An innovative flat-knit compression garment for lymphoedema patients led to better outcomes: a multicentre study

Objective: To evaluate the clinical performance, quality of life (QoL) and patient satisfaction with an innovative flat-knit compression garment for the daytime treatment of lymphoedema patients in daily routine.

Method: In a prospective multicentre observational study, patients with leg or arm lymphoedema (stage I-II, International Society of Lymphology (ISL) standards, 2016) received a made-to-measure flat-knit compression class 2 JOBST Confidence (BSN-JOBST GmbH, Germany) thigh-high stocking or arm sleeve. Primary endpoint was the oedema status as determined by the mean sum of the circumferences at the beginning and the end of the wearing period. Secondary endpoints included QoL-related parameters and patient satisfaction with product features assessed through questionnaires. The observation period lasted three weeks.

Results: A total of 97 patients (87 females, 10 males), of which 65 had leg lymphoedema and 32 had arm lymphoedema, received the study device. The oedema status was effectively maintained (slight reduction in mean sum of circumferences by –3.1±7.3cm; p=0.0001). For QoL-related parameters, the patients reported fewer limitations in work, leisure and psychological wellbeing after wearing the stocking or arm sleeve (all p-values <0.0001). They also experienced less limitations in function and movement, feeling of tension and heaviness, and fewer difficulties wearing clothes, shoes, jewellery or watches at study end (all p-values <0.0001). In terms of pleasant feeling on the skin, moisture management, softness of material, range of motion, overall wearing comfort and heat build-up under the garment, patients were more satisfied with the tested compression garment than with previously worn compression garments (all p-values <0.001).

Conclusion: In this study, the tested innovative compression product increased patient satisfaction with the improved product features while the lymphoedema status was successfully maintained.

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compression garment • flat-knit compression • lymphoedeoma • oedema management • quality of life • wound • wound care • wound dressing • wound healing

Compression therapy is considered the most important part of lymphoedema management.[1] However, treatment adherence is crucial for ensuring successful therapy outcomes.[2] Adherence is mainly affected by compression tolerability: poor choice of compression garment and its material can cause adverse effects, such as pain, discomfort, tightness, heat build-up under the garment, or skin irritation.[3,4] Such effects were shown to be one of the main reasons for non-adherence.[3] A survey among patients with lymphoedema revealed that 24% never wore their compression stockings.[5] Therefore, new technologies are needed to improve product features which are crucial for good therapy adherence.

To develop an innovative flat-knit compression garment which specifically addresses the needs of patients with lymphoedema, international market research was conducted on behalf of BSN medical GmbH, Germany, in Germany, France, the US and China (data unpublished).[6,7] This research confirmed the results of previously published data.[3,4] Compression garments were found to cause discomfort, restrict mobility, and be hot and sweaty to wear. The market research found that, overall, the wearing of compression garments restricted the daily life of patients and thus resulted in poor adherence (data unpublished).[6,7]

During product development, the patients' main complaints and needs were carefully considered. To identify different body shapes, three-dimensional scanning was used, and special knitting techniques were applied to better mimic the anatomical shape of patients with lymphoedema. The manufacture of flat-knit and round-knit garments is based on the premise that the limb, at the point of measurement, is, in essence, a perfect circle. Clearly, extremities are not exactly circular. Therefore, a unique, patented Contour Fit technology (BSN-JOBST GmbH, Germany) was used, allowing stitches to be added or reduced in four positions, instead of one position, as is common in traditional flat-knit garments. The improved fit and the specific material properties of the garment increase wearing comfort and support a better freedom of movement. The combination of a two-layer knitting structure and functional yarns enable moisture management and thermal wearing comfort. The hydrophobic inner layer pushes moisture onto the

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outer surface of the garment, while the hydrophilic outer layer pulls any moisture away from the skin. This helps to keep the skin dry and to reduce heat build-up.

