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# Sub-compression interface pressure measurements in vivo, comparing adjustable compression wraps and custom-made flat knit compression stockings

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# Sub-compression interface pressure measurements in vivo, comparing adjustable compression wraps and custom-made flat knit compression stockings

## In-vivo-Druckmessungen zum Vergleich medizinischer adaptiver Kompressionssysteme mit maßangefertigter Flachstrick-Kompressionsversorgung

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lymphoedema, phlebolymphoedema, adjustable compression wrap, compression therapy, flat knit compression, sub-compression interface pressure

Schlüsselwörter
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ZUSAMMENFASSUNG

**Hintergrund** Die in der Erhaltungsphase der komplexen physikalischen Entstauungstherapie notwendige Kompressionstherapie kann anstelle von Flachstrick-Kompressionsstrümpfen (FS) auch mit vom Patienten selbst anzulegenden Bandagen erfolgen, den sogenannten medizinischen adaptiven Kompressionssystemen (MAK).

**Methoden** MAK und FS wurden mittels In-vivo-Druckmessungen unter der von Probanden selbst angelegten Kompression direkt verglichen. Dazu wurden Drücke über Picopress®-Messgeräte und Sensoren (Microlab Elettronica, Italien) an n = 30 Patientenmit beidseitigen, symmetrischen, lymphostatischen Ödemen der Unterschenkel erfasst. FS und MAK wurden seitenrandomisiert zugewiesen. Nach Standardeinweisung und initialen Druckmessungen beider Systeme wurden MAK im Zeitverlauf von 2 und 4 h Tragedauer erneut gemessen. Static-Stiffness-Index (SSI) sowie Druckgradienten der Messhöhen B1-C wurden berechnet.

**Ergebnisse** MAK zeigen Ruhedruckwerte und SSI im therapeutischen Bereich, die signifikant höher ausfallen als bei FS ($p < 0{,}01$ bzw. $p < 0{,}001$). MAK erreichen signifikant höhere maximale Arbeitsdrücke ($p < 0{,}001$). Die Ruhedruckwerte von MAK zeigen nach 2 und 4 h, ohne Nachjustieren, keinen relevanten Druckabfall. Die mittleren Druckgradienten, bezogen auf die Messhöhen B1-C, unterscheiden sich nicht signifikant zwischen den Methoden.

**Diskussion** Die mit MAK erreichten Druckparameter untermauern deren therapeutische Effektivität. Die Anwendung von MAK ist auch ohne Nachjustieren druckstabil. Die Anwendung (Selbstanlage) kann als therapeutisch wirksam eingestuft werden. Eine gute Einweisung der Patienten ist jedoch bedeutsam.

ABSTRACT

**Background** Adjustable Compression Wraps (ACW) are used as an alternative to flat-knitted compression stockings (CS) in the maintenance phase of complex decongestive therapy treating of lymphoedema.

**Methods** Self-applied ACW and custom-made CS were compared using sub-compression interface pressure measurements in vivo. Measurements were recorded using manometer-based Picopress®-devices in a sample of n = 30 probands with bilateral symmetric lymphostatic lower leg oedema. Legs were randomised to CS side and ACW side. Following standardised instruction and initial pressure measurements

for both systems, ACW pressure measurements were repeated after 2 and 4 hours. Static Stiffness Index and pressure gradients between measuring points B1-C were calculated.

**Results** ACW showed resting pressures and SSI in therapeutic ranges and significantly higher than CS ($p < 0.01$; $p < 0.001$). ACW reached significantly higher working pressures ($p < 0.001$). Resting pressure sub-ACW did not show significant pressure drops after 2 and 4 hours, without re-adjusting. Average pressure gradients between ACW and CS did not differ significantly.

**Discussion** The pressure values reached with ACW underline their therapeutic effects. Pressures under self-applied ACW are relatively stable, even without re-adjusting. Self-application is interpreted as effective. A thorough instruction of patients is essential.

