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Adjustable Compression Wraps are Non-Inferior to Custom-Made Flat Knit Compression Stockings in the Maintenance Phase of Complex Decongestive Therapy

Medizinische Adaptive Kompressionssysteme sind Flachstrick-Kompressionsstrümpfen in der KPE Phase II nicht unterlegen

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Key words
lymphedema, phlebolymphedema, complex decongestive therapy (CDT), compression therapy, adjustable compression wraps

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ABSTRACT

Background Evidence supports the use of adjustable compression wraps (ACW) in the intensive phase of complex decongestive therapy (CDT), whereas evidence of its use in the maintenance phase of oedema therapy is sparse.

Methods Randomised controlled non-inferiority trial in the maintenance phase of oedema therapy (CDT phase II) of symmetric lymphostatic oedema of the lower leg. Oedema therapy was performed with ACW and custom-made flat knit compression stockings (FCS) as a reference therapy in parallel over 3 days in n = 30 subjects. The primary outcome was lower leg volume as measured with perometer. Safety of ACW self-application and the patient perspective were secondary outcomes.

Results ACW is non-inferior to custom-made FCS in CDT phase II of lymphostatic lower leg oedema. The differences of volume effects lie within the apriori defined equivalence interval of ± 50 ml (p = 0.163; 95 %-CI [− 38.2; + 6.8]). Self-administration of ACW has shown no relevant side effects. ACW are easier to put on and off, while wearing comfort is comparable.

Conclusions ACW are an alternative therapy option in the maintenance phase of CDT. Self-application seems to be safe, subject to diligent instruction of patients. Patients with difficulties putting on and off compression stockings could benefit from the use of ACW. Patients with pronounced limb volume may need to wear shoes with bigger sizes when wearing ACW. Further research with a longer observation time is to follow.

ZUSAMMENFASSUNG

Hintergrund Medizinische Adaptive Kompressionssysteme (MAK) sind mit Klettverschlüssen adjustierbare Kompressionsbandagen. Diese erweitern das Spektrum der therapeutischen Optionen in der komplexen physikalischen Entstauungstherapie (KPE). Die Studienlage zu MAK ist spärlich, es werden Vorteile in der der KPE Phase I beschrieben. Über die Durchführbarkeit und Sicherheit der Anwendung von MAK in der KPE Phase II existiert keine belastbare Evidenz.

Methoden Prospektive, randomisierte Nichtunterlegenheitsstudie. Probanden mit symmetrischen lymphostatischen Ödemen der Unterschenkel (n = 30) wurden parallel mit neu

angepasster Flachstrick-Kompression (FS) und MAK 3 Tage lang behandelt. Primäres Outcome waren die perometrisch gemessenen Volumeneffekte der MAK im Vergleich mit der Referenztherapie (FS). Zudem wurden die Anwendungssicherheit und die Handhabung (Patientenperspektive) überprüft.

Ergebnisse MAK sind, auch ohne regelmäßiges Nachjustieren, der Referenztherapie mit FS in der KPE Phase II nicht unterlegen (Vergleich der Differenzen der Volumeneffekte; p = 0,163; 95 %-KI [− 38,2; + 6,8] bei einem apriori definierten Äquivalenzbereich von ± 50 ml). MAK zeigten keine Nebenwirkungen. Patienten berichten im Vergleich mit FS ein signifikant leichteres An- und Ablegen der MAK bei vergleichbarem Tragekomfort.

Schlussfolgerung Die Daten belegen die Nichtunterlegenheit von MAK gegen die Referenztherapie mit FS. MAK können in der Erhaltungstherapie von lymphostatischen Erkrankungen als alternative Kompressionstherapie eingesetzt werden. Die Anwendung (Selbstanlage) kann als sicher eingestuft werden. Eine gute Einweisung von Patienten ist bedeutsam. Patienten mit Schwierigkeiten in der Handhabung von Kompressionsstrümpfen beim An- und Ausziehen können von MAK profitieren. Patienten mit sehr ausgeprägten Ödemen müssen während der MAK-Nutzung gegebenenfalls größere Schuhe tragen. Studien mit längeren Beobachtungsdauern sollten folgen.