Both the clinical effectiveness of the compression garment and treatment adherence are important for achieving optimal therapy outcomes.[8] Improved

Table 1. Overview of inclusion and exclusion criteria

Inclusion	Exclusion
• Signed informed consent form • Male, female or non-binary patients aged between 18–70 years with full legal competence • Mentally and physically able to participate in the study • Capable of understanding the subject information and providing conscious informed consent • Capable and willing to follow protocol requirements • All female or non-binary patients of childbearing age must agree to use a reliable method of contraception • Mild-to-moderate lymphoedema of the lower and/or upper extremities (International Society of Lymphology (ISL) stage I or II) • Indication and possibility of treatment with a flat-knitted compression garment during the day • Must be familiar with wearing compression garments • Indicated for complete decongestive therapy phase II (maintenance phase) • Willingness to wear the study product at least five days per week for at least six hours per day	• Pregnancy or lactation • Alcohol and/or drug misuse • Patients who need a different compression class (higher or lower than compression class 2) • Pronounced skin folds or shape distortions • cG (maximum thigh circumference) >90cm for thigh-high compression stocking • Indicated for complete decongestive therapy phase I • Known allergy or intolerance to ≥1 components of the product • Advanced arterial insufficiency including ischaemia • Uncontrolled congestive heart failure • Untreated septic phlebitis • Phlegmasia cerulea dolens • Immobility (confined to bed) • Conditions in which increased venous and lymphatic return is not desired • Weeping dermatosis • Cutaneous infections • Severely compromised skin sensibility and impaired sensitivity of the limb • Advanced peripheral neuropathy • Rheumatoid arthritis • Complex regional pain syndrome (CRPS, Morbus Sudeck) • Malignant lymphoedema • Gangrene • Open wounds in the test area • Diuretics, except low doses for treatment of hypertension (≤12.5mg hydrochlorothiazide) • Nephrotic syndrome • Staff of sponsors or manufacturer

Table 2. Treatment protocol

Study visit	Timing	Location	Purpose
Visit 1: screening visit	28 to 14 days before baseline visit	Practice of the principal investigator	• Obtaining the declaration of informed consent • Collection of information on current lymphoedema treatment • Completion of patient questionnaire on quality of life (QoL)-related parameters and satisfaction with their previous garment • Issuance of order sheets for the study device, prescribed to be either used as a standalone compression garment or in combination with additional compression garments (e.g., bermuda, glove or toe caps) if necessary
Visit 2: ordering visit	14 to 5 days before baseline visit	Sanitary supply store	• Ordering of the study device
Visit 3: baseline visit	Day 0		• Issuance of the study device • Lymphoedema assessment • Circumference measurements • Evaluation of product fit
Visit 4: control visit	7 to 11 days after baseline visit		• Documentation of wearing habits • Lymphoedema assessment • Circumference measurements • Evaluation of performance parameters of the study device (including product fit and oedema management within the last 7 days)
Visit 5: control visit	14 to 18 days after baseline visit		
Visit 6: final visit (end of wearing period)	21 to 25 days after baseline visit	Practice of the principal investigator	• Documentation of wearing habits • Lymphoedema assessment • Circumference measurements • Evaluation of performance parameters of the study device (including product fit and oedema management within the last 7 days) • Completion of patient questionnaire on QoL-related parameters and satisfaction with the study device

product characteristics with a focus on comfort, fit, mobility, heat and moisture management can lead to better adherence and therapy outcomes, as shown by previous case reports.[5,9]

Objectives

The aim of this study was to evaluate clinical performance, parameters related to quality of life (QoL) and patient satisfaction with innovative, made-to-measure, flat-knit compression garments for the daytime treatment of patients with leg or arm lymphoedema in their daily routine.

Methods

This prospective, multicentre observational study was conducted at four sites in Germany from August 2021 to December 2022. Patients with lymphoedema of the arm(s) or leg(s) and who were experienced in wearing compression garments were recruited for the study.

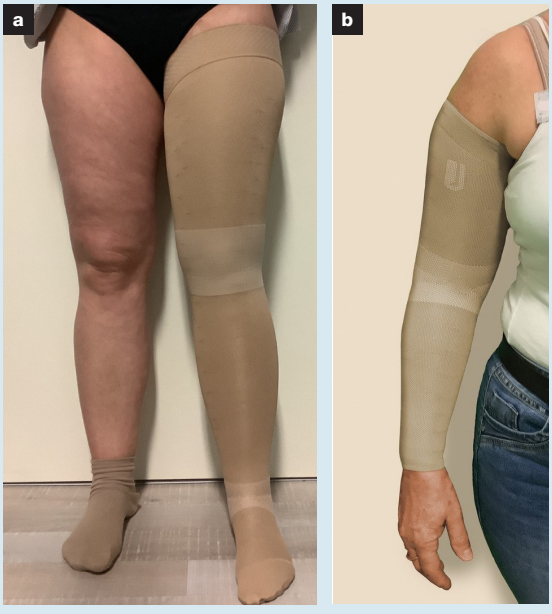
Ethical approval and patient consent

The study complied with the Declaration of Helsinki and the International Organization for Standardisation (ISO) 14155. The study was approved by the Ethics Committee of Ärztekammer Sachsen-Anhalt, Germany, with the ethics approval reference 36/21, on 14 July 2021. Written informed consent was obtained from all the participants, including for the publication of photographs. The study was fully conducted under General Data Protection Regulation.

