

Prospective, randomized, controlled trial comparing the effectiveness of adjustable compression Velcro wraps versus inelastic multicomponent compression bandages in the initial treatment of leg lymphedema

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Background: Inelastic multicomponent compression (IMC) bandages applied by specialized medical staff are the standard of care for compression therapy of lymphedema of the extremities. However, new adjustable compression wraps (ACWs), which can be applied by patients themselves and, up to now, have been mainly recommended for the maintenance treatment phase of lymphedema, may be an important step toward the self-management of the initial treatment phase.

Methods: This prospective, randomized, controlled comparative study assessed the effectiveness of an ACW in the treatment of leg lymphedema, compared with the traditional treatment with conventional IMC bandages. Included were 30 hospitalized patients admitted due to moderate to severe unilateral lymphedema (stages 2-3) of the leg. The primary outcome measures in both groups were reduction in volume of the affected leg and interface pressure after 2 and 24 hours. Patients were randomized into two groups of 15 patients: group A received ACW and group B received IMC bandages, both applied by experienced staff. After 2 hours, the staff replaced IMC bandages and the patients applied ACW, as previously instructed. Finally, compression was removed after 24 hours. Classic water displacement volumetry was performed before compression and after 2 hours and after 24 hours of compression. The interface pressure was measured immediately after application of compression, 2 hours after compression, before

and after compression renewal, and finally, after 24 hours. Patients in the ACW group were allowed to adjust the wrap themselves when they considered it necessary.

Results: The reduction in median volume after 2 hours was 109 mL (interquartile range [IQR], 64-271 mL; -3.1%) in the ACW group and 75 mL (IQR, 41-135; -2.4%) in the IMC group (not significant). After 24 hours, the reduction in median volume was 339 mL (IQR, 231-493 mL; -10.3%) in the ACW group and 190 mL (IQR, 113-296 mL; -5.9%) in the IMC group ($P < .05$). The interface pressure dropped significantly after 2 and 24 hours in the IMC group (-50% and -6%), but significantly less in the ACW group (-26% and -44%), mainly due to self-readjustment. The median pressures achieved after self-application of ACW (52 mm Hg; IQR, 44-61 mm Hg) were of the same order as those produced by the nurses after the first application of ACW (53 mm Hg; IQR, 39-59 mm Hg), with less variation.

Conclusions: In patients with moderate to severe lymphedema of the legs, ACW achieved a significantly more pronounced reduction in volume after 24 hours than IMC bandages. Patients were able to apply and adjust the device after being instructed in its use and after an initial 2-hour period of wear. Autonomous handling of ACW seemed to improve the clinical outcome and is a promising step toward self-management involving effective compression. (J Vasc Surg: Venous and Lym Dis 2013;1:13-9.)

Compression therapy is the cornerstone of lymphedema treatment. Despite their efficacy, some traditional bandaging materials have disadvantages because they are

bulky and must be applied by professional health care workers. In terms of self-management, new materials have been developed that will allow patients to apply the bandages themselves, thus making the patient independent from specialized medical staff. To compare results and efficacy of bandaging materials and methods, it is necessary to use standardized bandaging materials, bandaging methods, and measuring equipment.

In 2006, the International Compression Club (ICC) published recommendations for measurements of interface pressure and stiffness,¹ as well as the classification of bandaging materials, by defining four complex central properties of compression bandages: pressure, layers, components, and elastic properties (P-LA-C-E).² These recommendations encourage more evidence-based medical practices in compression therapy. A newly developed adjustable compression wrap (ACW) called Juxta-Fit (CircAid Medical Products, San Diego, Calif) is recommended for the maintenance treatment phase of lymphedema. To our knowledge, the effect on interstitial fluid mobilization

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and volume reduction in the treatment phase of lymphedema and the interface pressures achieved by trained staff or by educated patients applying wraps has not been studied.