Background

Lymphoedema, like phlebolymphostatic oedema, is treated with complex decongestive therapy (CDT). In an initial intensive phase of treatment, manual lymph drainage [1], skin care, compression bandaging, movement therapy and education in self-management are performed daily for several days to weeks to decrease the volume of the oedema and avoid or reduce fibrosis of the tissue (CDT phase I). In phase I of the complex decongestive therapy (CDT), the compression bandages allow the compression pressure to be adjusted daily to the individual tissue conditions. This is followed by a maintenance phase or a so-called conservation phase (CDT phase II) in which the treatment frequency of manual lymph drainage is reduced and the bandaging is replaced with custom-made compression stockings [1].

In recent years, alternative compression systems have been developed which use Velcro closures to allow regular adjustment of the compression pressure. These flexibly adjustable compression bandages are included in the current S2k guideline “Medizinische Kompressionstherapie der Extremitäten mit Medizinischem Kompressionsstrumpf (MKS), Phlebologischem Kompressionsverband (PKV) und Medizinischen adaptiven Kompressionssystemen (MAK)“ [Medical compression therapy of the extremities with medical compression stocking (MCS), phlebological compression dressing (PCD) and medical adjustable compression wraps (ACW)] (AWMF registry number: 037/005) under the name “adjustable compression wraps (ACW)” [2]. ACW have been used to date primarily in the case of phlebolymphostatic oedema and in the treatment of venous ulcer [3]. ACW are already widely used in other countries (such as the USA, UK, Austria) in the usual treatment of venous and lymphatic diseases[4].

The literature contains indications that costs and care requirements in the therapy of chronic ulcers decrease with ACW and patient satisfaction increases [5, 6]. With regard to the treatment of lymphoedema using CDT phase I, Damstra et al., in a randomised controlled trial, found benefits in the volume reduction with a combined therapy of inelastic bandaging and ACW in comparison with inelastic bandaging alone [7]. Mosti et al. also found significantly advantageous results in an RCT with regard to volume reduction with a 7-day CDT phase I in the case of lymphoedema. They describe significantly better volume reduction with the use of ACW in comparison to inelastic bandages [8]. Both studies (Damstra et Partsch and Mosti et al.) classify the possibility of ongoing adjustment of the compression pressure of the ACW as being crucial for the improved volume reduction in comparison to inelastic bandaging. It is known that the compression pressure initially applied with inelastic bandaging does not last and in addition, a high rate of incorrect applications can be observed [9].

Since there are no reliable studies on the value of ACW in the maintenance phase of decongestive therapy of lymphostatic oedema (CDT phase II) known to the authors to date, a non-inferiority study vs. conventional treatment with flat-knit compression stockings was planned in a random sample of patients with lymphostatic extremity oedema in the maintenance phase.

To evaluate the effects of therapy in the maintenance phase of the decongestive therapy for the first time, the hypothesis that therapy with ACW is not significantly inferior to therapy with flat-knit compression stockings was tested.

Materials and Methods

Study design

An investigator-initiated, prospective, controlled randomised observational study on patients with bilateral lymphostatic lower leg oedema was planned. The selection of patients with bilateral oedema that could be regarded as symmetrical permits intraindividual comparison of the compression methods with randomisation of the intervention side. After the start of the study, no changes were made to the methodology. Inclusion and exclusion criteria as well as criteria for discontinuation are shown in ▶ **Tab. 1**.

Intervention

The study subjects were recruited via a university-based lymphology special outpatient unit. After providing information and obtaining consent, each study subject was fitted with a new compression treatment according to the individual medical prescription. This comprised a custom-made flat-knit compression stocking as usual care on the control side (model: Flebovar, Varitex BV, Netherlands) as effective reference therapy, as well as a multipart ACW (model: ReadyWrap, Lohmann & Rauscher GmbH & Co KG, Rengs-

▶ **Tab. 1** Inclusion and exclusion criteria and discontinuation criteria.

