deviations. Two-tailed t-tests for paired samples were used as tests of significance for the NRS, the circumferences and volumes, with the Wilcoxon ranked sum test used for the rest: $p < 0.05$ was taken as being statistically significant. We used SPSS™ for Windows 24 (Armonk, NY: IBM Corp, USA) to perform the analysis.

▶ **Tab. 2** Distribution of the types of oedema in the study population.

Type of oedema	Frequency	Percentage
Lipoedema	26	63.4
Lymphoedema	5	12.2
Phleboedema	1	2.4
Lipoedema & lymphoedema	2	4.9
Lipoedema & phleboedema	2	4.9
Lymphoedema & phleboedema	3	7.3
Drug-induced or general medical condition	2	4.9
Total	**41**	**100.0**

Results

Forty-one subjects took part in the study: 4 men and 37 women. The mean age was 47.1 years the mean BMI was 30.1 kg/m^2 (▶ **Table 1**). The patients had had swollen legs for a mean of 12.1 years (± 12.5, min 1, max 56, median 8 years). 95 % of the patients regularly wore compression stockings, 56 % of which were calf-length. Twenty-one legs were randomised to the 'Left long' group and 20 legs to the 'Right long' group. Four subjects had been wearing compression stockings on both legs on the day of the investigation.

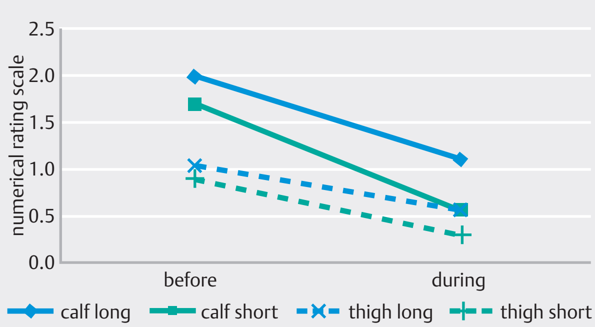
▶ **Table 2** shows the types of oedema represented.

Phleboedema was present in five legs treated with the long device and four legs treated with the short device. Except for one leg in the 'long' group with C4a varicose veins, all were in CEAP class C_3. Two legs in each group had previously been operated on (stripping of the great saphenous vein), one leg in the 'long' group had reflux into the deep venous system.

▶ **Table 3** shows the symptoms experienced in the week before treatment. The most common symptom was a feeling of heaviness, followed by swelling and tiredness of the legs. Overall, the symptoms were rated at about 2.5 points for the calf and 1.9 for the thigh. There were no differences between the two legs with respect to the symptoms.

▶ **Tab. 3** Symptoms in the week prior to treatment, using a numerical rating scale from 0 to 10, and a comparison of the symptoms between the 'Long' and 'Short' groups (p-value in the right-hand column). SD = standard deviation, p = significance.

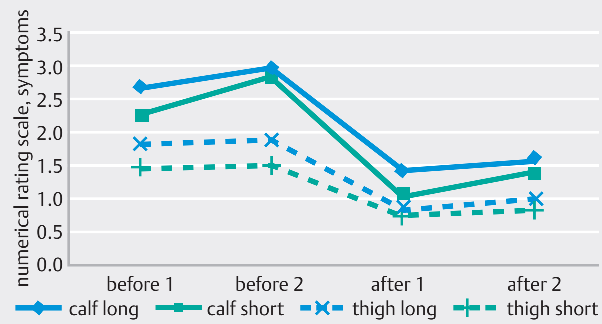
Type of device	**Long**	**Short**	
Symptom	**Mean ± SD**	**Mean ± SD**	**p**
Feeling of heaviness	3.08 ± 0.97	2.98 ± 1.00	0.378
Swelling	2.88 ± 1.01	2.83 ± 0.92	0.570
Tiredness	2.70 ± 1.22	2.68 ± 1.27	0.661
Tension	2.48 ± 0.82	2.48 ± 0.88	1.000
Sensation of pressure	2.33 ± 1.07	2.25 ± 1.06	0.446
Pain	2.18 ± 1.04	2.20 ± 1.22	0.785
Sensation of warmth	1.81 ± 1.24	1.84 ± 1.34	0.711
Tingling	1.80 ± 0.94	1.75 ± 0.93	0.623
Burning	1.69 ± 1.06	1.67 ± 1.08	0.767
Dragging sensation	1.56 ± 0.91	1.62 ± 0.94	0.421
Muscle cramps	1.54 ± 0.72	1.51 ± 0.68	0.767
Itching	1.45 ± 0.65	1.58 ± 0.89	0.058
Stabbing pain	1.38 ± 0.91	1.41 ± 0.91	0.711
Symptoms in the calf	**2.65 ± 1.19**	**2.53 ± 1.15**	**0.133**
Symptoms in the thigh	**1.90 ± 0.96**	**1.90 ± 0.84**	**1.000**



