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Adjustable Velcro® Compression Devices are More Effective than Inelastic Bandages in Reducing Venous Edema in the Initial Treatment Phase: A Randomized Controlled Trial

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WHAT THIS PAPER ADDS

In routine clinical practice edema is treated by means of inelastic bandages exerting a strong pressure but these require specialized personnel to be applied. Adjustable Velcro® compression devices (AVCDs), or elastic stockings, are used only after the so called initial decongestive phase, in order to maintain the results and prevent the recurrence of the edema. This study shows that AVCDs can be more effective than inelastic bandages in exerting a very strong pressure in the initial treatment phase and are at least equally well tolerated. This study is also relevant from a practical point of view as it could change the traditional treatment of edema. The opportunity to use AVCDs in the initial decongestive phase may allow self-application and self-treatment, significantly reducing the cost of treatment with regard to materials and specialized personnel.

Objective/Background: The objective of this study was to compare the efficacy and comfort of inelastic bandages (IBs) and adjustable Velcro® compression devices (AVCDs) in reducing venous leg edema in the initial treatment phase.

Methods: Forty legs from 36 patients with untreated venous edema (C3EpsAsdPr) were randomized to two groups. Patients in the first group received IBs ($n = 20$) and those in the second AVCDs ($n = 20$). Both compression devices were left on the leg day and night, and were renewed after 1 day. Patients in the AVCD group were asked to re-adjust the device as needed when it felt loose. Leg volume was calculated using the truncated cone formula at baseline (T0), after 1 day (T1) and after 7 days (T7). The interface pressure of the two compression devices was measured by an air filled probe, and the static stiffness index calculated after applying compression at T0 and T1, and just before removal of compression on T1 and T7. Patient comfort with regard to the two compression systems was assessed by grading signs and symptoms using a visual analog scale.

Results: At T1, the median percent volume reduction was 13% for the IB group versus 19% for the AVCD group; at T7 it was 19% versus 26%, respectively ($p < .001$). The pressure of the IBs was significantly higher compared with the AVCDs at T0 (63 vs. 43 mmHg) but dropped by $> 50\%$ over time, while it remained unchanged with AVCDs owing to the periodic readjustment by the patient. Comfort was reported to be similar with the two compression devices.

Conclusion: Re-adjustable AVCDs with a resting pressure of around 40 mmHg are more effective in reducing chronic venous edema than IBs with a resting pressure of around 60 mmHg. AVCDs are effective and well tolerated, not only during maintenance therapy, but also in the initial decongestive treatment phase of patients with venous leg edema.

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INTRODUCTION

To reduce leg edema, inelastic bandages (IBs) are usually recommended for the initial treatment phase.[1,2] The disadvantages of IBs are that they lose pressure quickly following application and need to be reapplied by specialized staff.[3,4]

Elastic stockings, and particularly elastic kits, have been shown to be effective, even in the therapy phase, achieving similar edema reduction as IBs.[5,6] However, stockings may be difficult to apply and are often not well tolerated during the night.

The aim of this study was (i) to compare adjustable Velcro® compression devices (AVCDs) with IBs in terms of effectiveness in the treatment of venous edema; and (ii) to assess patient comfort related to the two different compression modalities.

METHODS

Patients

Forty legs from 36 patients (17 men, 19 women; mean ± SD age 71.4 ± 10.2 [range 52–85 years]) affected by chronic leg edema due to chronic venous disease were randomized to receive two different compression systems, to be applied for 1 week: group A received IBs and group B received AVCDs.

The following inclusion criteria were applied: patients had to be 18–85 years age and affected by chronic lower leg edema due to primary and/or secondary chronic venous disease (CEAP C3EpsAdsPr) for > 3 months.

Exclusion criteria included: patients with skin changes due to venous insufficiency (CEAP C4–C6), clinical signs of lymphedema (positive Stemmer's sign at the base of the toes), cardiac/renal failure, conditions requiring diuretics, corticoids, Ca^{++} antagonists, compression therapy in the last 3 weeks, and an ankle–brachial pressure index < 0.8.

Patients with venous edema were investigated with color duplex ultrasound (Esaote MyLab 60 with a multi-frequency linear probe of 7.5–12.0 MHz; Esaote s.p.a., Genoa, Italy), according to the generally accepted recommendations.[7] Thirty-five lower limbs were affected by superficial venous insufficiency (C3EpAsPr) and five by deep venous insufficiency (post-thrombotic syndrome) (C3EsAdPr). Patient characteristics are summarized in Table 1.