Inclusion criteria	**Age > 18**
	Diagnosis of lymphoedema or phlebolymphostatic oedema
	▪ Stage II
	▪ Bilateral
	▪ Symmetrical (± 200 ml difference in volume in the lower leg region, measured optoelectronically)
	▪ Stemmer's sign positive bilaterally
	Compliance with therapy in wearing the compression
	Maintenance therapy existing and indicated (CDT phase II)
	Sufficient speech comprehension and mental health
	Basic physical ability for self-management of the compression therapy
	Consent given
Exclusion criteria	Skin creases with indication for additional padding
	Maximum dimensions for the use of the ACW system exceeded
	Expected noncompliance/expected dropout (estimation of the investigator)
	Absolute or relative contraindications to CDT
	Patients who regularly apply bandages (including in addition) themselves
	Unclear aetiology of the oedema
Discontinuation criteria	Intolerance of the compression therapy
	New appearance of contraindications
	Voluntary withdrawal of participants

▶ **Fig. 1** Custom-made flat-knit compression and adjustable compression wrap (with surgical shoe).

dorf, Germany) on the intervention side in individual sizes fitted according to the manufacturer's instructions (▶ **Fig. 1**). The study subjects were instructed in the use of the ACW according to a standardised protocol, according to the manufacturer's recommendation, and it was verified that they applied it properly. Where necessary, the study subjects were asked to make corrections and the application was verified once again. The study subjects were then instructed to wear the compression aid during the daytime for 3 days, and the compression was to be worn on both sides (intervention and control) for an equally long period. At night, both compression aids could be removed. To ensure that therapy in the maintenance phase (CDT phase II) is represented, the patients were explicitly instructed not to readjust the compression pressures of the ACW.

Primary endpoint: change in volume

To compare the efficacy of therapy with regard to volume, the extremity volume was recorded initially and after 72 hours optoelectronically (Perometer type 400 NT, Software PeroPlus 2000, Pero-System Messgeräte GmbH, Germany) [10–13]. The change in volume was determined based on individual measurements: these included the area of the lowest measurement that could be displayed technically with the foot planted as far as the subject's tibial plateau. Repeat measurements were reproduced via the electronically adjustable measurement with millimetre accuracy. Three volume measurements were taken pre- as well as post-interventionally in each case and averaged.

Clinical examination

Before and after the observation phase, a standardised clinical lymphology examination was performed. The location of the oedema with maximum findings and clinical extent of the fibrosis was described separately for each leg. In addition, the study subjects were examined for the presence of constrictions, redness, blistering and sensitivity disorders.

Patient perspective

To represent the patient perspective, the study subjects were surveyed using questionnaires before and after the intervention. Using a 100 mm visual analogue scale, feelings of tension were recorded separately for the intervention and control side. After the observation phase, estimations regarding wear comfort and the subjective treatment success were documented, also using the VAS. Study subjects were asked about subjective side effects such as slipping, redness or itching, as well as their location and frequency, where applicable. It was also possible to voluntarily enter free text regarding the advantages and disadvantages of ACW in a direct comparison with flat-knit compression stockings in CDT phase II. The responses were clustered according to

content after all data were available and evaluated descriptively with details on frequency.

Sample size estimation, randomisation, statistical methods, registration

The optoelectronically measured volume of ACW and flat-knit compression was used in a comparison of both sides to estimate the sample size. With a sample size of n = 27, an associated t-test in the case of a one-tailed alpha error of 0.025 has a power of 80 % of rejecting the null hypothesis of non-equivalence if the expected mean difference is − 50 ml, based on a 50-ml equivalence limit and a standard deviation of the differences of 175 ml. Taking three dropouts into account, the sample size was thus determined to be n = 30 patients for whom one extremity represents the verum side and whose contralateral extremity represents the control side. The sample size estimation was generated with the software nQuery 7.0.