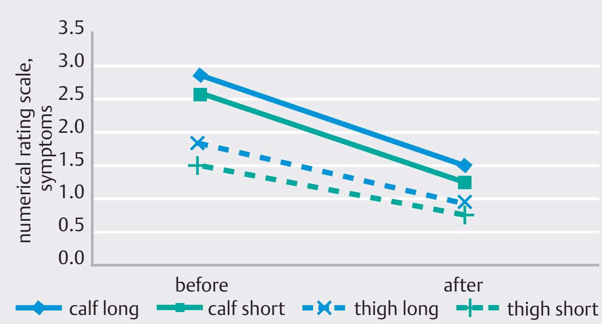
▶ **Fig. 2** Symptoms with the patient lying down, before and during treatment (see ▶ **Table 4**). All before/during changes are significant, but there are no significant differences between the groups. NRS Beschwerden = numerical rating scale, symptoms, on a scale of 0 to 10; vorher = before; während = during; Wade lang = calf long: group with the long device, symptoms related to the calf; Wade kurz = calf short: group with the short device, symptoms related to the calf; OS lang = thigh long: group with the long device, symptoms related to the thigh; OS kurz = thigh short: group with the short device, symptoms related to the thigh.

The course of the symptoms experienced before, during, and after the investigation can be seen in ▶ **Table 4** and ▶ **Fig. 2** – ▶ **Fig. 4**.

The symptoms when lying down before and during the investigation, as experienced in the calf (shown in ▶ **Fig. 2** and ▶ **Table 4**) were significantly different for both devices, while the pain score in the thigh was significantly reduced only with the long device. During treatment, symptoms were significantly less in both the calf and the thigh with the short device (p < 0.05). Overall, the mean difference, i. e. the efficacy of treatment with the two devices, was not significant.



▶ **Fig. 3** Changes in symptoms with the patient standing, immediately after standing in position in the apparatus (before 1 and after 1) and after 5 minutes standing still (before 2 and after 2) before and after treatment (see ▶ **Table 4**). All before/after changes are significant, but there are no significant differences between the groups. NRS = numerical rating scale, symptoms, on a scale of 0 to 10; calf long: group with the long device, symptoms related to the calf; calf short: group with the short device, symptoms related to the calf; thigh long: group with the long device, symptoms related to the thigh; thigh short: group with the short device, symptoms related to the thigh.



▶ **Fig. 4** Symptoms with the patient standing (mean of the two measurements), before and after treatment (see ▶ **Table 4**). All before/after changes are significant, but there are no significant differences between the groups. NRS = numerical rating scale, symptoms, on a scale of 0 to 10; Groups calf long, calf short, thigh long and thigh short see legend to **Fig. 3**.

The symptoms when standing (▶ **Fig. 3** and 4, ▶ **Table 4**) improved considerably after treatment when compared with the values obtained before treatment, at measurement 1 (immediately after standing) and at measurement 2 (5 minutes later), and the mean, in the calf (p = 0.001 or < 0.001) and to a lesser extent in the thigh (p between 0.004 and 0.04). There were no significant differences between the two systems in either the lower leg or the thigh.