METHODS

The Medical Ethics Committee of Nij Smellinghe Hospital approved the study, and all patients signed informed consent forms.

Study design and population. This study was conducted as a prospective, randomized, controlled trial at the Lymphedema Department at Nij Smellinghe Hospital in Drachten, the Netherlands, from January 2010 to August 2011. The study was registered under <http://ClinicalTrials.gov> identifier NCT01068431.

Patients. The study enrolled 30 patients hospitalized for nonoperative treatment of moderate to severe lymphedema of the leg, not responsive to ambulatory lymphedema treatment with compression and manual lymph drainage for at least 6 weeks. The participants were randomized into two groups by sealed envelopes: group A was treated with ACW and group B with inelastic multicomponent compression (IMC) bandages. Both groups consisted of six men and nine women. Patients were a mean age of 54.5 years (range, 33-80 years) in group A and 59.9 years (range, 25-88 years) in group B. The primary-to-secondary lymphedema ratio was 6:9 in group A and 9:6 in group B. The duration of lymphedema at the time of the study was 16.6 years in group A and 11 years in group B.

After the study, patients received our normal treatment program, which consists of decongestive lymphatic treatment, including compression therapy with IMC bandages, manual lymph-drainage, exercise, training in self-care and self-management, dietary guidance, and psychosocial support.

Bandaging materials and techniques. Group A was treated with the Juxta-Fit ACW, consisting of two components: an initial protective cotton tube liner covered by an adjustable inelastic compression wrap (Fig 1). The ACW devices were individually tailored to patient legs.

Group B was treated by means of a three-component Trico IMC system (BSN Medical GmbH, Hamburg, Germany) consisting of an initial protective layer (Tricofix, BSN Medical GmbH) and covered with two layers of synthetic cast wadding (Delta-Rol S; BSN Medical GmbH). Two layers of Trico (12 cm × 4 m) bandaging material were applied over the synthetic cast wadding. Bandage characteristics are summarized in the Table. Personnel who had undergone in-service training in application techniques applied the bandages from the base of the toes to the knee or adjusted and taught the patients how to use the Juxta-Fit wrap.

In both groups, the initial systems were removed after 2 hours. After the initial application, ACWs in group A were reapplied by the patients in cooperation with the hospital personnel, and patients were further instructed in how to readjust the straps for the remainder of the study. In group B, the staff applied new bandages during the

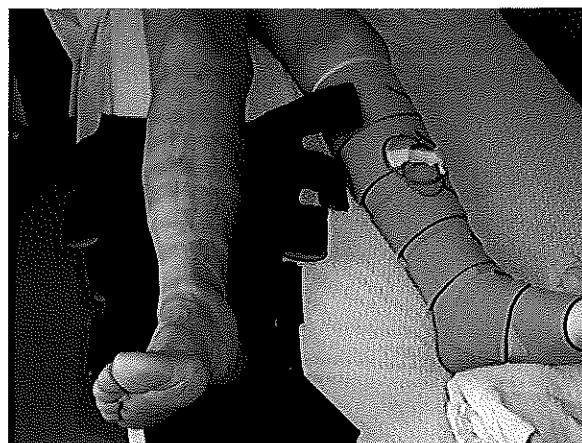


Fig 1. The adjustable compression wrap (ACW) is shown "opened" on the right leg and adjusted on the left leg with the pressure device in place.

following 24 hours. After application of both compression systems, all patients were encouraged to move as much as possible. No other therapeutic intervention was performed before or during the study period.

The primary outcome parameter was the change in volume achieved by the compression systems. We expected to determine the noninferiority of ACW compared with the established IMC bandage system. Changes in sub-bandage pressure and stiffness were considered as a secondary outcome.