The randomisation was performed using PASS software (NCSS LLC, Utah, USA) [14–16].

The primary target variable was investigated using t-tests for paired samples for the significance of the mean differences of the volume effects. The 95 % confidence intervals were calculated and correlated with the a priori defined equivalence limit [17]. Other secondary target variables as well as other demographic and clinical characteristics were descriptively analysed as a function of their scaling and distributional properties. Explorative comparisons between the sides of the body were accordingly performed using t-tests or Wilcoxon tests in the case of asymmetric distribution. The resulting p-values are considered to be exploratory. The analyses were performed using the software SPSS 23.

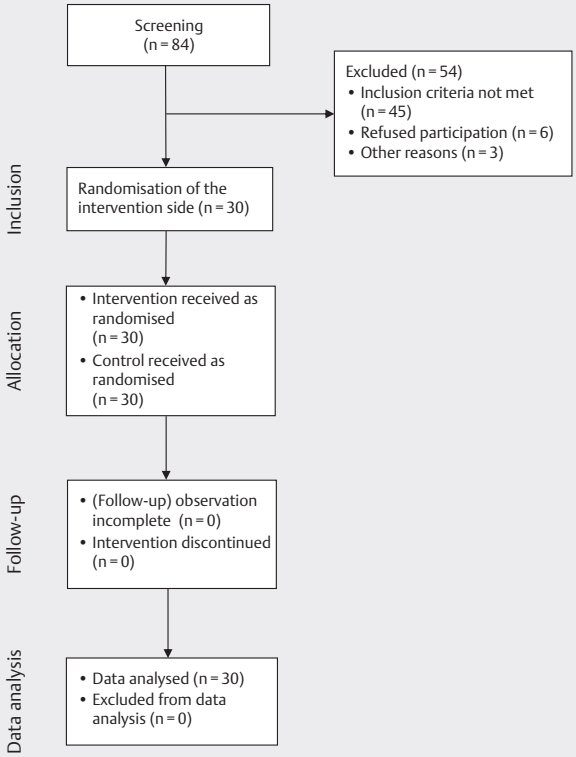
The study was approved by the ethics committee of the Charité – Universitätsmedizin Berlin (ethics committee vote EA1/013/19). The regulatory data protection officer was consulted beforehand regarding data protection. The procedure, which received a positive vote, was adhered to at all times. The study was registered in the German Clinical Study Registry (DRKS) prior to the first patient (DRKS00016665). The sequence of the presentation follows the structure according to CONSORT 2010 [17]. In vivo pressure measurements with ACW and flat-knit stockings were performed on the same sample prior to conducting the study; these measurements are reported elsewhere.

Results

Of 84 interested persons who were screened, n = 30 study subjects were included after applying the inclusion and exclusion criteria. ▶ **Figure 2** shows this in detail as a flow chart. No discontinuations or exclusions after randomisation were recorded. All study subjects received the pressure measurements, intervention and control (usual care) provided for by the protocol and were analysed with regard to the primary endpoint. The recruitment and observation took place in the period from 11/03/2019 to 26/09/2019. The demographic and disease-related basic data are shown in ▶ **Tab. 2**.

Primary outcome: Change in volume

The volumes of the control and intervention side before (t0) and after (t1) the observation period, averaged from 3 measurements,



▶ **Fig. 2** Flow chart.

▶ **Tab. 2** Demographic basic data and clinical information.