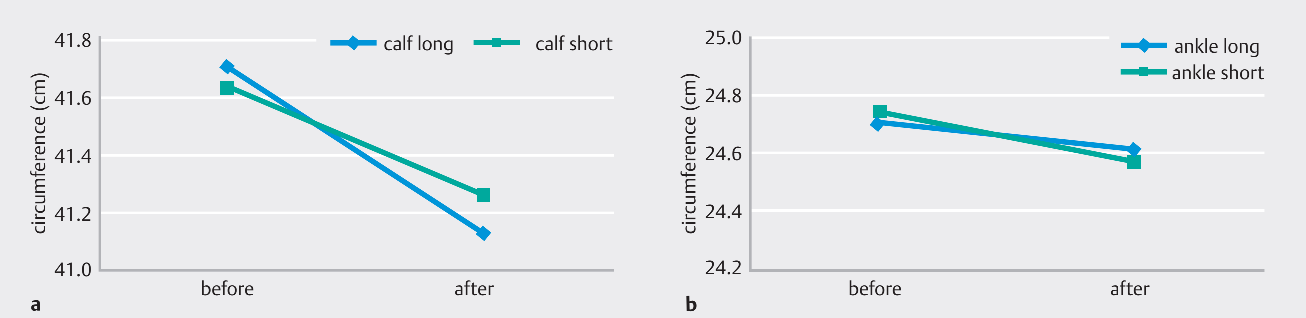
The circumference before and after treatment is shown in ▶ **Table 5** and ▶ **Fig. 5**. With the exception of the circumference of

▶ **Tab. 4** Changes in the symptoms on the NRS 0–10. Data were collected when the patient was lying before and during the treatment and when standing before and after treatment. The mean and SD were calculated for each leg. The results are presented in columns according to whether the leg was treated with the long or short device. The third column shows the difference between the legs, i. e. between the long and short systems, and the fourth column shows the significance. The result obtained with the short device was subtracted from that of the long device, so that positive values for the standard deviation of the mean indicate better results for the short device and negative values show better results for the long device. The lines give the absolute values for each leg: the first line gives the value before treatment, the second line during or after treatment, and the third line shows the difference in the means of the values in the same leg when lying down before and during the treatment or when standing before and after treatment. Both measurements are shown (before/during or before/after) with the mean and standard deviation (SD). In the third line each time, the difference in the means before and during or after treatment has been calculated. In all cases the values are lower, so that the results are shown with a minus sign. The fourth line shows the significance of the difference. * Statistically significant results.