Inclusion and exclusion criteria

Eligibility criteria are shown in Table 1.

Fig 1. Patients wearing JOBST Confidence (BSN-JOBST GmbH, Germany) thigh-high stocking **(a)** and arm sleeve **(b)**



Treatment protocol

The observational period covered three weeks (wearing time) and six study visits. The timing and purpose of each study visit is shown in Table 2.

Study device

The study device was a made-to-measure flat-knit compression class 2 JOBST Confidence thigh-high stocking or arm sleeve (BSN-JOBST GmbH, Germany) (Fig 1).

Primary endpoint

The clinical performance of the device was evaluated by comparing the lymphoedema status at the beginning and end of the wearing period of the tested compression product. This was determined by the mean sum of circumference measurements at selected points (taken manually using a measuring tape).

Secondary endpoints

Secondary endpoints were evaluated via patient questionnaires and included QoL-related parameters, such as limitations in work, leisure and psychological wellbeing due to the lymphoedema, before and after wearing the tested compression product. Further secondary endpoints were parameters related to patient satisfaction, such as wearing comfort, freedom of movement, moisture management and heat build-up. A comparison of these parameters was made between the previously worn compression garments and the tested compression product. Questionnaires were completed before wearing the tested compression product and again at the end of the study.

Statistical analysis

Sample size

A total of 110 patients were considered for enrolment in the study. The expected drop-out rate was 20% (22/110).

Statistical methods

Mean±standard deviation (SD), percentiles, and minimum and maximum values were displayed for the primary endpoint, and frequencies of responses were shown as percentages for the secondary endpoints. Descriptive statistics were performed for baseline data, treatments, as well as primary and secondary endpoints. A t-test was used to assess the primary endpoint as the assumption of a normal distribution could not be rejected. For the secondary endpoints, a normal distribution could not be assumed, thus a Wilcoxon signed-rank test was used. Results were considered statistically significant when the p-value was <0.05.

The following data sets were evaluated:

- For primary endpoint analysis: all participants who wore the tested compression product for at least one week and attended at least one of the follow-up visits.
- For the secondary endpoint analyses: all participants who wore the tested compression product for at least one week and attended the final visit.

Results

A total of 99 patients were screened, 98 were included in the study and 97 received the study device (one patient was lost to follow-up after visit 1, before receiving the study device). The study was completed by 88 patients (90.7%).

Study population

The study population of 97 patients included 87 (89.7%) women and 10 (10.3%) men. Of these, 65 (67%) patients had leg lymphoedema and 32 (33%) patients had arm lymphoedema (stage I-II, International Society of Lymphology (ISL) standards[10]), and 21 (21.6%) patients were diagnosed with primary lymphoedema and 77 (79.4%) were diagnosed with secondary lymphoedema; one patient had both primary and secondary lymphoedema. The average patient had 2.7 concomitant diseases. The most frequent concomitant diseases were: hypertension (44 patients), hypothyroidism (29 patients), and breast cancer (23 patients; either ongoing or condition after). The mean age was 54.8±9.9 years (minimum: 18 years; maximum: 70 years). The mean body mass index was 30.2±6.4kg/m^2). All 97 patients had previously worn flat-knitted compression garments.

Primary endpoint

In all, 92 patients were eligible for the primary endpoint analysis.

Circumference measurements

The analysis showed a slight reduction of –3.1±7.3cm in the mean sum of the circumferences at the end of the wearing period (p<0.0001) (Table 3).

Secondary endpoints

A total of 85 patients were eligible for the secondary endpoint analysis.

Evaluation of QoL-related parameters

Questionnaires were used to assess the impact of the oedema on psychological wellbeing, leisure time and work. The patients evaluated these parameters for the previously worn product at visit 1 and for the tested compression product at visit 6 (Fig 2). Significantly more patients reported no or almost no restrictions in all rated categories when wearing the tested compression product compared with their previously worn product (all p-values <0.0001). No study participant reported severe restrictions when wearing the tested compression product.