## Background

Complex physical decongestive therapy (CPDT) is considered the standard in the therapy of lymphostatic oedema [1]. In the maintenance phase of the therapy, in this part of the world, compression therapy is usually carried out with custom-made flat-knit compression stockings with the objective of volume maintenance [1]. Clinical practice shows that there are care situations which limit the use of custom-made compression stockings. These include, in particular, pronounced osteoarthritis of the hand and finger joints, general loss of strength and also the parallel necessity for wound care in the oedematous region. Alternative compression bandages, which allow regular adjustment of the compression pressure with Velcro® fasteners, known as adjustable compression wraps (ACW), may be used in CPDT phase I and also in CPDT phase II [2–7]. In addition to effective decongestion, benefits are also described for self-management of compression therapy, therapy compliance and also easier handling [2, 3]. Overall, the study situation is still sparse and not all possible parameters have as yet been examined. However, due to the option of readjustment, ACW appear to have advantages for specific indications by compensating pressure losses and reducing proneness to error [2, 3, 5–8].

In a comparative evaluation of the differences in volume effects, ACW, even without regular readjustment, were found not to be inferior to the CS reference therapy in CPDT phase II. Compared to CS, patients additionally reported that putting on and taking off the ACW was significantly easier, with comparable wear comfort [7]. The German Association of the Scientific Medical Professional Societies [AWMF] S2k-guideline “Medical compression therapy of the extremities with medical compression stocking (MCS), phlebological compression bandage (PCB) and adjustable compression wraps (ACW)” now even includes ACW in the guideline title [9].

This study investigates the self-application of ACW compared to custom-made flat-knit compression stockings by in-vivo pressure measurements on a sample of patients with symmetrical oedema with a lymphostatic component in the maintenance phase of CPDT. Conclusions are drawn about the material properties, German Institute for Quality Assurance and Certification [RAL] conformity and clinical efficacy of the ACW with regard to appropriate and stable therapeutic compression pressures with self-application. Furthermore, safe handling of ACW with self-application will be assessed.

## Materials and Methods

### Study design, recruitment and preparation

In-vivo pressure measurements were planned on bilateral, symmetrical, lymphostatic lower leg oedema in order to assess to assess the material properties, therapeutic efficacy and safe handling of self-application of the ACW.

Randomisation was carried out with application of adjustable compression wraps (ACW) on the intervention side and application of custom-made flat-knit compression stockings (CS) on the reference side. The compression device was applied by the proband according to the inclusion criterion. The sample consisted of the participants of a randomised controlled study with the primary endpoint of oedema volume [7]. On the basis of this endpoint, the case number was calculated as $n = 30$. The in-vivo pressure measurements were recorded from all probands prior to the start of the RCT. The results of this study relating to oedema volume have been reported elsewhere [7].

Patients were recruited for the study from a lymphoedema special outpatient clinic. The study included patients of legal age with bilateral lymphoedema or stage II phlebolymphostatic oedema and symmetrical clinical findings (± 200 ml in the lower leg region, measured optoelectronically with a Perometer type 400 NT, PeroPlus 2000 software, Pero-System Messgeräte GmbH [Pero-System Measurement Devices GmbH], Germany) with a positive Stemmer’s sign on both sides. In addition, patients had to be in the maintenance phase of complex physical decongestive therapy. Exclusion criteria were: exceeding the maximum dimensions for application of the ACW, skin folds with the need for additional padding as well as oedema of undetermined origin. Intolerance of compression therapy and pressure damage, also due to the measuring devices, were defined a priori as termination criteria [7].

Following informed consent, the probands were newly fitted with a class II custom-made flat-knit compression stocking, already prescribed to them previously (model: Flebovar 2, Varitex BV, Netherlands). For the intervention side, a multi-component ACW (model: ReadyWrap, Lohmann & Rauscher GmbH & Co KG, Rengsdorf, Germany) was fitted according to the manufacturer’s size chart. In accordance with the instructions for use of the ACW, the probands were briefed in self-application of the compression system. During the briefing, the application was checked and if necessary the application technique was corrected [7].