	Long	**Short**	**Long – Short**	
	Mean ± SD	**Mean ± SD**	**Difference in means ± SD**	**p**
Calf				
NRS lying, before	1.99 ± 2.3	1.72 ± 2.08	0.27 ± 1.29	0.192
NRS lying, during	1.12 ± 2.05	0.57 ± 1.25	0.55 ± 1.31	0.011
Difference in means, before/during	–0.87 ± 2.36	–1.15 ± 1.87	**0.28 ± 1.91**	**0.352**
p before/during	0.024*	< 0.001*		
NRS standing, before 1	2.68 ± 2.58	2.28 ± 2.26	0.40 ± 1.29	0.057
NRS standing, after 1	1.44 ± 1.82	1.05 ± 1.6	0.39 ± 1.27	0.062
Difference in means, before/after	–1.31 ± 1.67	–1.27 ± 1.67	**–0.04 ± 1.05**	**0.821**
p before/after	< 0.001*	< 0.001*		
NRS standing, before 2	3.00 ± 2.56	2.83 ± 2.26	0.17 ± 1.43	0.448
NRS standing, after 2	1.58 ± 2.08	1.42 ± 1.84	0.15 ± 1.23	0.438
Difference in means, before/after	–1.21 ± 2.04	–1.24 ± 1.96	**0.04 ± 1.08**	**0.825**
p before/after	0.001*	< 0.001*		
NRS mean standing, before	2.86 ± 2.49	2.59 ± 2.19	0.27 ± 1.27	0.173
NRS mean standing, after	1.53 ± 1.79	1.25 ± 1.50	0.28 ± 1.17	0.132
Difference in means, before/after	–1.33 ± 1.79	–1.34 ± 1.75	**0.01 ± 0.92**	**0.966**
p before/after	< 0.001‘	< 0.001*		
Thigh				
NRS lying, before	1.05 ± 1.78	0.89 ± 1.45	0.16 ± 1.24	0.426
NRS lying, during	0.61 ± 1.14	0.29 ± 0.78	0.32 ± 0.85	0.022
Difference in means, before/during	–0.44 ± 1.66	–0.60 ± 1.2	**0.16 ± 1.44**	**0.478**
p before/during	.100	0.003*		
NRS standing, before 1	1.84 ± 2.65	1.46 ± 2.12	0.38 ± 1.27	0.070
NRS standing, after 1	0.85 ± 1.27	0.75 ± 1.24	0.10 ± 1.17	0.593
Difference in means, before/after	–1.01 ± 2.04	–0.73 ± 1.82	**–0.28 ± 1.41**	**0.220**
p before/after	0.004*	0.016*		
NRS standing, before 2	1.89 ± 2.63	1.52 ± 2.14	0.37 ± 1.24	0.066
NRS standing, after 2	1.04 ± 1.68	0.82 ± 1.43	0.22 ± 1.52	0.375
Difference in means, before/after	–0.69 ± 1.9	–0.60 ± 1.77	**–0.09 ± 1.81**	**0.759**
p before/after	0.028*	0.040*		
NRS mean standing, before	1.84 ± 2.61	1.48 ± 2.10	0.37 ± 1.22	0.063
NRS mean standing, after	0.93 ± 1.35	0.76 ± 1.26	0.18 ± 1.23	0.362
Difference in means, before/after	–0.91 ± 2.03	–0.72 ± 1.83	**–0.19 ± 1.47**	**0.416**
p before/after	0.007*	0.016*		

the ankle treated with the long device, all the changes measured were significant, as expected. There were no significantly different results between the two devices.

The calf volume (▶ **Table 6**, ▶ **Fig. 6**) increased on standing and was reduced by the IPC. The mean of the two measurements was significantly smaller after treatment for both devices. There was a tendency for the calf volume to increase more slowly after the IPC. The thigh volume increased on standing for the first time in both groups. After IPC with the long device, the volume was significantly reduced, but with the short device it remained virtually constant – the difference was not significant. Both thigh volumes after treatment fell during the five minutes of standing still (▶ **Fig. 6**).



▶ **Figure 5** Changes in the circumference (a) of the calf and (b) at the ankle, before and after treatment (see ▶ **Table 4**). With the exception of the circumference at the ankle of the leg treated with the long device, all the before/after changes are significant. There are no significant differences between the groups treated with the long and short devices. calf long: group with the long device, measured at the calf; calf short: group with the short device, measured at the calf. ankle long: group with the long device, measured at the ankle; ankle short: group with the short device, measured at the ankle.

▶ **Tab. 5** Changes in circumference (cm) of the calf and ankle, measurements taken before and after treatment. See ▶ **Table 4** for explanation.
* Statistically significant results.

	Long	**Short**	**Long – Short**	
	Mean ± SD	**Mean ± SD**	**Difference in means ± SD**	**p**
Circumference of calf, before	41.71 ± 4.1	41.64 ± 4.12	0.07 ± 0.91	0.608
Circumference of calf, after	41.13 ± 4.17	41.26 ± 4.2	−0.13 ± 1.19	0.482
Difference in means ± SD	−0.58 ± 0.86	−0.38 ± 0.97	**−0.20 ± 0.99**	**0.192**
p before/after	< 0.001*	0.017*		
Circumference at ankle, before	24.71 ± 1.99	24.75 ± 2.07	−0.04 ± 0.65	0.722
Circumference at ankle, after	24.62 ± 1.87	24.58 ± 2	0.04 ± 0.48	0.586
Difference in means ± SD	−0.10 ± 0.38	−0.17 ± 0.38	**0.08 ± 0.53**	**0.349**
p before/after	0.121	0.006*		

To assess whether there was a difference between the two devices (inferiority/non-inferiority), the differences in the means were calculated for the NRS, circumference, and volume. ▶ **Fig. 7** shows the means and the 95 % confidence intervals (CI) of the differences. All the differences are far from significant, i. e. the 95 % CI never lies entirely on one side of zero.