Leg volumetry. Leg volume was measured by means of a water-displacement device consisting of an acrylic container filled to the outflow portal with a known amount of water at 30°C.³ The lower leg was then positioned slowly into the apparatus with the patient standing. The displaced water was collected and weighed on a precision scale. This method precisely measures the total amount of leg volume, including the volume of the foot and toe.^{4,5} Leg volumetry was performed on both groups before bandage application, after removal of the initial bandages 2 hours later, and again 24 hours later after second removal.

Measurement of interface pressure. Interface pressures were sampled in both groups by a PicoPress pressure transducer (Microlab Elettronica, Roncaglia di Ponte San Nicolò, Italy), which measures pressures from 0 to 189 ± 3 mm Hg. Silicone pressure sensors (Ø 5 cm × 200 µm, Microlab, Italy) were applied under the bandage material (Fig 2). The submaterial pressure sensor was placed at location B1 (the transition of the Achilles tendon to the calf muscle).¹ Pressures were measured by connecting the sensor to the transducer via a Luer-Lock and using the built-in syringe to inflate the pressure sensors slightly with ambient air (2 mL). Pressures were measured to the nearest mm Hg. Interface pressure was measured statically and dynamically five times in real-time with the patient supine and standing: (1) after the initial bandage application, (2) 2 hours later, (3) before removal, (4) after bandage renewal, and (5) after 24 hours before final removal.

Table. Comparison of two compression materials according to the pressure, layers, components, and elastic properties classification system

Bandage	Pressure (mm Hg)	Layers	Components	Elastic properties
ACW	Strong (40-60)	Two	2	Elastic (moderate stiffness)
IMC	Strong (40-60)	Multilayer	3	Nonelastic (high stiffness)

ACW, Adjustable compression wrap; IMC, inelastic multicomponent compression.

The Static Stiffness Index, calculated by subtracting the supine interface pressure from the standing pressure ($SSI = P_{standing} - P_{lying}$), is an indicator of the stiffness properties of the compression product.⁶ During the dynamic pressure measurements, patients were requested to perform several maximal dorsal flexions before returning the foot to the resting position. The difference between maximum pressure due to dorsiflexion and resting pressure was calculated as the Dynamic Stiffness Index ($DSI = P_{maximum\ movement} - P_{rest\ lying}$).^{7,8}

Statistical analysis. GraphPad Prism 5.0 software (GraphPad Software Inc, San Diego, Calif) was used for statistical evaluation. Values of $P < .05$ were considered statistically significant. Continuous variables are expressed as medians and interquartile ranges (IQR) for skewed

data. Matched pairs (non-Gaussian distribution) were compared using the Wilcoxon matched-pairs test. Results of the two treatment groups were compared with the Mann-Whitney rank sum test.

RESULTS

Leg volume reduction. The median lymphedema leg volume before bandaging was 3570 mL (IQR, 3262-3833 mL) for the ACW group and 3268 mL (IQR, 2982-3707 mL) for the IMC group (Fig 3). After 2 hours, a median volume reduction of 3.1% was measured in the ACW group compared with 2.4% in the IMC group, which was not significant. After 24 hours, the median volume reduction was 339 mL (IQR, 231-493, -10.3%) in the ACW group and 190 mL (IQR, 113-296, -5.9%) in the IMC group (Mann-Whitney, $P < .05$).

Loss of compression pressure. Fig 4 illustrates the loss of interface pressure in both groups when patients were positioned after material application. The median initial (T0) interface pressures were 53 mm Hg (IQR, 39-59 mm Hg) for ACW and 49 mm Hg (IQR, 45-60 mm Hg) for IMC bandages. During the next 2 hours (T2), interface pressures dropped significantly, by 26.1% under ACW and by 50% under IMC (both $P < .001$). After 2 hours, the compression materials were reapplied; ACWs by the patients under supervision, IMC bandages by the staff. Median interface pressures after bandage renewal (T2) were 52 mm Hg (IQR, 44-61 mm Hg) for ACW and 53 mm Hg (IQR, 46-65 mm Hg) for IMC. After 24 hours, the median interface pressures decreased significantly to 33 mm Hg (IQR, 23-40 mm Hg) underneath ACW and to 25 mm Hg (IQR, 21-29 mm Hg) underneath IMC ($P < .001$).