Patients were also asked to assess the following categories with regard to their affected extremity: limitation in function and movement; feeling of tension; feeling of heaviness; and difficulty wearing clothes, shoes, jewellery or watches (Fig 3). In these categories, patients perceived significantly fewer limitations due to their lymphoedema at the end of the study (all p-values <0.0001). Of note, no patient reported a strong limitation in function and movement, or very strong feelings of tension and heaviness at visit 6.

Evaluation of product features

The patients evaluated different product features, such as: general wearing comfort; range of motion; fit; softness of the material; moisture management; pleasant feeling on the skin; and heat build-up under the garment (Figs 4 and 5). All product features were

Fig 2. Patients' evaluation of restrictions to psychological wellbeing, leisure time, and work due to their lymphoedema for the previously worn product at visit 1 (screening, V1) and the tested compression product at visit 6 (end of wearing period, V6)

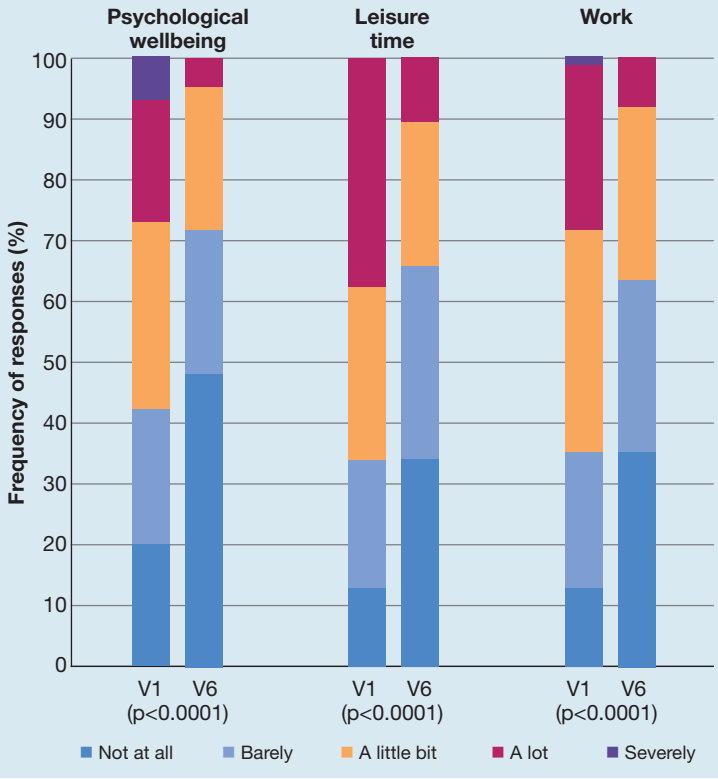
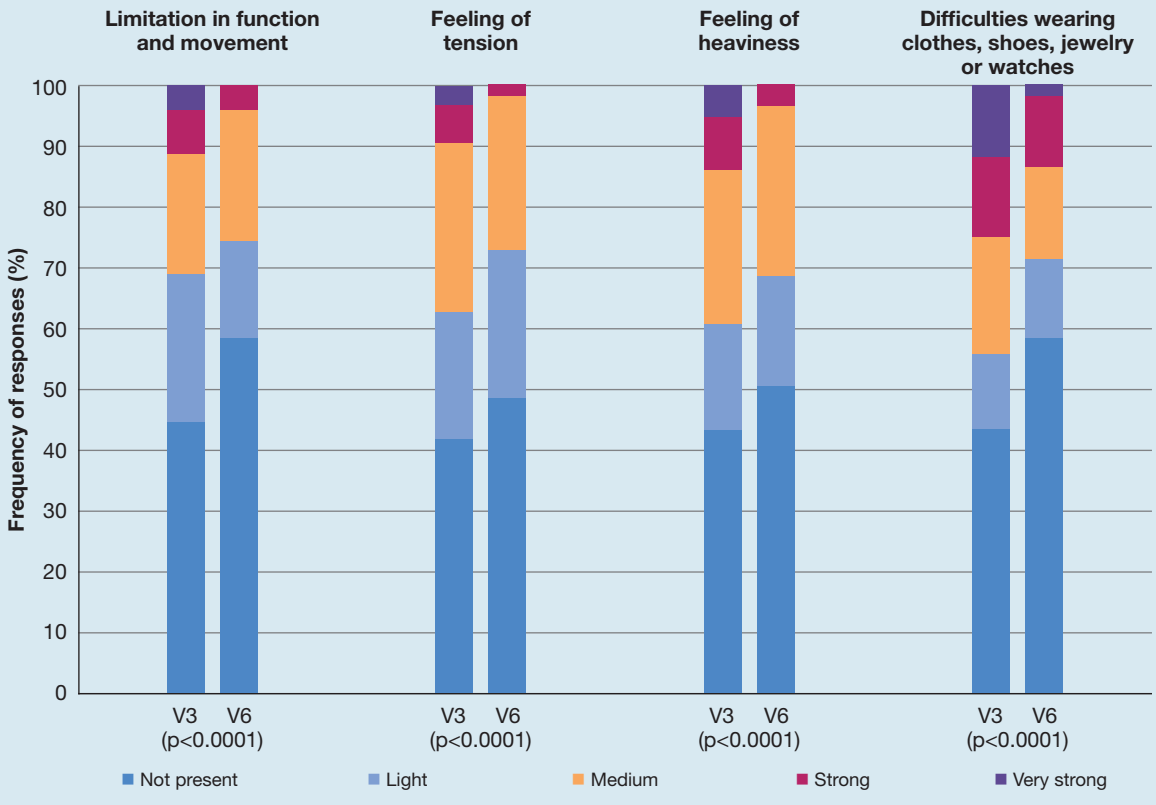