All individuals were informed about the trial and gave their written, informed consent.

Ethical committee consent for the study was also obtained from the local health authorities.

The primary end point was edema reduction; secondary outcome parameters were the interface pressure (IP) of the compression device in the supine and standing position, and the comfort of the compression systems reported by the patient.

Compression

In group A patients a multilayer, multi-component IB consisting of a cotton padding layer, a short stretch cohesive bandage, and a short stretch non-adhesive bandage on top was applied in a spiral fashion, with 50% overlap between the layers, from the base of the toes up to 2 cm below the knee. The bandages were applied under full stretch to exert a supine pressure of around 60 mmHg, which is classified as very strong according to the International Compression Club's classification of compression materials.[8] An AVCD (Circaid Juxtafit®; Medi GmbH, Bayreuth, Germany) adjusted to exert a pressure around 40 mmHg in the lying position (moderate pressure) was applied to the patients in group B.[8] Both compression devices were applied by well trained and experienced staff that also measured the IPs. While patients in the group A were instructed not to manipulate their bandages during wearing time, patients in group B were advised to readjust the Velcro® straps when they felt a decrease or "loosening" of the compression pressure.

Study protocol

Patients were randomly allocated to the treatment groups using a list randomizer (http://www.random.org/lists/). Venotonic drugs and compression devices, when used routinely by the patient, were stopped at enrollment, 7 days before the start of the study (washout period), and remained discontinued for the study period, during which the patients were encouraged to maintain their usual lifestyle.

On day 0 (T0) leg volume was calculated, and either IBs or AVCDs were applied. Patients were asked to wear the assigned compression device day and night. The IP of the applied compression device was measured and the static stiffness index (SSI) calculated. Patients were asked to fill out the questionnaire assessing their subjective feelings concerning compression comfort. On day 1 (T1), IBs and AVCDs were removed, lower leg volume was measured again, and the compression devices were reapplied. IP was measured and SSI calculated before removing and after reapplying the compression devices. The patients were asked to fill out the comfort questionnaire.

Table 1. Case series demographic data.

	Patients (*n*)	Legs (*n*)	Age (mean ± SD)	Sex (*n*)	BMI (mean ± SD)	VD (*n*)	LV (mean ± SD)
AVCD	19	20	72.7 ± 8.4	10 F; 9 M	24.5 ± 8.5	SVI: 14; DVI: 6	2,854 ± 445
IB	17	20	71.2 ± 11.4	9 F; 8 M	24.8 ± 7.8	SVI: 15; DVI: 5	2,838 ± 697

Note. The difference between groups is not statistically significant. BMI = body mass index; VD = venous disease; LV = leg volume; AVCD = adjustable Velcro® compression device; IB = interface pressure; F = female; M = male; SVI = superficial venous insufficiency; DVI = deep venous insufficiency.

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On day 7 (T7), compression devices were removed after IP and SSI assessment and the lower leg volume was measured. The patients were again asked to fill out the comfort questionnaire.

Outcome parameters

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

Leg volume was calculated by measuring the lower leg circumference with a tape starting immediately above malleolar level and continuing measurements every 4 cm for eight leg segments.[9] Using a specific Access based computer program the leg volume was calculated using the mathematical formula of the truncated cone ("Kuhnke formula").[10] All measuring points on the leg were marked at T0 to allow the repetition of the measurements at exactly the same site at T1 and T7. Edema reduction (%) was calculated by subtracting the volume at T1 and T7 from the baseline volume at T0 in relation to baseline volume.

The IP between the compression devices and the skin was measured in the supine and standing positions by means of a pneumatic pressure transducer connected to a pressure probe (Picopress® Microlab Italia, Padua, Italy). The probe, 5 cm in diameter and < 1 mm in thickness when filled with 2 mL of air during measurement, was attached to the skin at the B1 point and kept empty and in place for 1 week.[11] This device has been shown to provide accurate, linear, and reproducible measurements.[12,13]

SSI was calculated by subtracting the supine from the standing pressure.[14]

Patient perception of the compression system was assessed using a visual analog scale (VAS) in accordance with the outcome of an International Compression Club meeting in Maastricht 2014 (http://www.icc-compressionclub.com). Validation studies are in preparation. The following items were assessed: the wearing comfort of the compression devices (pain, heaviness sensation, swelling sensation, edema related discomfort, itching, restless leg), and parameters specifically related to the compression device (application difficulty, symptoms worsening, difficulty in wearing shoes, re-adjustment difficulty, cosmetic appearance).