Readjustment of the ACWs and patient satisfaction. Patient interventions in the ACW group were recorded. During the second phase of the study, nine patients made 26 readjustments: the ACW was tightened 14 times and loosened 12 times. Four patients did both, three patients just tightened, and two just loosened. Six patients left the ACWs in place and did not perform a readjustment. During the study, patients were asked to comment on the treatment. In the control group treated with IMC, no complaints were made. In the ACW group, one patient readjusted her ACW five times: three times stiffer and twice looser. The other eight patients, who made readjustments, reported as positive that they could interfere with their treatment according to their perception of the compression.

SSI and DSI results. After bandage application, the IMC group showed a significantly higher SSI and DSI

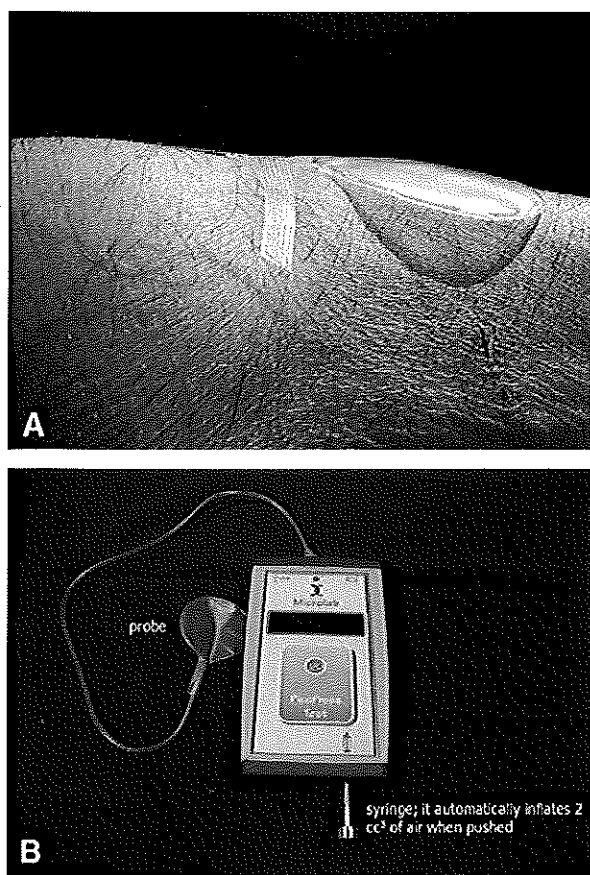


Fig 2. A, Pressure sensor placement on the skin. B, The PicoPress pressure sensor (Microlab Elettronica, Roncaglia di Ponte San Nicolò, Italy).