In the subjective assessment at the end of treatment, subjects stated that they found the long device more effective than the short one (p < 0.001) but that the short device was more comfortable (p = 0.225). With respect to the calf, this difference was not statistically significant: 17 participants found the long device more effective on the calf, while 8 felt that the short device was better. Fifteen participants found no difference in the effectiveness of the two devices, while one patient felt that neither was effective. One patient, who was not included in the evaluation, dropped out of the study because of pain when wearing the long device.

The question of whether the subjects would recommend the device to others was addressed at the end of the second standing phase. There were 14 positive recommendations for the thigh-length device, 15 recommendations for the calf-length device, 10 participants would recommend both devices, and one subject would not recommend either; there was no significance in favour of one or the other model.

Discussion

Homogeneity of the groups

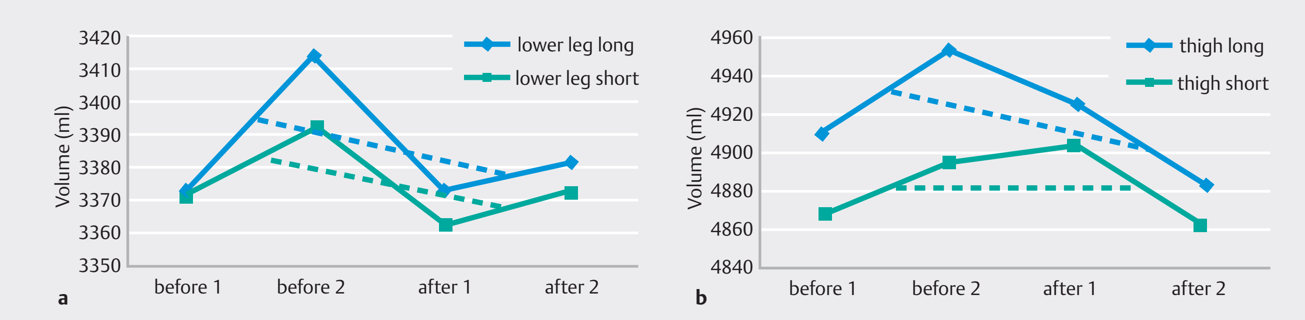
The diagnosis and symptoms in the legs were similar in the two groups (‘long’ and ‘short’) in the week before treatment (▶ **Table 3** and ▶ **Table 4**). As we compared the two legs of the same person, there was obviously no difference in age or sex. With 20 and 21 patients having ‘Right long’ and ‘Left long’ respectively, randomisation was likewise homogeneous.

Sample size

Evaluation after recruiting 41 subjects produced a significance sufficiently high to consider that the sample size was adequate to answer our questions.

Validity of the parameters measured

Recording the increasing symptoms and calf volumes when standing was based on tests with the BT 600 carried out by Blättler et al. on healthy volunteers [16]. In their study, the mean increase in calf volume after standing for 10 minutes was 44 mL; class II compression stockings reduced this increase by half (22 mL). The increase in symptoms on standing gave a mean of 2.9 points without compression and 2.3 with compression.



▶ **Figure 6** Changes in the volumes of (a) the calf and (b) the thigh, measured with the BT 600, measurement repeated twice each time, before and after treatment, and the mean calculated from the two measurements (dotted line) (see ▶ **Table 6**). Significant volume reduction in the calf on both sides, but only in the thigh with the long device. Wade lang = calf long: group with the long device, measured at the calf; Wade kurz = calf short: group with the short device, measured at the calf; OS lang = thigh long: group with the long device, measured at the thigh; OS kurz = thigh short: group with the short device, measured at the thigh.