Table 3. Comparison of the mean sum of circumferences between the baseline visit (V3) and end of the wearing period (V6)

Variable	n	Mean	SD	Min	Q1	Median	Q3	Max	p-value
Mean sum of circumferences (V6 minus V3)	92	–3.1	7.3	–2.1	–7.5	–2.6	1.8	14	0.0001

Max—maximum; Min—minimum; Q—quarter; SD—standard deviation

Fig 3. Patients' evaluation of how oedema limited their function and movement, the feeling of tension, the feeling of heaviness, and difficulties wearing clothes, shoes, jewellery, or watches at visit 3 (baseline, V3) and visit 6 (end of wearing period, V6)



rated better for the tested compression product than for the previously worn product. Statistical significance ($p<0.001$) was reached for all features, except for product fit ($p=0.2083$).

Furthermore, patients had slightly fewer difficulties putting on and taking off the compression product, and needed significantly less help compared with their previously used products (help with putting on the product V6–V1: mean –0.2±0.5; $p=0.0156$). Finally, when patients were asked whether they would recommend the tested compression product, most patients said that it is 'very likely' (56.5%) or 'rather likely' (16.5%) ($p<0.0001$) that they would recommend it to others (rating was based on a five-point scale ranging from 'very likely' to 'very unlikely).