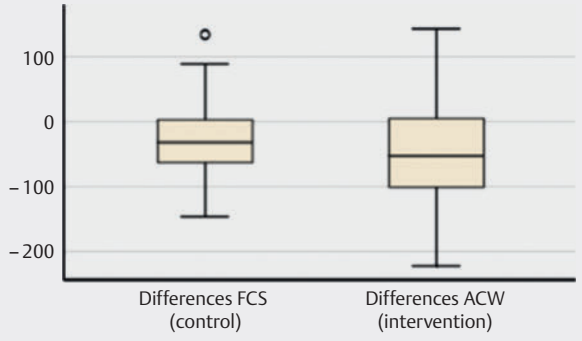
n	30
Sex [female]	25; 83.33 %
Age [years]	57.9 ± 13.6 (21–81)
BMI [MV; SD; min-max]	31.9 ± 7.1 (19.7–47.5)
Obesity [BMI ≥ 30]	14; 46.67 %
Obesity, grade III [BMI ≥ 40]	3; 10 %
Primary lymphoedema	6; 20 %
Secondary lymphoedema without CVI	8; 26.67 %
Phlebolymphostatic oedema	16; 53.33 %
Duration of illness [years]	23.1 ± 13.91 (2–52)
Stage II	30; 100 %

are shown in ▶ **Tab. 3**. The volume effects of the groups are shown in ▶ **Fig. 3** as boxplots. In both groups, a decrease in the volume was visible; this was more pronounced on the intervention side at 40.3 ± 91.3 ml than on the control side at 24.6 ± 62.7 ml. Accordingly, ACW demonstrated a volume reduction effect which was greater by 15.7 ± 60.1 ml on average. In the comparison of the volume effects of both sides using the t-test for paired samples, no significant difference is seen (p = 0.163). If the 95 % confidence in-

terval [− 38.2; + 6.8] is correlated to the *a priori* defined equivalence limit of 50 ml, non-inferiority can be assumed (▶ **Fig. 4**).

▶ **Tab. 3** Volume measurements over the course of the study and volume effects (differences t0–t1) with standard deviations (STD). FCS: Flat-knit compression stockings, ACW: Adjustable compression wraps.

n = 30	Mean value [ml]	STD [ml]
Control (FCS) t0	3.403	896
Control (FCS) t1	3.379	909
Intervention (ACW) t0	3.408	919
Intervention (ACW) t1	3.367	932
Volume effect control t1–t0	− 24.6	62.7
Volume effect intervention t1–t0	− 40.3	91.3



▶ **Fig. 3** Differences in the volumes in control and intervention group. Boxplots (y axis: volume effects in ml).

Clinical examination

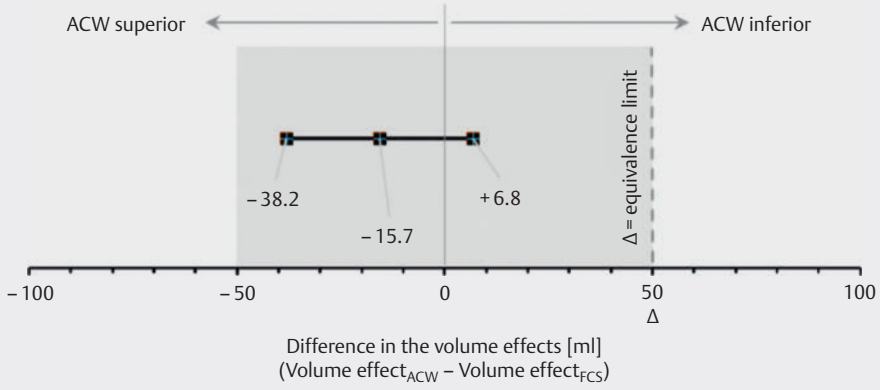
In 29 out of 30 study subjects, the locations of the findings extended from the region of the toes up to and including the lower leg. Involvement of the knee region was recorded in only one case. The maximum findings were described in 70 % of cases as being in the lower leg and in 20 %, the maximum involved the perimalleolar region and in 10 %, the forefoot region. All oedema was noted to be stage II with mild (60 %) to moderate (40 %) fibrosis. All study subjects were patients with a chronic course and in the maintenance phase of CDT, who had already previously been treated with custom-made flat-knit compression stockings. At the time of study inclusion, all 30 study subjects were being treated with compression class (CCL) II.