▶ **Tab. 6** Changes in volume (mL) in the lower leg and thigh (mean of the two measurements). Measurements taken before and after treatment. See ▶ **Table 4** for explanation. * Statistically significant results.

	Long	**Short**	**Long – Short**	
Variable	**Mean ± SD**	**Mean ± SD**	**Difference in means± SD**	**p**
Volume of lower leg, before	3394 ± 625	3383 ± 627	11 ± 103	0.514
Volume of lower leg, after	3378 ± 620	3368 ± 618	10 ± 113	0.592
Difference in means ± SD	–16 ± 50	–15 ± 46	**–1 ± 45**	**0.877**
p before/after	0.047*	0.049*		
Volume of thigh, before	4932 ± 967	4882 ± 982	51 ± 248	0.197
Volume of thigh, after	4904 ± 945	4883 ± 976	21 ± 230	0.562
Difference in means ± SD	–28 ± 89	2 ± 155	**–30 ± 143**	**0.189**
p before/after	0.048	0.948		

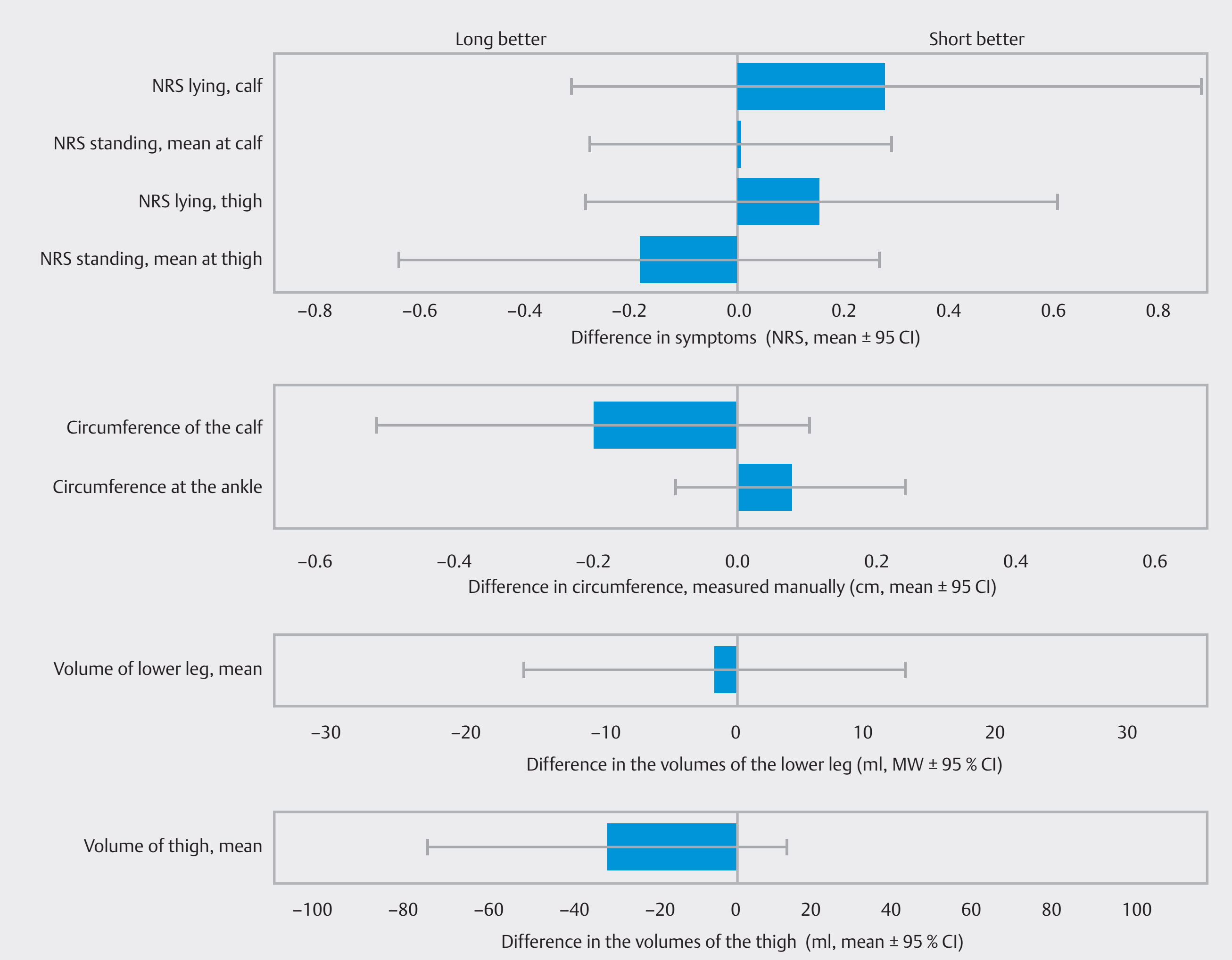
The increase in symptoms in our study was measured between the beginning and end of the standing phase (only 5 minutes and not 10 minutes as in Blättler's study), both before and after treatment. In addition, we calculated and compared the means of these two measurements (beginning and end of the standing phase before treatment, and the beginning and end of the standing phase after treatment) (▶ **Table 4**).