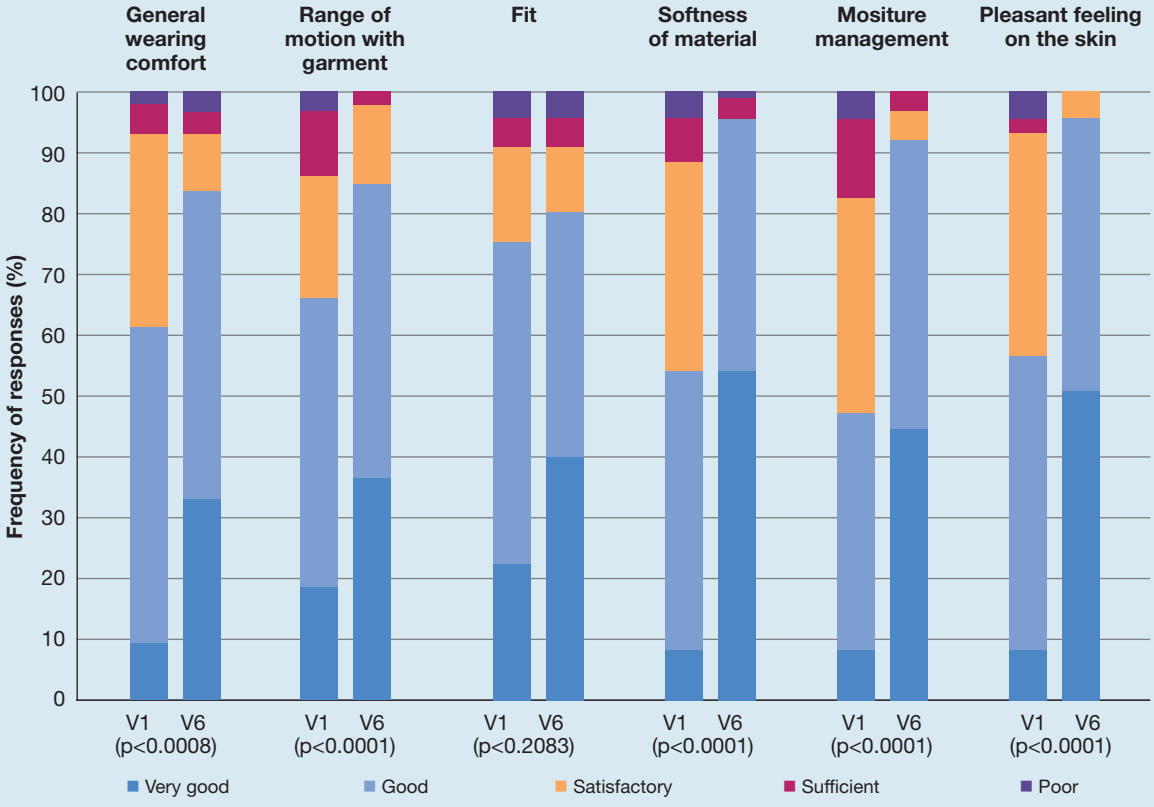
Discussion

Wearing comfort, mobility, moisture management and thermal wearing comfort are critical aspects for adherence in wearing compression garments in patients with lymphoedema (data unpublished).[6,7] The tested compression product used in this study was shown to improve these factors, while the lymphoedema was successfully managed. Compared with their previously worn product, significantly more patients reported no or almost no restrictions when it came to work, leisure time and their psychological wellbeing due to their lymphoedema when wearing the tested product.

Even though the importance and effectiveness of compression therapy is well known, there is little evidence on the impact of materials of which compression garments are made or of other product features (e.g., material surface and structure, fit/form, ability to manage heat, moisture etc.). In this study, most patients agreed that the tested compression product produced a pleasant feeling on the skin and confirmed the softness of the material. The tested compression product was also evaluated to be more comfortable and to provide a better range of motion compared with previously worn products. The improved product features resulted in increased comfort, while still effectively maintaining oedema status.

The patients reported improved QoL-related parameters when wearing the tested compression product. However, the impact of such features on treatment adherence and QoL in general needs further investigation. At present, there is no consensus on the most appropriate definition and measurement of treatment adherence.[11] Both the number of hours per day and the number of days per week that the compression garment is worn are important considerations.[11] However, the lack of a standardised approach to measuring treatment adherence makes it difficult to compare different study results.[11,12]

Fig 4. Patients' evaluation of product features of the previously worn product at visit 1 (screening, V1) and of the tested compression product at visit 6 (end of wearing period, V6)