All these parameters were graded at T0, T1, and T7 using a VAS. The absence of symptoms was graded 0, increasing to 10 for the most severe symptoms. The sum of the first block of symptoms was calculated in order to have a global "comfort index" and, separately, the second block of parameters.

Statistical analysis

Based on a previous study,[4] it was calculated that a sample size of 20 patients per group would have a 90% power to detect a difference between means of 5.59% volume reduction with a significance level of .05 (two-tailed).

Medians with interquartile ranges (IQRs) and maximum and minimum values are given. For repeated measures, analysis of variance was used to compare the volume and pressure changes on the same leg. The non-parametric Mann–Whitney test was used to compare the effects of IBs and AVCDs. Differences with a p-value $< .05$ were considered to be statistically significant.

The graphs and the statistical evaluations were generated using GraphPad Prism, version 5 (GraphPad Inc., San Diego, CA, USA).

RESULTS

There were no significant differences with regard to age, sex, venous pathology, body mass index, or baseline leg volume between the groups (Table 1).

Volume

Both compression systems achieved a significant reduction of total lower leg volume at T1 and T7 compared with baseline ($p < .0001$) (Fig. 1). In comparing the effects of the different compression devices, AVCDs were significantly more effective than IBs after both 1 and 7 days ($p < .001$), with a median volume decrease of 19% and 26% for the AVCD, respectively, and of 13% and 19% for the IB, respectively (Fig. 2).

IP

Immediately after application, IP was significantly higher with IBs compared with AVCDs, both in the supine (median 62.5 mmHg [IQR 60.2–64.7] vs. 43.0 mmHg [IQR 41.0–45.0]; $p < .0001$) and standing positions (median 79.0 mmHg [IQR 75.0–84.0] vs. 50.5 mmHg [IQR 49.2–54.7]; $p < .0001$).

Standing pressure was significantly higher compared with lying pressure for both compression systems (Fig. 3). After 24 h, IP dropped significantly under the IBs but not under the AVDCs, resulting in a significantly lower pressure with IBs in the supine position (median 21.5 mmHg [IQR 19.2–25.0] vs. 42.0 mmHg [IQR 41.0–44.5]; $p < .001$) (Fig. 4). The corresponding standing values (data not shown) were 29 mmHg (IQR 28–31.7) and 50.5 mmHg (IQR 49.2–53.0), respectively ($p < .001$). Similar results occurred after 1 week: after the second application the IB pressure was again significantly higher than AVCD pressure, both in the supine (median 62.0 mmHg [IQR 59.5–65.5] vs. 43.0 mmHg [IQR 41.0–45.0 mmHg; $p < .0001$) and standing positions (median 78.5 mmHg [IQR 78.0–80.7] vs. 52.0 mmHg [IQR 50.2–55.5]; $p < .0001$). At T7, before removal, the pressure of the IBs had dropped to a median of 31.0 mmHg (IQR 28.5–34.0) in the supine position and to a median of 40.5 mmHg (IQR 35.7–43.7) in the standing position in contrast to AVCD, which maintained pressure owing to re-adjustments by the patient. As a consequence, the pressure of the AVCDs was significantly ($p < .0001$) higher both in the supine (median 43 mmHg [IQR 41–45]) and standing position (median 52.0 mmHg [IQR 49.0–53.7]) (Fig. 4). The median SSI for the IBs was 17.0 (IQR 15.0–19.7) and 9.0 (IQR 8.0–10.0) for the AVCDs ($p < .0001$).

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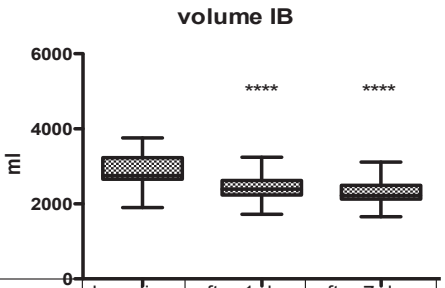
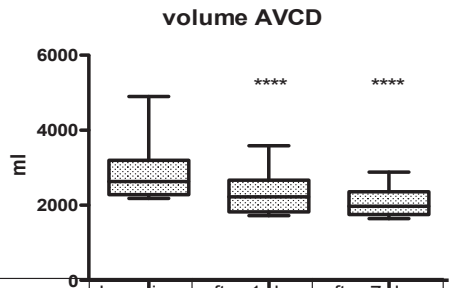
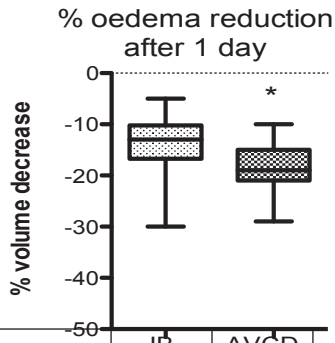