## Pressure measurements

▶ **Table 1** shows the preparatory measures and the measuring protocol for the in-vivo pressure measurements. The levels B1 (at the junction of the Achilles tendon with the muscle belly of the gastrocnemius muscle, 12 cm proximal to the lateral malleolus) and C (level of the largest circumference of the calf) were used as measuring points [10]. The measurements were carried out with two Picopress measuring devices (Microlab Elettronica, Italy) and connected laptops [11, 12]. ▶ **Fig. 1** illustrates the placement of the corresponding Picopress sensors.

First, the mean resting pressure values at B1 and C were determined and the mean values compared. The pressure values at B1 were classified according to the compression class classification valid in Germany to check the effectiveness of self-application of the ACW by the proband with regard to the compression pressures applied [11, 12].

The Static Stiffness Index (SSI) was calculated from the mean pressure measurements in the supine and standing position (difference in standing minus supine at measuring level B1), which corresponds to the so-called "absolute resting pressure difference" (aRPD) and is considered an important measure for the therapeutic efficacy of decongestion [11]. The mean SSI of the ACW side was compared with the SSI values of the control side.

As a further indication of effective and safe handling of the self-application, the pressure gradient was determined. This involved establishing the difference between the pressure values at measurement levels B1 and C in each case with CS and self-applied ACW. The mean gradients of the ACW side and the CS side were compared.

The maximum working pressure (exercise) under both compression variants was determined by averaging the respective maximum pressure values from 10 pressure peaks during exercise (repetitive dorsiflexion and plantar flexion). The mean maximum working pressure of the ACW was compared with that of the CS compression.

Then the pressure measurements on the ACW side were repeated after 2 and 4 hours, in order to monitor the effectiveness of the non-readjusted ACW over time.

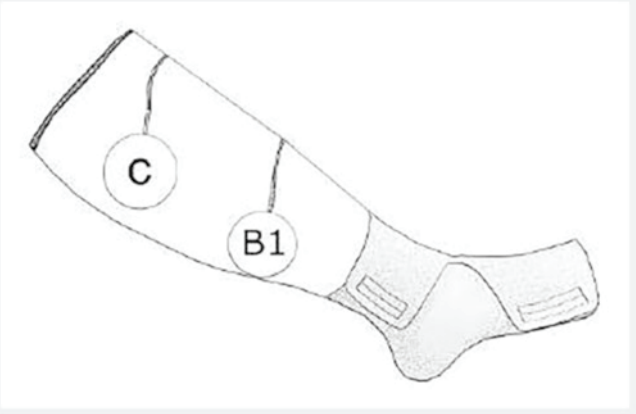
## Statistical methods

PASS software (NCSS LLC, Utah, USA) was used for randomisation. Depending on their scaling and distribution properties, a descriptive analysis of the target variables was performed using absolute and relative frequencies for categorical or mean values, standard deviation and range for quantitative characteristics. Comparisons between the examined body sides were carried out using t-tests and, for asymmetrical distribution, using Wilcoxon tests for dependent samples. Resulting p-values are considered exploratory and Bonferroni correction was not performed. Analyses were performed with SPSS 25.

The study was approved by the Ethics Committee of Charité-Universitätsmedizin Berlin (Ethics Committee vote EA1/013/19) [7]. Advice on the data protection concept was provided beforehand by the official Data Protection Officer.

▶ **Table 1** Pressure measurements protocol.

| **Pressure measurements** |
|---|
| **Preparation** |
| Recruitment and informed consent |
| Randomised allocation of sides |
| Measurement and ordering of the compression material |
| Check of fit |
| **Training**<br>Standardised briefing of the probands according to protocol/manufacturer's instructions-for-use including trial application and, if necessary, repetitions |
| Experimental setup<br>Placement of the Picropress sensors at points B1 and C on both sides |
| **Measuring protocol** |
| Placement of ACW and CS by the probands |
| Setup of pressure measurement devices for B1 and C, zero adjust |
| Positioning lying down, heel supported, lower leg not contacting anything, 2 min resting time |
| Supine: Measurement while lying down at B1 and C (30 s stable measurement value) |
| Exercise: 10 × repetitive dorsiflexion/plantar flexion, measurement of maximum pressures at B1 and C |
| Positioning standing (feet hip-width apart, 2 min standing still) |
| Standing: Measurement while standing at B1 and C (30 s stable measurement value) |
| Removal of the material and re-application by the proband |
| Measurement series repeated twice |
| Compression material and measuring sensors under ACW kept on |
| After 2h: Measurement at B1 and C (positioning lying down, lower leg not contacting anything, 2 min resting time; only ACW) |
| After 4h: Measurement at B1 and C (positioning lying down, lower leg not contacting anything, 2 min resting time; only ACW) |




▶ **Fig. 1** Sensor placement at measuring points B1 and C (in this case with ACW foot part applied).