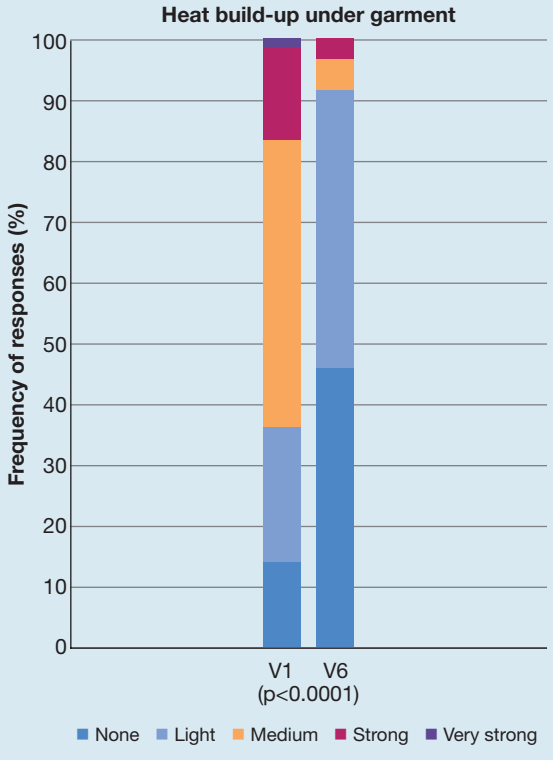


Treatment adherence to the tested compression product was defined, in this present study, as patients wearing the product for at least five days per week and at least six hours per day, and was investigated as an exploratory endpoint of the study (data not shown). The mean adherence with the tested compression product ranged from 77.2±19.2% to 84.9±16.7% depending on the imputation method for missing values. There is currently limited information from scientific literature about the treatment adherence with compression therapy.[13] A study with a large cohort of 3144 patients with chronic venous disease (CVD) revealed very low compliance to compression, with only 21% of patients reported as using the stockings on a daily basis, 12% using them most days, and 4% using them less often. The remaining 63% did not use the stockings at all or had abandoned them after a trial period in the past.[14] In contrast, a summation analysis of compliance with compression hosiery for patients with CVD or post-thrombotic syndrome, including 37 randomised trials and 21 prospective studies, showed that, overall, there was good compliance with compression in 5371 of 8104 (66.2%) patients.[4] The same study also demonstrated that different factors, such as the applied pressure and study type, influenced compliance.[4] However, since there is no standardised approach for measuring treatment adherence, reported values for patients with CVD range between 20–98% in real-world studies.[15] So far, data on adherence in patients with lymphoedema is limited to case studies.[16]

As mentioned above, the assessed QoL-related parameters were significantly better for the tested compression product compared with the previously worn product. QoL in patients with lymphoedema is affected by various factors, including the presence of pain, skin quality, psychological factors and reduced mobility, among others.[17] There is limited information about which of these factors has the strongest impact on QoL; however, skin problems such as dryness and itching are frequently reported.[18] Since no standardised questionnaire was used in this study to analyse QoL on a more detailed and comparable level, the significance of the results needs verification.

Therefore, future studies are needed to evaluate the impact of improved product features on both treatment adherence and QoL. Valid and reliable tools to measure patient-reported outcomes specific to lymphoedema are also needed to better evaluate treatment efficacy from a patient's perspective.[19] The Dutch International Compression Club Compression Questionnaire (ICC-CQ), for example, could be a suitable method to assess the effect of compression and its acceptance in patients with lymphoedema or CVD.[20] In addition to assessing the improvement of QoL during treatment, it

Fig 5. Patients' evaluation of heat build-up under the garment for the previously worn product at visit 1 (screening, V1) and for the tested compression product at visit 6 (end of wearing period, V6)



also considers comfort of the material, ease of application and removal, and assesses the skin under the compression material.[20]

Limitations

Single-arm studies are generally limited due to the lack of a control group. A direct comparison of the tested compression product to another compression garment could have resulted in a more robust assessment of product features and QoL-related parameters.

Furthermore, different health professionals (HPs) evaluated the same parameters at different timepoints, e.g., study visit 1 and visit 6 were performed at the principal investigator's sites by physicians, whereas the intermediate visits 2–5 were performed by the fitters at the sanitary supply store. The comparison of the data from the baseline visit 3 and final visit 6 might have been more calibrated if carried out by the same HP.

In addition, 21 patients changed the style of their compression garment at study entry. Although this was not planned, the physicians deemed it necessary. Patients who had previously worn a knee-high compression garment switched to the thigh-high tested compression product. This may have impacted several parameters. A subgroup analysis showed, for example, that reduction in leg circumference was more pronounced in those who previously wore knee-high stockings. This was probably due to additional decongestion in the thigh region. The analysis also revealed that the majority of critical or negative ratings for the study device seemed to accumulate within the subgroup of patients who were not previously familiar with wearing thigh-high compression garments. This is in line with additional subgroup analysis results, which revealed that patients with lymphoedema of the upper extremity generally evaluated the study device more positively. Hence, some study results might have been weakened by mixing the two groups.

Conclusion

This study demonstrated that the tested compression product, an innovative flat-knit garment with improved product features, effectively managed the oedema in patients with lymphoedema. The device improved wearing comfort, freedom of movement, moisture management and thermal wearing comfort, and decreased oedema-related restrictions to work, leisure time and wellbeing. Further studies are required to assess the impact of improved product features on treatment adherence. JWC

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Reflective questions

- Do compression garments with such improved product features also improve treatment adherence?
- To what extent do improved product features impact the quality of life of patients with lymphoedema?
- What is the best way to measure therapy outcomes in patients with lymphoedema?

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