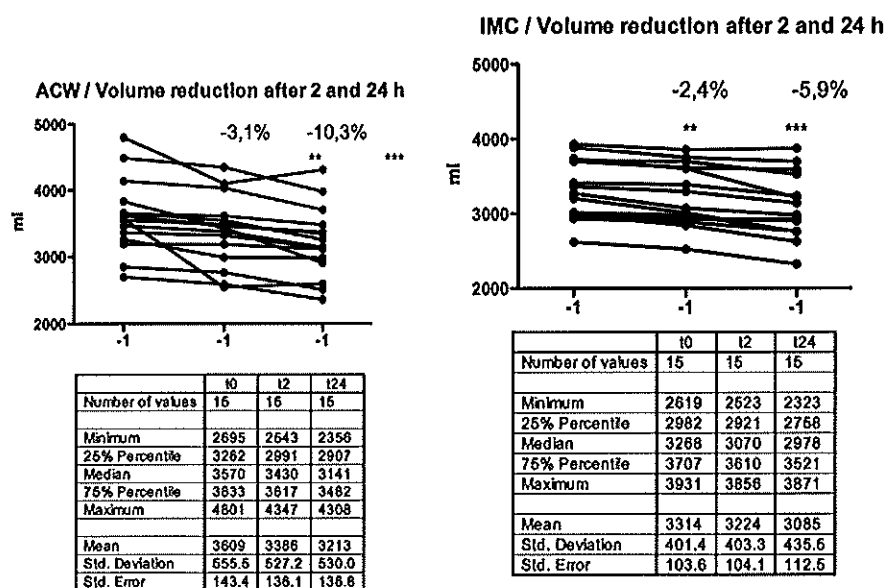


Fig 3. Median volume of the lymphedematous legs is shown before compression and 2 and 24 hours after compression for (left) the adjustable compression wrap (ACW) and (right) the inelastic multicomponent compression (IMC) bandages.

compared with ACW, with median SSI values of 2 mm Hg (IQR, -1 to 7 mm Hg; $P < .001$) for ACW and 12 mm Hg (IQR, 9-21 mm Hg; $P < .05$) for IMC. The corresponding values for DSI were 8 mm Hg (IQR, 2-15 mm Hg) and 12 mm Hg (IQR, 10-22 mm Hg). Fig 5 illustrates the SSI and DSI for both groups.

DISCUSSION

Compression therapy is a fundamental and very potent therapeutic modality in the treatment of lymphedema. Increasingly, new materials are available to provide limb compression. These compression technologies all claim effectiveness and should be proven experimentally. The

Pressure over 24 hours

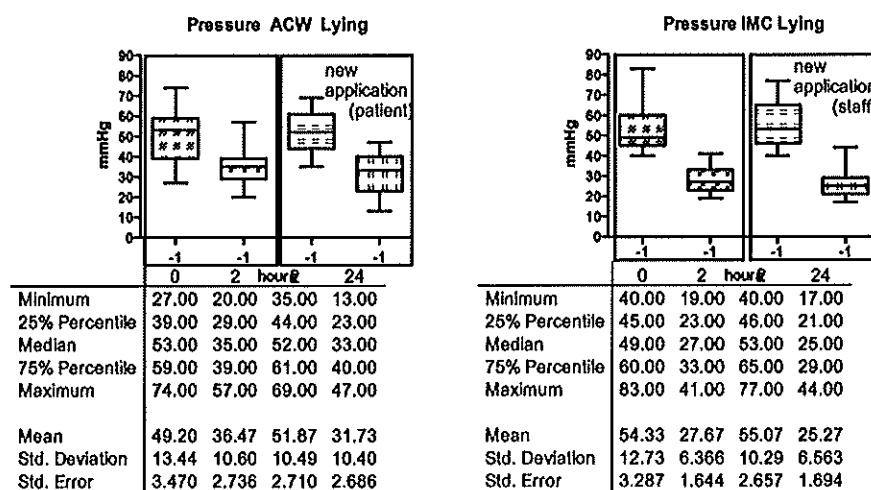


Fig 4. Median supine interface pressure profiles are shown over 24 hours. The initial pressures of the adjustable compression wrap (ACW) and inelastic multicomponent compression (IMC) bandages did not differ significantly after the first application at T0 or after the second application 2 hours later (T2 second). Pressure loss within 2 hours (T2 first) was significant for both types of bandage ($P < .001$). After renewal (T2 second), the pressure range achieved by patients in the ACW group was of the same order as that after the initial application by the staff; however, standard deviation was smaller. The horizontal line in the middle of each box indicates the median; the top and bottom borders of the box mark the 75th and 25th percentiles, respectively, and the whiskers mark the 90th and 10th percentiles.