The mean of the pain score in the calf fell by 1.33 points (long) and 1.34 points (short) during treatment, both p < 0.001 and with no difference between the two devices. Looking at the symptoms experienced in the first minutes after standing in position in the apparatus (▶ **Fig. 6**), we found that they did not increase significantly before treatment (figures of 0.32 (calf, long) and 0.55 (calf, short)), as with the results obtained by Blättler. However, the graphs presented in that study show a relatively linear increase in symptoms, so that we would expect a lesser effect in our study, with the subjects standing still for only 5 minutes instead of 10. It is of interest to note that the before/after comparison shows that the pain scores in the calf decreased after treatment with both devices, not only immediately after standing in position (by 1.31 [long] and 1.27 [short] points), but also after standing still for 5 minutes (1.21 and 1.24 points, respectively); in each case, the difference was highly significant. The volume increase in the calf was delayed after treatment and the symptoms also appeared more slowly (▶ **Fig. 3** and 6). The study results presented here are consistent with the results from Blättler's study [16], so that we can start by assuming that they are consistent with expectations and there have been no system errors.

Scope of the research issue

With one single treatment, we cannot determine how long the effects will be sustained in everyday life. But this was not the aim of the study. As with other therapeutic procedures in medicine in general (e. g. administering tablets) and in the treatment of oedema in particular (bandaging, wearing compression stockings, and manual lymphatic drainage), we know that the effects of this measure will last for only as long as the effects of a medication or application, i. e. a few hours or (in the case of compression and manual lymphatic drainage) a few days afterwards.

For this reason, we looked at the efficacy of the calf device compared with the thigh-length device in a single treatment session. However, we can assume that its efficacy on repeated days is just as good as wearing compression stockings or repeated thigh-length IPC therapy over several days.



▶ **Figure 7** Mean and 95 % confidence interval of the differences between the long and short devices before and after treatment (standing) and before and during treatment (lying). NRS = numerical rating scale, on a scale of 0 to 10; OS = thigh; US = lower leg; Mean = mean value; Vol = volume; CI = confidence interval.

The target group had only mild oedema, as we considered it unethical to ask patients with severe oedema to go without compression therapy for a whole day before the investigation. In the case of severe oedema, however, we can assume that IPC only on the calf would have also an effect on higher degrees of oedema, the same as only calf-compression stockings do. This hypothesis would, however, have to be tested in a separate study.