	baseline	after 1 day	after 7 days
Minimum	1903	1724	1657
25% Percentile	2655	2240	2130
Median	2750	2393	2221
75% Percentile	3232	2620	2493
Maximum	3755	3240	3110
Mean	2854	2437	2295
Std. Deviation	445.2	370.4	346.6
Std. Error	99.54	82.83	77.51

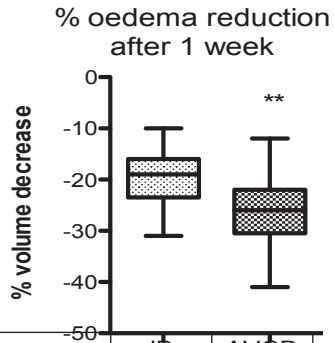


	baseline	after 1 day	after 7 days
Minimum	2180	1720	1644
25% Percentile	2281	1822	1754
Median	2631	2223	1970
75% Percentile	3200	2665	2358
Maximum	4897	3585	2883
Mean	2838	2296	2077
Std. Deviation	697.2	498.2	366.0
Std. Error of Mean	155.9	111.4	81.84

Figure 1. Leg volume in the inelastic bandage (IB) and adjustable Velcro® compression device (AVCD) groups at baseline, and after 1 and 7 days. ****$p < .0001$.



	IB	AVCD
Minimum	-30.00	-29.00
25% Percentile	-16.75	-21.00
Median	-13.00	-19.00
75% Percentile	-10.25	-15.00
Maximum	-5.000	-10.00
Mean	-14.30	-18.70
Std. Deviation	6.182	5.202
Std. Error	1.382	1.163



	IB	AVCD
Minimum	-31.00	-41.00
25% Percentile	-23.50	-30.50
Median	-19.00	-26.00
75% Percentile	-16.00	-22.00
Maximum	-10.00	-12.00
Mean	-19.76	-25.95
Std. Deviation	6.156	7.871
Std. Error	1.343	1.718

Figure 2. Percent edema reduction after 1 day and 1 week with inelastic bandages (IBs) and adjustable Velcro® compression devices (AVCDs). *$p < .01$; **$p < .001$.

Patient comfort

The "comfort index", derived from the sum of VAS figures referring to pain, sensations of heaviness and swelling, edema related discomfort, itching, and restless leg did not show any statistical difference at baseline before compression. The sum score decreased significantly with both compression devices, from 15.0 (IQR 9.0—17.8) in group A and 15.0 (IQR 5.0—18.5) in group B to 7.0 (IQR 3.3—9.5) and to 5.5 (IQR 0—10.0) at T1, respectively, and to 2.0 (IQR 1.0—4.0) and 2.0 (IQR 0—4.8) at T7, respectively ($p < .001$), without any statistical difference between the two compression modalities.

Regarding symptoms and parameters in relation to the compression device, there was no worsening of symptoms in any case, and application and re-application was considered quite easy in group B (not applicable to group A, where the IBs were wrapped by expert personnel). Cosmetic appearance was judged to be better with AVCDS ($p < .05$) along with the ease of putting on shoes ($p < .0001$).

DISCUSSION

The classic recommendation for the treatment of leg edema is to start with strong bandages for the decongestive treatment and to switch to compression stockings for the maintenance therapy phase. It was demonstrated in a previous study that this concept is more based on economic concerns than on differences regarding edema reducing

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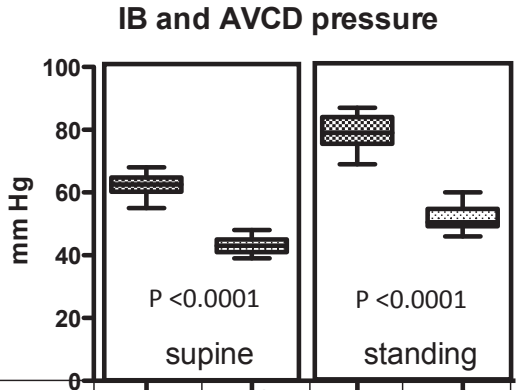