## Results

The pressure measurements were performed on n = 30 probands. The demographic and disease-related basic data are presented in ▶ **Table 2**.

### Resting and working pressure

The mean resting pressure values (lying down) at B1 were 27.9 ± 4.0 mmHg on the CS side, and 33.8 ± 7.7 mmHg on the ACW side. At measuring point C, the pressures were 24.0 ± 3.5 mmHg for CS, and 31.1 ± 6.9 mmHg for ACW. In the group comparison, ACW showed significantly higher pressure values than the CS treatment of the respective control sides (measurement level B1: $p = 0.002$; measurement level C: $p < 0.001$).

If the in-vivo pressures at B1 are assigned to the German compression classes, CCL II or III was effectively reached lying down for 97 % of the flat-knit side. On the ACW side, 43 % reached CCL II and 43 % CCL III after self-aplication; pressure values corresponding to CCL I were only observed in 2 cases; 7 % even reached CCL IV.

The working pressure values (pressure measurements while standing) turned out to be higher. Assignment to the compression classes in this case resulted, for CS, in 2 cases for CCL I (7 %); 28 cases were CCL II (60 %) or III (33 %). For the ACW side, it was consistently CCL II (23 %), CCL III (50 %) or even CCL IV (27 %) (▶ **Fig. 2**).

### Static Stiffness Index

The Static Stiffness Index (SSI) was calculated in vivo for ACW and CS and compared. The mean SSI of the ACW, at 8.2 ± 6.0, revealed significant superiority of the ACW compared to CS ($p < 0.001$). The SSI of the CS side, at 2.6 ± 3.5, was markedly lower (▶ **Fig. 3**).

### Pressure gradient

The pressure gradient between the measuring levels B1 and C was 3.9 (± 3.9) mmHg for CS and 2.7 (± 4.8) mmHg for ACW. Comparison of the gradients showed no significant difference ($p = 0.26$).

73 % of ACW self-applications and 83 % of CS measurements showed RAL-compliant pressure gradients in vivo [10].

### Maximum working pressure (exercise)

The mean maximum working pressure was 32.2 ± 4.50 mmHg, on the CS side and 45.6 ± 10.7 mmHg on the ACW side. Thus the mean maximum working pressure for ACW is markedly higher and significantly superior ($p < 0.001$) (▶ **Fig. 4**).

### Pressure measurements over time

The temporal pressure course measured under the ACW was stable. The mean resting pressure values fell from 33.8 mmHg to 31.9 mmHg after 2 hours and to 31.0 mmHg after 4 hours (▶ **Fig. 5**). Thus, despite a minimal tendency for pressure losses, no significant or clinically relevant pressure losses occurred.

▶ **Table 2** Demographic basic data and clinical information [7, 13].

| | |
|---|---|
| n | 30 |
| Gender (female) | 25; 83.33 % |
| Age (years) | 57.9 ± 13.6 (21–81) |
| Disease duration (years) | 23.1 ± 13.91 (2–52) |
| Stage II | 30; 100 % |
| BMI (mean; SD; min-max) | 31.9 ± 7.1 (19.7–47.5) |
| Obesity (BMI ≥ 30) | 14; 46.67 % |
| Obesity III (BMI ≥ 40) | 3; 10 % |
| Primary lymphoedema | 6; 20 % |
| Secondary lymphoedema without CVI | 8; 26.67 % |
| Phlebolymphostatic oedema | 16; 53.33 % |
| CVI with obesity | 8; 26.67 % |