Constrictions due to existing compression, redness, blistering or sensitivity disorders were not observed initially in the two groups. Post-intervention, no changes due to the newly applied compression treatment in the form of constriction were recorded beyond the usual impressions at the edges of the material. Blistering and sensitivity disorders were not noted. In 3 out of 30 study subjects (10 %), redness of the area between the toes was documented on the intervention side. Occasional itching in the area of the toes (6.7 %) and the forefoot (3.3 %) was described in 3 out of 30 (10 %) study subjects on the intervention side, but also in 4 out of 30 (13.3 %, toe area) study subjects on the control side.

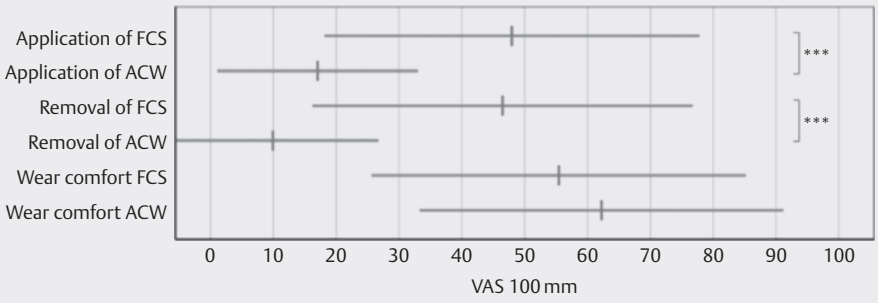
Patient perspective

Using a VAS, the handling and wear comfort of ACW and FCS were evaluated by the study subjects. ▶ **Fig. 5** shows the mean values and standard deviations of the results. ACW are rated far more highly in comparison to FCS in terms of application and also removal ($p = 0.000$ in each case). In the comparison of wear comfort of the compression materials, no significant difference was found in the evaluation($p = 0.68$).

In the retrospective, clustered free text response section of the questionnaire, the study subjects predominantly (60 %) defined the



▶ **Fig. 4** 95 % Confidence interval of the difference of the volume effects with respect to the equivalence limit (highlighted in grey: a priori defined equivalence range).



▶ **Fig. 5** Handling and wear comfort in comparison (visual analogue scale: 0 = very easy/comfortable; 100 = very difficult/uncomfortable; mean values and standard deviations).

advantages of ACW therapy to be the fact that ACW was easier to put on/take off when compared to the tried-and-tested flat-knit compression. Advantages mentioned secondarily were a pleasant feeling during wear (13 %) and the individually adjustable pressure (13 %). The study subjects considered the disadvantages of ACW in particular to be regular footwear which no longer fits (67 %) as well as inadequate compression of the ACW foot element in the retromalleolar area (17 %). In this connection, 60 % of the study subjects indicated that they wished to continue using the ACW received during the study, while 33 % refrained from further use and 7 % did not provide any information in this regard.

Adverse events

No adverse events occurred.

Discussion

Limitations

The study design was based on non-inferiority. The non-inferiority was confirmed statistically. Despite the relatively short observation period of 3 days, different though non-significant volume effects are already seen. The potential influence of a possible longer observation period must be discussed with limitations here.

The study subjects were intentionally trained to put on the ACW themselves without regular readjustment because of the defined CDT phase II context. However, the material would allow a more therapeutically effective treatment if regular readjustment was performed. Here, too, an effect may have been disregarded because of the study design.

A selection bias through the recruitment of patients who have had many years of chronic oedema with close management in a special outpatient unit also cannot be excluded. The clinical presentation allows the interpretation that this was treatable oedema. The tissue was not significantly fibrotic. The study did not include patients with difficult-to-treat stage III lymphoedema. With regard to the patients with chronic venous insufficiency among the study subjects, it should be noted that no ulcers are described here. The handling of any wound treatment under the compression was not investigated.