	IB	AVCD	IB	AVCD
Minimum	55.00	39.00	69.00	46.00
25% Percentile	60.25	41.00	75.50	49.25
Median	62.50	43.00	79.00	50.50
75% Percentile	64.75	45.00	84.00	54.75
Maximum	68.00	48.00	87.00	60.00
Mean	62.05	43.05	79.40	51.90
Std. Deviation	3.591	2.502	4.957	3.432
Std. Error	0.8029	0.5595	1.108	0.7674

Figure 3. Supine and standing pressure with inelastic bandages (IBs) and adjustable Velcro® compression devices (AVCDs).

effectiveness.[5,6] In a recent study,[5] it was shown that compression stockings exerting a pressure of about 30 mmHg at the ankle were nearly as effective as inelastic compression bandages applied with an initial pressure of 60 mmHg with regard to edema reduction. However, in daily practice new compression stockings would be needed after a few days because of the reduction in leg size, which would be economically unfavorable. In this study, only C3 patients were enrolled in order to obtain results not biased by different underlying pathologies. However, from a practical point of view the measured volume reduction of swollen limbs may also be expected in patients with C4—C6, and also in those with lymphedema.

It has been shown in patients with lymphedema that AVCDs can be applied and readjusted correctly, after short didactic demonstration, by the patients themselves.[15] This led, after 1 day, to a significantly greater reduction in leg volume compared with lymphedema bandages. To date, the present results provide the only quantitative data in the literature regarding the efficacy of AVCDs on leg edema. It has been demonstrated in the present study that AVCDs, re-adjusted by the patients when needed, achieved a significantly more pronounced reduction of venous edema than IBs, not only after 1 day, but also after 7 days.

As shown in Fig. 4, there is a drop in IP under IBs of $>$ 50% after 1 day, which is in contrast to AVCDs, where the pressure is maintained owing to re-adjustment by the patient. The same happens a few days after the re-application of the bandage. As shown in a previous study, the pressure loss under the IBs is mainly due to a volume reduction of the leg.[3] The consistently higher pressure exerted over time by the AVCDs compared with the IBs might explain its greater effectiveness.

Proper self-application may be difficult, especially in very overweight patients and in those with severe disfiguration of the legs. Such patients were not seen in the present series. As long as the patient is able to put on shoes and handle shoe laces, an AVCD can be used. Proper education or help from relatives may overcome potential problems.

Despite high pressure on the leg, distal swelling of the ankle and foot due to a tourniquet effect was not observed in the present series, demonstrating that the tubular device and the half-stocking provided with the ACVD is sufficient to prevent foot swelling. Minor swelling of the uncovered parts, which may occur in the morning after waking up, disappears as soon as the patient starts to walk. Some methodological points to be discussed relate to the methods of measurement: edema reduction was calculated by subtracting leg volume after 1 and 7 days from the baseline volume, which was calculated by the truncated cone formula.[10] This method of assessing leg volume showed good reproducibility,[9,16] and an excellent correlation with volumetry assessed by water displacement (Pearson's $r = .983$; 95% confidence interval 0.96—0.99),[6,17,18] which is considered the gold standard technique, with good accuracy and reproducibility.[17,19,20] In contrast to water displacement, the method used does not include foot volume.

Measurements of IP and SSI using a Picopress probe, which can be left on the same site day and night, has become a standard method in clinical compression studies.[4—6,21] This method revealed that the average pressure over time is higher with AVCDs than with IBs. The SSI was significantly higher for the IBs compared with the AVCDs, showing that the Circaid Juxtafit material is more elastic. As a consequence of this study, it is proposed that AVCDs can be used effectively for the initial treatment of venous edema. The superiority of AVCDs over IBs is mainly based on the fact that they can be handled and readjusted quite easily by the patients themselves. This is an important step in the direction of self-management, with the obvious limitation of the patient's cooperation.

Concerning the subjective perception of the compression devices, both devices were well tolerated. Patients did not complain about cosmetic appearance, and the ability to wear shoes was significantly better with AVCDs.