## Discussion

### Principal findings

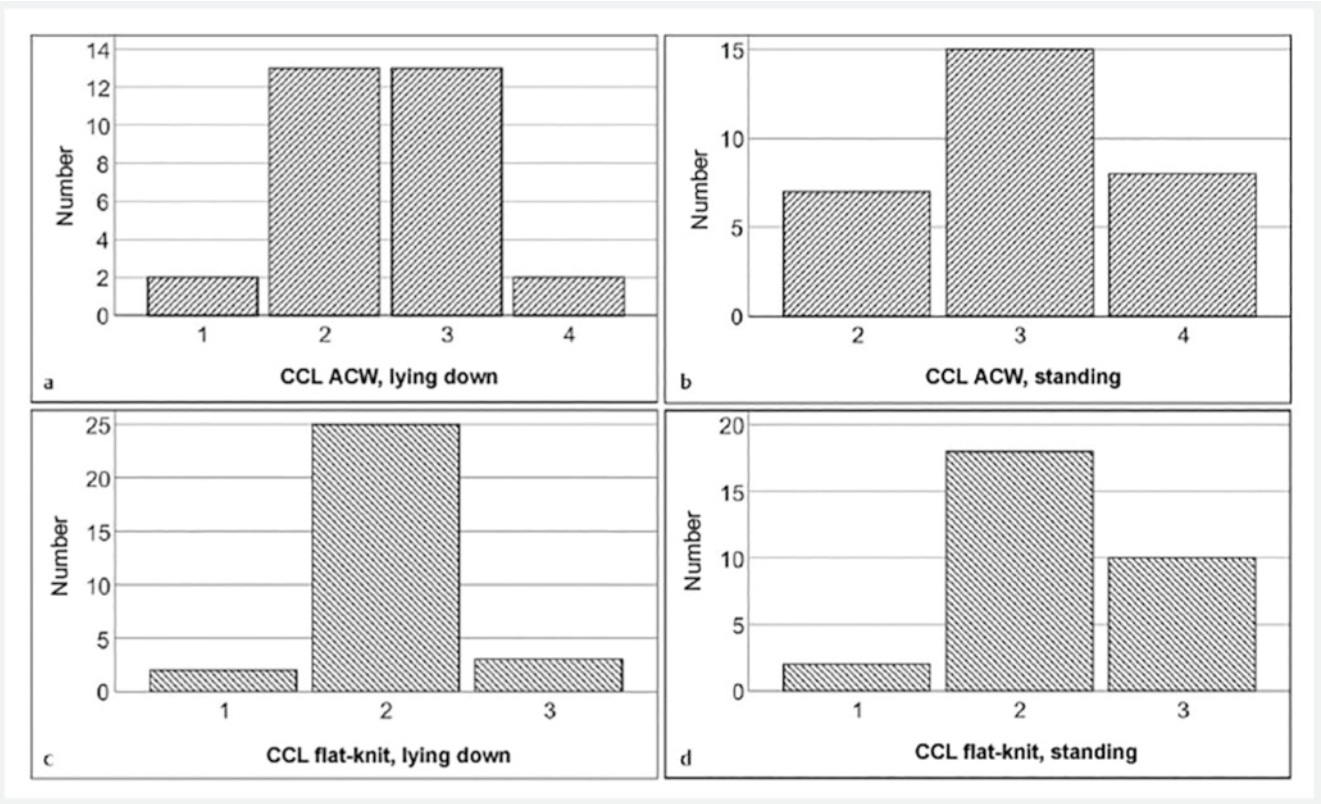
The gender ratio represented in the sample and the phlebolymphostatic insufficiency and obesity distributions are consistent with the results of previous analyses on comorbidities of lymphoedema conditions [13].

The material properties of ACW, in particular the high level of stiffness, point to their therapeutic effectiveness. Other authors also estimate the clinical effectiveness as comparably good, on the basis of the currently available literature [14]. With regard to the recorded pressure values, ACW achieve effective pressure values at rest while lying down and when standing, compared to the pressure ranges specified by the German compression classes. The Static Stiffness Index is markedly higher with ACW than with the current CS. The maximum working pressure values and the SSI of the ACW already tend towards short-stretch bandages. This is an important factor for the effectiveness of treatment in terms of oedema volume and fibrosis [15–19].