IMC Has significantly higher stiffness

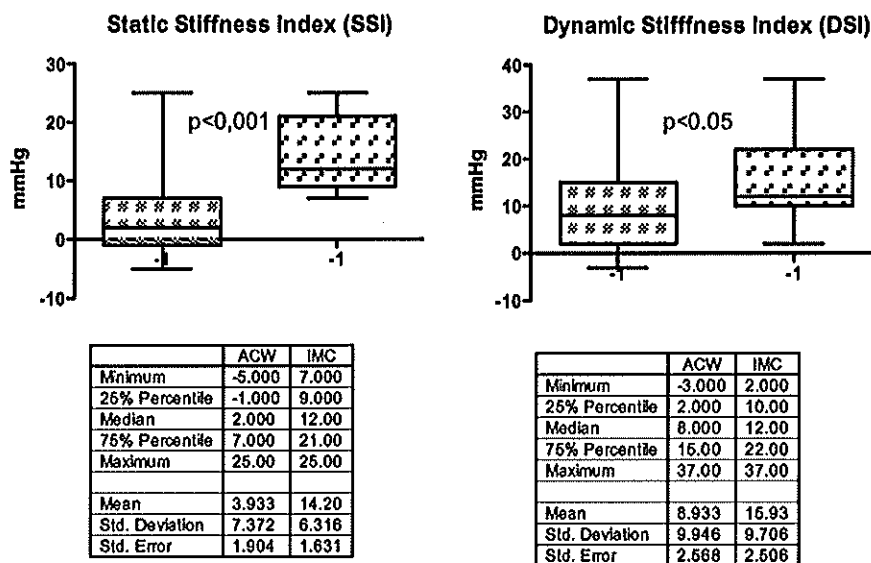


Fig 5. The median Static Stiffness Index (SSI) and Dynamic Stiffness Index (DSI) values of the inelastic multicomponent compression (IMC) bandages were significantly greater than those of the adjustable compression wrap (ACW) at each measurement. This means that inelastic multicomponent compression bandages have a higher stiffness than the ACW. The horizontal line in the middle of each box indicates the median; the top and bottom borders of the box mark the 75th and 25th percentiles, respectively, and the whiskers mark the 90th and 10th percentiles.

effectiveness of treatment depends mainly on the selection of appropriate materials and the application methods used. To obtain a fair comparison between the ACW and IMC compression devices tested in this study, we followed the P-LA-C-E guidelines of the ICC that assess the pressure, layers, components, and elastic properties of compression bandages.² As seen from the Table, "pressure" is related to the magnitude of the compression applied by the bandager (interface pressure), and there was no significant difference between the groups, even after self-application of the ACW device. This system had fewer layers and components, thus making it much less bulky and stiff compared with the conventional lymph bandage.

Up until now, the Velcro compression wrap was mainly used in the maintenance phase of lymphedema treatment. One of the advantages of this wrap is that patients can make their own adjustments, resulting in a better fit. Patient involvement in his or her own treatment is a part of self-management⁹ and is becoming more and more common in chronic disease management. Some of these concepts are based on generic programs developed in the United States, such as the Chronic Disease Self-Management Program (CDSMP). These programs enable the patients to develop appropriate awareness, self-treatment, and self-care skills.¹⁰ In principle, patients who are able to put on their shoes should also be able to apply the ACW system. In cases where self-application may be a problem, such as extreme obesity, relatives may be able to take over home-therapy.

In this study, we explored whether ACW is suitable for the initial treatment phase of lymphedema, as well as later on, when edema reduction needs to be maintained.

Studies concerning volume reduction achieved by compression in leg lymphedema are rare. A previous study from our group, using the same methodology described here with different compression products, reported volume reductions in lymphedematous legs of 4.4% to 8.4% after 24 hours.¹¹ Also, the compression pressures achieved were in the same range as reported in this study. We have learned from these previous trials that despite the same pressure, less bulky bandages that allow for more freedom of movement achieved better results.¹²

Also in our present study, there was significantly greater edema reduction by ACW after 24 hours than with the IMC bandaging system, despite the same initial compression pressure. Patients were allowed to tighten ACWs when it felt loose. This leads also to an increase of the working pressure, producing a stronger massaging effect during walking. The ACW system was less bulky compared with IMC; therefore, it was easier for patients to wear shoes and to walk.