Concerning the re-application of IBs, the present study reflects a realistic scenario. Usually, such bandages are left on the leg day and night for a period of 1 week, during which bandage renewal may be recommended when it is getting loose. This bandage loosening is due to a reduction in edema, which is most pronounced immediately after bandage application.[3] The renewal of the bandage after 1 day seems to be an appropriate regime, as at that time the pressure will have already dropped to more than half. However, the optimal timing for renewing bandages needs further investigation.[21]

A weak point of this study is the lack of a fair comparison in the timing of IB and AVDC renewal. Nevertheless, in

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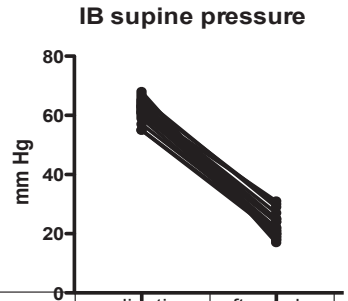
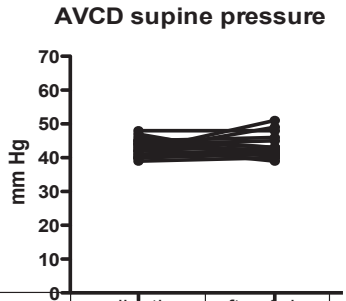
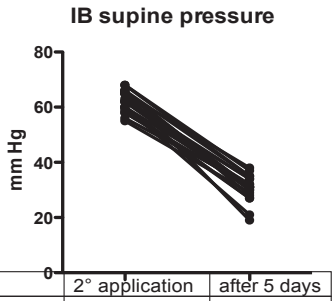


	application	after 1 day
Minimum	55.00	17.00
25% Percentile	60.25	19.25
Median	62.50	21.50
75% Percentile	64.75	25.00
Maximum	68.00	31.00
Mean	62.05	22.60
Std. Deviation	3.591	4.147
Std. Error of Mean	0.8029	0.9274

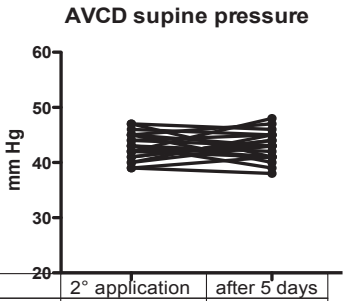


	application	after 1 day
Minimum	39.00	39.00
25% Percentile	41.00	41.00
Median	43.00	42.00
75% Percentile	45.00	44.50
Maximum	48.00	51.00
Mean	43.05	43.05
Std. Deviation	2.502	3.187
Std. Error of Mean	0.5595	0.7126

first application



	2° application	after 5 days
Minimum	55.00	19.00
25% Percentile	59.50	28.50
Median	62.00	31.00
75% Percentile	65.50	34.00
Maximum	68.00	38.00
Mean	62.33	30.62
Std. Deviation	3.825	4.610
Std. Error of Mean	0.8348	1.006



	2° application	after 5 days
Minimum	39.00	38.00
25% Percentile	41.00	41.00
Median	43.00	43.00
75% Percentile	45.00	45.00
Maximum	47.00	48.00
Mean	42.90	42.95
Std. Deviation	2.469	2.625
Std. Error of Mean	0.5520	0.5870

second application

Figure 4. Supine pressure loss after the first (top) and second application (bottom) of inelastic bandages (IBs) and adjustable Velcro® compression devices (AVCDs).

clinical practice the AVCD is adjusted, not just after the first 24 h, but more frequently: the re-adjustment of the Velcro® straps by the patients according to the subjective feeling is a successful arrangement.

However, comparing a daily re-adjusted AVCD with a daily re-wrapped IB could produce different results, with a possible improvement of the overall efficacy of the IB, but the socio-economic burden of this daily re-bandaging regime by trained personnel would be extremely high.

The reported results have some practical and economic implications. Usually, edema treatment starts with IBs, which need to be applied by expert personnel; then, elastic stockings are used after decongestion to maintain results and prevent recurrences. With this new approach only one device needs to be used—a device that is self-applicable after short training, and self re-adjustable. Even when leg volume is reduced by the initial treatment phase the device can be resized to adjust it to the new leg volume, allowing considerable cost savings. The AVCD can be washed and reused by the patient. It can be cut and adjusted to the new leg size so that the same device can be utilized not only in the maintenance phase, but also in the therapy phase for several months. The most important factor concerning potential cost saving is not the price of the device but its applicability without needing trained medical staff. However, studies on cost-effectiveness should be carried out in the future, comparing the lifetime and usability of inelastic materials with that of AVCDs.

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CONCLUSIONS

In patients with chronic venous leg edema, a compression pressure in the range of 40 mmHg exerted by an ACVD is more effective in reducing chronic venous edema than an IB with an initial resting pressure of around 60 mmHg, with comparable patient comfort. This AVCD based approach could allow a considerable cost saving due to self-management, thereby avoiding costs associated with specialized medical staff.

CONFLICT OF INTEREST

None.

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