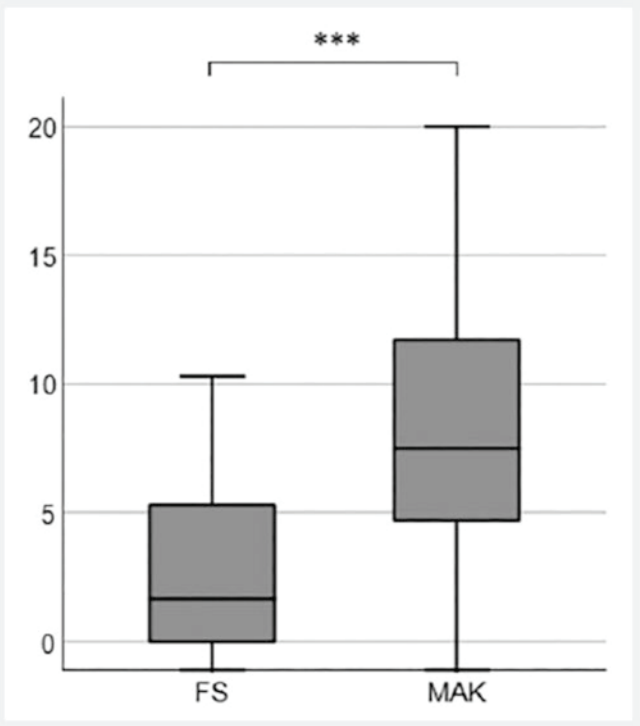
The use of ACW is associated with good pressure stability even without readjustment. In contrast to short-stretch bandages, which lose pressure over the wearing period, ACWs can exert stable pressure over a longer time period. Mosti and Partsch provided evidence of this over a markedly longer wearing time and with self-application with readjustment. This is also demonstrated over 4 hours in this study, though without readjustment [3, 18]. This is noteworthy since the compression effect of non-adjustable compression systems, such as compression bandaging with short-stretch bandages, is known not to last as long [19].

To obtain valid results in terms of effectiveness of self-application, the protocol was designed so that the probands received 3 repeated measurements at the measuring time point, prior to which the ACS was re-applied each time by the probands themselves.

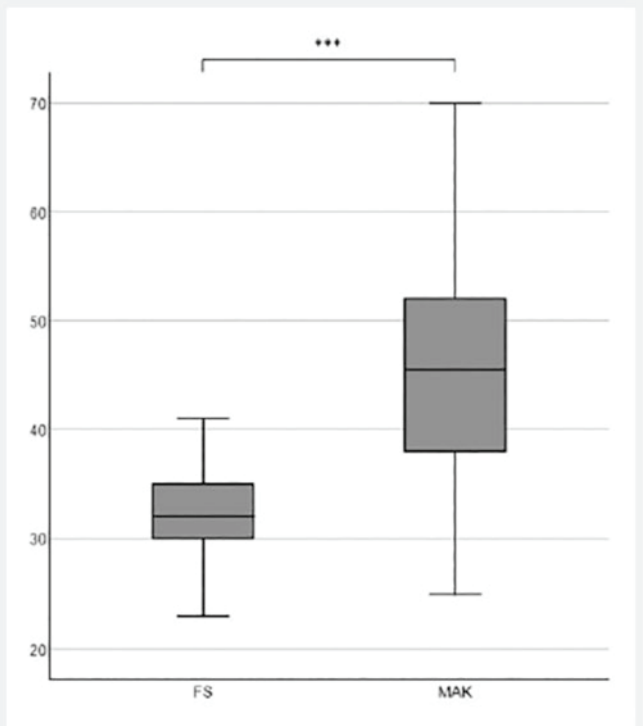
It is understandable that, in this experimental setting of chronic oedema in the maintenance phase, only small volume effects can be expected or observed within a 4-hour observation