The reference therapy also demonstrates a volume effect – albeit smaller – in the direction of a decrease in volume. This appears at first to be unusual for the maintenance phase, but it can be explained by the fact that all study subjects received a new, custom-made flat-knit compression stocking at the same time for the purpose of an effective reference therapy. The observed volume effect can be explained by the compression treatment for about 6 months prior to new stocking fabrication at the start of the study. It is possible that the compression effect of the treatment to be exchanged was no longer optimal, while the observation phase was then conducted with new, custom-made flat-knit stockings [18]. Systematic errors cannot be excluded; however, both sides would be equally affected. This circumstance additionally very clearly shows the need for new compression aids on a regular basis.

Discussion of the main results

To the authors' knowledge, this study is only the third randomised controlled study of ACW and the first which investigated the use of CDT in the maintenance phase in comparison to flat-knit compression stockings.

ACW are not inferior to FCS with regard to their volume effects in the maintenance phase of therapy for lymphostatic oedema. ACW demonstrated a somewhat more effective but statistically not significantly different decrease in volume. Superiority of ACW cannot be inferred due to the selected study design and the existing data.

If the results of this study are extrapolated, it could be expected that, with readjustment and a longer period of therapy, greater therapeutic effects can be achieved than those that are possible with FCS in CDT phase II. This opens the discussion on indications for conditioning or preparation prior to fitting new compression stockings and also in the transition period of CDT phase I and II. In any event, there is a need for further research here. Since ACW with different materials and applications are now available on the market, these should be compared in tests that allow the results to be generalised.

Another point of discussion should be the possible advantages for compression therapy compliance, an aspect that is difficult to measure but greatly significant in treatment outcome.

Safety

No adverse effects were identified during the clinical examination in this study. Therefore the authors assess self-application of ACW as safe. This confirms the experience of other authors who describe that proper application is comparably comparably successful proper application following professional instruction by experienced nursing staff as well as by inexperienced laypersons [19]. However, in the case of pedal oedema, for technical reasons insufficient compression is a possibility in the retromalleolar area and on the instep. "Window oedema" can occur in the area of the instep. This was the case in training situations. However, such window oedema was not observed clinically in any case. The foot volume was not a part of this investigation, for technical reasons (Perometer measurement). Worsening of oedema due to application errors also did not occur. The redness between the toes frequently occurs as a maceration effect during compression treatment. This can be counteracted by padding between the toes with gauze compresses.

Handling

Application and removal are significantly easier in the case of ACW than flat-knit stockings. This suggests that the use of ACW in certain patient groups could reduce nursing services. For outpatient treatment with compression stockings, a recent study from Germany found that daily costs ranged from 2.29 Euro without nursing care up to 34.29 Euro if nursing support is needed to put the stockings on and take them off every day [20]. In addition, obesity and functional disorders of the musculoskeletal system frequently make it more difficult to put on and take off compression stockings [21]. The ACW could therefore be useful not only medically but also economically, for specific indications.

The wear comfort of ACW and FCS is assessed as comparable. However some patients with marked oedema no longer fit into their normal footwear during the application of ACW and need to be provided with surgical shoes or recommended to use shoes in a larger size.

Summary and outlook

In the authors' view, ACW can be used in the maintenance therapy of lymphostatic diseases as an alternative means of compression. In addition, the effect on the volume is better than that of newly adjusted flat-knit compression in the maintenance phase. Although well aware that this is not an objective of custom-made compression stockings, additional applications can be inferred from this observation. The indication for ACW for the individual patient should be decided based on the described advantages and disadvantages. Additional studies with longer periods of observation should follow.

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Conflict of interest

AR and ML received speakers' fees from Juzo GmbH.