Strange result

Although the changes found in the volume of the thigh (▶ **Fig. 6**) are surprising, they are explicable. In the first standing phase, the volume increases as expected. After IPC with the thigh-length device the volume decreases but with the calf-length device it increases. This can be explained by the fact that during IPC, the fluid volume in the calf is displaced into the next compartment, i. e. from the calf to the pelvis when wearing the long device so that the volume in the thigh is decreased, and from the calf to the thigh when wearing the short device, so that the volume in the thigh is increased.

What is most interesting is the 4th measurement: after standing following treatment and independent of the sleeve used, the thigh volumes fell. One possible explanation is that the thigh fills from the calf via both the venous and the lymphatic systems. After IPC treatment of the calf, the available fluid volume is reduced. If the thigh is emptied proximally as usual (both venous and lymphatic drainage) without any replenishment from the calf, the thigh volume will at first decrease. This phenomenon was seen to about the same extent in both groups (the lines in ▶ **Fig. 6** showing the volumes in the thigh between 'after 1' and 'after 2' run parallel for the two devices).

What is more surprising, however, is that the volumes in both cases fell to a lower value than baseline. It can therefore be said for both devices that fluid volume is displaced from the thigh and from the leg.

Comparing the mean volumes of the whole leg at the beginning of the investigation ('before 1': long 8284 mL, short 8240 mL) with the volume at the end of standing after treatment ('after 2': long 8266 mL, short 8236 mL) we can see a very slight reduction of 18 mL for the long device and just 4 mL for the short. These differences are not significant and very small considering the scatter seen with the two devices. However, they show that the calf-length device has an effect on the whole leg that goes beyond the displacement of fluid volume from the calf to the thigh.

Use in clinical practice

The subjects selected for this study had mild peripheral oedema of different origins. This target group is increasing in our general population due to the increase in obesity [11–13] and to the many hours that we remain standing or sitting in our so-called civilised world without activating the muscle pump. In addition to the measurable oedema, the subjects had symptoms that can reduce the quality of life irrespective of any increase in oedema. Blazek et al. impressively demonstrated this impaired quality of life in a study on hairdressers without chronic venous insufficiency. Compression significantly improved the quality of life, independent of the fact that it also affected the volume of the calf [17].

In this study, the calf-length IPC device reduced the pain scores when standing still after treatment in just the same way as the thigh-length device. It can therefore be suggested that the short IPC device is sufficient to treat people who experience symptoms only in the calf. The same reduction in calf volume was seen in both groups, so that the calf-length device can be used instead of the thigh-length device without any disadvantage to patients with oedema exclusively in the calf. A study on patients with more severe oedema would be extremely interesting.

As a rule, patients with oedema affecting the whole leg have more pronounced symptoms in the calf due to orthostasis. Nevertheless, the most common form of treatment for these patients in Germany is the prescription of compression stockings. Complex decongestive therapy is seldom carried out and long-term manual lymphatic drainage is even more rarely prescribed, as the association of statutory health insurance physicians punish such prescriptions with budget overruns and threatened recourse for the doctors. Until this lack of provision can be solved systematically, patients would do well to purchase for themselves a device that costs considerably less than other commercially available ones.

If it were to be implemented in routine practice, we could see the advantage for the general population, since IPC therapy with the financially viable calf-length device – preferably in combination with compression stockings – is better than no treatment for the discomfort due to problems of civilisation (sedentary life, obesity) or symptoms and oedema in the calf, especially as the calf-length version is as effective as the thigh-length device. This statement (better than nothing) possibly also applies to whole-leg oedema.

The demonstration of volume reduction and symptom relief with a calf-length device in these mildly symptomatic patients suggests that a large proportion of the population would benefit appropriately from this simple solution.

Confirmation is now needed from a patient population with more pronounced symptoms.

CONCLUSIONS

Treatment with the IPC devices significantly reduced the leg circumference and volume and the symptoms due to leg swelling. We found no significant difference between the calf-length and thigh-length devices with respect to measurement at either the calf or the thigh.

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Conflict of interest

FA was paid for the statistical evaluation by Global Mind. EM declares to have no conflict of interest.

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