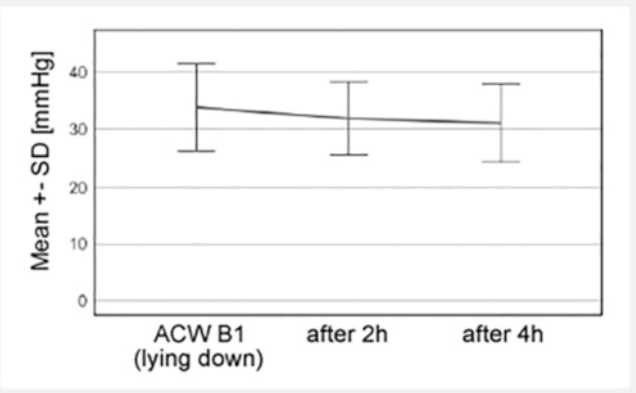

▶ **Fig. 2** Compression class levels of lying-down and standing pressure values.




▶ **Fig. 3** Comparison of Static Stiffness Index ($p < 0.001$).




▶ **Fig. 4** Comparison of maximum working pressure (box plots; y-axis: mmHg; $p < 0.001$).




▶ **Fig. 5** Pressure measurement for resting pressure B1 (ACW) over time after 2 and 4 hours.

period, which are also influenced by circadian and mobilisation-dependent factors. In terms of compression pressure, the observed values show that self-application of ACW not only allows effective pressure values and SSI to be achieved in the short term, but also that pressure remains stable. This is, of course, of particular importance in view of the fact that the compression therapy for lymphoedema must be worn for many hours daily, generally from morning to evening.

The measured pressure values were obtained through self-application of the compression by the proband following careful instruction in handling. Self-application could thus have advantages regarding treatment compliance as the expectation of self-efficacy is improved. This must especially be understood, given that both putting on and taking off the ACW is perceived to be much easier than flat-knit compression stockings, even if wearing comfort is not perceived to be better [7].

There were no side effects due to application errors. Thorough instruction in handling of the ACW should be provided according to the manufacturer's instructions and is of particular importance. 73 % of ACW self-applications showed RAL-compliant pressure gradients. The mean pressure gradient of the ACW did not differ significantly from the situation with custom-made flat-knit stockings checked for fit. In addition, negative pressure gradients occurred on the CS side in 17 % of measurements, which limits the informative value of the measured pressure gradient in terms of safety of application. ACW therapy safety with self-application should be investigated further and is also the aim of continuing research [7].

### Limitations

Possible systematic errors primarily concern the study design and measuring technique. Since proband recruitment took place in a lymphological specialist outpatient clinic and there were many cases of long-term oedema among the probands, influencing factors might arise through tissue changes present for many years or treatments might be influencing factors. Systematic measurement errors are also conceivable. Attempts were made to reduce these by randomisation to intervention and control sides.

The pressure measurements on the CS side were not studied and compared against ACW over time, since, on the one hand, the material properties of the RAL-compliant compression stocking are assumed to be constant and, on the other hand, the objectives of the pressure measurements were feasibility and compression characteristics of self-application of the ACW. A comparative study of ACW and CS was additionally carried out in the described RCT [7]. Nevertheless, this study design might have allowed tissue changes during the compression to remain undiscovered.

10 % (3/30) of the probands also exhibited forefoot oedema. Since perometry was only performed from the ankle to the tibial crest, the volume changes cannot be represented by precise data. However, no changes came to light in the oedema findings with ACW.

## Summary and outlook

The in vivo pressure measurements show that ACW can be self-applied by patients, with therapeutically effective compression pressure values. Application of ACW maintains stable pressure even without re-adjustment. Self-application can be classified as therapeutically effective. However, good patient instruction is important. The measured pressure values are more likely to be classified in the range above (German) compression class II. The stiffness characteristics tend rather to be similar to those of short-stretch bandages. Further studies should investigate therapeutic options with ACW in the different phases of CPDT, differentiating various types of lymphostatic oedema.

## Conflict of interest

Lohmann & Rauscher GmbH & Co. KG (Westerwaldstraße 4, D-56 579 Rengsdorf) supported the study with third-party funding and provided the compression material.

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