References

[1] AWMF S2k. Leitlinie Diagnostik und Therapie der Lymphödeme. AWMF Reg.-Nr. 058-001. https://www.awmf.org/uploads/tx_szleitlinien/058-001l_S2k_Diagnostik_und_Therapie_der_Lymphoedeme_2019-07.pdf (accessed September 17, 2019)

[2] AWMF S2k Leitlinie Medizinische Kompressionstherapie der Extremitäten mit Medizinischem Kompressionsstrumpf (MKS), Phlebologischem Kompressionsverband (PKV) und Medizinischen adaptiven Kompressionssystemen (MAK). AWMF-Reg.-Nr. 037/005. https://www.awmf.org/uploads/tx_szleitlinien/037-005l_S3k_Medizinische-Kompressionstherapie-MKS-PKV_2019-05.pdf (accessed September 17, 2019)

[3] Reich-Schupke S, Protz K, Dissemond J et al. Neue Entwicklungen in der phlebologischen Kompressionstherapie. Dtsch Med Wochenschr 2017; 142: 679–686

[4] Ehmann S, Whitaker J, Hampton S et al. Multinational, pilot audit of a Velcro adjustable compression wrap system for venous and lymphatic conditions. J Wound Care 2016; 25: 513–520

[5] Stather PW, Petty C, Howard AQ. Review of adjustable velcro wrap devices for venous ulceration. Int Wound J 2019; 16: 903–908

[6] Blecken SR, Villavicencio JL, Kao TC. Comparison of elastic versus nonelastic compression in bilateral venous ulcers: a randomized trial. J Vasc Surg 2005; 42: 1150–1155

[7] Damstra RJ, Partsch H. Prospective, randomized, controlled trial comparing the effectiveness of adjustable compression Velcro wraps versus inelastic multicomponent compression bandages in the initial treatment of leg lymphedema. J Vasc Surg Venous Lymphat Disord 2013; 1: 13–19

[8] Mosti G, Cavezzi A, Partsch H et al. Adjustable Velcro Compression Devices are More Effective than Inelastic Bandages in Reducing Venous Edema in the Initial Treatment Phase: A Randomized Controlled Trial. Eur J Vasc Endovasc Surg 2015; 50: 368–374

[9] Callam MJ, Haiart D, Farouk M et al. Effect of time and posture on pressure profiles obtained by three different types of compression. Phlebology 1991; 6: 79–84

[10] Stanton A, Northfield J, Holroyd B et al. Validation of an optoelectronic limb volumeter (perometer). Lymphology 1997; 30: 77–97

[11] Stanton A, Badger C, Sitzia J. Non-invasive assessment of the lymphedematous limb. Lymphology 2000; 33: 122–135

[12] Man I, Markland K, Morrissey M. The validity and reliability of the Perometer in evaluating human knee volume. Clin Physiol Funct Imaging 2004; 24: 352–358

[13] Deltombe T, Jamart J, Recloux S et al. Reliability and limits of agreement of circumferential, water displacement, and optoelectronic volumetry in the measurement of upper limb lymphedema. Lymphology 2007; 40: 26–34

[14] Piantadosi S. Clinical Trials – AA Methodological Perspective. 2005. John Wiley & Sons. New Jersey

[15] Pocock SJ. Clinical Trials – A Practical Approach. 1983 John Wiley & Sons. New York

[16] Rosenberger WF, Lachin JM. Randomization in Clinical Trials – ATheory and Practice. 2002. John Wiley & Sons. New York

[17] Piaggio G, Elbourne D, Pocock S et al. Reporting of Noninferiority and Equivalence Randomized Trials. Extension of the CONSORT 2010 Statement. JAMA 2012; 308: 2594–2604

[18] Protz K, Heyer K, Verheyen-Cronau I et al. Loss of interface pressure in various compression bandage systems over seven days. Dermatology 2014; 229: 343–352

[19] Muldoon J, Hampton S. Validity, Inter-rater and Intra-rater reliability of an Adjustable Compression Device Application. 2017. SAWC, San Diego

[20] Dissemond J, Protz K, Moelleken M et al. Kompressionstherapie bei Patienten mit Ulcus cruris – welche Kosten entstehen wirklich? Dtsch Med Wochenschr 2019; 144: e94–e101

[21] Reißhauer A, Schuester L, Kling A et al. Prävalenz von Komorbiditäten bei Lymphödemerkrankungen. Phys Med Rehab Kuror 2019; 29: 282–289

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