Higher stiffness usually correlates with a stronger massaging effect, while less stiff, more elastic materials applied with the same pressure are not as well tolerated due to high resting pressure. This was not the case in our present study, because the patients were able to readjust the compression of the more elastic ACW system. They were able to loosen it during the night and tighten it

when walking. Stiff material generally exerts a stronger massaging effect during walking but leads to an immediate pressure loss due to edema reduction. This disadvantage of pressure loss is compensated by the readjustment of the straps by the patients.

An interesting finding was that after instruction, the patients applied the device with exactly the same average pressure as they were shown previously. They avoided extreme pressures, which can be seen by the smaller scattering of single pressure values. In other words, patients were able to quickly identify the pressures that worked best. Analysis of dose-response studies regarding the optimal amount of pressure needed to reduce extremity edema indicates that pressures <30 mm Hg are adequate for arm edema¹³ and pressures of 50 to 60 mm Hg are adequate for leg edema.¹⁴ This latter pressure range was also reached by the self-application of ACWs.

This study has several limitations. The study was not blinded, and the study period was short. Because only the lower legs were compressed, some shift of fluid toward the noncompressed parts of the leg was expected, but this was not observed clinically. Future studies measuring the water content of different regions by bioimpedance may clarify this possible effect.¹⁵ The small imbalance in numbers between primary and secondary lymphedema in both groups could theoretically be considered as a bias, although the few other studies of lymphedema and leg compression made no distinction between primary and secondary lymphedema. Therefore, we consider these data just as observational to describe our study group.

A statistical weakness of our study is the relatively small sample size. To achieve a power >80% with 95% reliability, we calculated necessary sample sizes of 741 for a 10% difference in volume reduction between the two study groups and 119 for a 20% reduction. These numbers are not realistic from a practical point of view, however. Another shortcoming of the study is that we were unable to quantify the feelings of the patients concerning the comfort of the compression systems due to the short treatment period.

However, this study indicates good results when patients are involved in their own treatment. The ACW, initially developed for the maintenance phase of lymphedema treatment, was shown to be suitable for the initial treatment phase. Because patients will have varying degrees of leg lymphedema, it is necessary for this device to be available in different sizes. This is to ensure that the device does not need to be changed frequently as swelling subsides. This type of self-care offers an interesting alternative: patients depend less on the professional health care worker and the result of compression therapy is enhanced compared with the traditional ICM bandage.

We deliberately did not include the aspect of cost-effectiveness in the study, although an ACW is much more expensive than a traditional ICM. To obtain a clean comparison of two compression products, no additional treatment modalities, such as manual lymph drainage or intermittent pneumatic compression, were used, and the treatment period was kept short. Because self-adjustable

wraps may offer an innovative way of self-management in the initial treatment phase of lymphedema, the main goal of our investigation was to study its characteristics of exerted pressure and edema reduction and to assess its dynamic and static stiffness *in vivo*, in comparison with conventional bandaging.

CONCLUSIONS

In patients with moderate to severe lymphedema of the legs, ACW achieved a significantly more pronounced volume reduction after 24 hours than ICM bandages. Patients are able to apply and adjust the device after being instructed in its use and after an initial 2-hour period of wear. Autonomous handling of ACW seems to improve the clinical outcome and is a promising step toward the self-management of chronic diseases concerning compression.

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AUTHOR CONTRIBUTIONS

Conception and design: RD, HP

Analysis and interpretation: HP, RD

Data collection: RD

Writing the article: RD

Critical revision of the article: HP

Final approval of the article: RD, HP

Statistical analysis: HP

Obtained funding: RD

Overall responsibility: RD

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