

BRITISH JOURNAL OF
COMMUNITY
NURSING

Impact of seamless compression
garments on limb functionality,
comfort and quality of life

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ABSTRACT

Lymphoedema is a chronic disease affecting the patients' quality of life (QoL) especially with regard to mobility and daily activities. Lymphoedema cannot be cured but symptoms can effectively be improved by a comprehensive approach and the continuous use of compression therapy. An appropriate fitted compression garment is essential for compliance and thus a prerequisite for successful lymphoedema management. Compression garments with bulky seams are not only uncomfortable they also can lead to severe pressure marks or even reduce the mobility and function of the affected limb, which may negatively impact the already reduced QoL of lymphoedema patients.

A prospective multicentre observational study was conducted to compare compression garments without and with a seam for hands and toes in 143 patients with lymphoedema.

Product performance, lymphoedema symptoms, functionality of hands/toes, QoL and patient satisfaction were documented for the previously worn compression garment as well as for the 3D flat knitted JOBST® Elvarex Plus compression garment without a seam.

The JOBST Elvarex Plus glove was perceived very positively by patients, who rated the mobility of the fingers, the adaptability to the shape of the hand/fingers, the fit of cuffs/welts, and the tactile sense of the fingers to be significantly better compared to the previous glove. Also pressure marks between fingers/toes and pressure marks due to cuffs/welts were significantly less frequent when wearing JOBST Elvarex Plus. Also pain, sensation of heaviness, swelling, tightness and dryness of skin were significantly improved when wearing JOBST Elvarex Plus gloves. Furthermore, 80% of the patients rated the wearing comfort of JOBST Elvarex Plus to be better than their previous garments with a seam. Regarding functionality, patients were significantly less limited in their daily activities when wearing JOBST Elvarex Plus garments. Finally, when wearing JOBST Elvarex Plus gloves and toe caps, patients rated the negative effect of their lymphoedema on their QoL to be significantly lower. In conclusion, the application of anatomically adapted compression garments without a seam led to improving patient's reported lymphoedema symptoms, increased patient's satisfaction with the compression garment and supported a better QoL.

KEY WORDS

- ◆ lymphoedema ◆ compression garments without a seam
- ◆ limb functionality ◆ quality of life

Accepted for publication: August 2017

Lymphoedema is a chronic disease characterised by accumulation of interstitial lymph fluid leading to swelling and progressive tissue transformation. It is either congenital (primary) or acquired (secondary) abnormality of the lymphatic system (Rankin and Cooper, 2016). Cancer treatment-related secondary lymphoedema is a significant health issue (Hayes et al, 2008). Hayes et al (2008) reported that from 6–18 months after breast cancer surgery, 33% (n=62) of the patients were classified as having lymphoedema; of these, 40% had long-term lymphoedema. It can appear in any area of the body, depending on the initial tumour site and the related surgical procedures. Arms and hands are most commonly affected in women suffering from breast cancer (Karadibak and Yavuzsen, 2015; Caffo et al, 2003; Engel et al, 2003; Voogd et al, 2003) and correspondingly, lower limb lymphoedema is a frequent complication of gynecological or urological cancer treatment (Deura et al, 2015; Beesley et al, 2015; Hyngstrom et al, 2013; Campanholi et al, 2011).

Lymphoedema patients develop symptoms such as swelling, feelings of heaviness, pain and discomfort, which significantly reduces their physical functioning, mobility, and ability to perform daily life activities (Teo et al, 2015; Karadibak and Yavuzsen, 2015). In addition, patients show mental and emotional distress, commonly including increased levels of anguish, feelings of helplessness, fear of the possible progression of disease, as well as adverse changes in body image and reduced self-esteem (Beesley et al, 2015; Ferreira et al, 2016; Finnane et al, 2011; Taghian et al, 2014; Yost et al, 2014; Devoogdt et al, 2014; Lockwood-Rayermann, 2007; Williams et al, 2005). It is widely accepted that lymphoedema-related restrictions in everyday activities have a major impact on the patients' quality of life (International Society of Lymphology, 2013).

Lymphoedema cannot be cured but effectively managed by the application of compression treatment, manual lymphatic drainage, skin care and exercise (Oremus et al, 2012) with the goal of lymphoedema reduction, skin improvement and an increase of mobility and function (National Lymphoedema Network, 2011). Complex

decongestive therapy is today's gold standard for the treatment of lymphoedema (International Society of Lymphology, 2013). It is composed of the systematic application of manual lymph drainage, compression therapy with short-stretch bandages, exercise, skin care and supported self-management with compression garments (Mayrovitz, 2009; Szuba et al, 2000). Surgery treatments have been developed e.g. lymphatic-venous anastomosis, which has been demonstrated to be an effective strategy to treat lymphoedema, especially in secondary cases in early stages (Gennaro et al, 2016). Nevertheless, most of the patients need lifelong compression therapy.

Compression garments direct the lymph fluid out of the affected limb and can support the overall mobility (Partsch, 2012; International Lymphoedema Framework, 2012). After a maximal volume reduction, a well-fitted compression garment maintains the lymphoedema at a reduced level. In order to manage lymphoedema successfully, compression garments should be well tolerated and worn as much as possible (Hobday, 2016). A perfectly fitted compression garment is essential for the patient's compliance to compression therapy. Bulky seams or improper fitting garments are not only uncomfortable but can lead to severe health problems such as pressure damage or even necrosis (Williams, 2003; Hampton, 2003). In addition, reduced mobility and function of the oedematous limb caused by the compression garment may result in a reduced quality of life for patients who already suffer from a reduced quality of life due to their oedema (Williams et al, 2005; Lee and Wigg, 2013). Viehoff et al recently assessed the impact of lymphoedema from the patient's perspective using the international classification of functioning, disability and health. Results confirmed that even though improving their symptoms, patients considered garments and bandages as barriers to a normal daily life (Viehoff et al, 2015).

Compression garments are available in a wide variety of types and styles (Elwell, 2016). They can differ based on their knitting technology (round-knit or flat-knit), overall fit (ready-to-wear or custom-made) and compression class (Partsch, 2012). This variety allows individualised treatments based on patients' needs.

To offer an effective compression garment that allows for a continuous and successful treatment with improved patient comfort, JOBST® Elvarex Plus gloves and toe caps were developed. Both flat-knit compression garments are produced through a unique 3D flat-knitting technology allowing seamless processing and anatomical fit, anticipating a better wearing adherence.

Purpose of the study

The overall aim of this observational study was to gain a better understanding of the effect that the use of different flat-knit compression garment with a seam as well as the seamless 3D flat-knitted JOBST Elvarex Plus has on the life of lymphoedema patients.

Methods

Study design and settings

This prospective multicentre observational study was designed to assess and compare performance parameters and patient opinions on flat-knitted compression garments (gloves and toe caps) with and without a seam.

All patients were experienced with compression therapy (garments with seams by any manufacturer including JOBST®). Within the scope of the study, patients were equipped and treated with either a custom-made, seamless JOBST Elvarex Plus compression glove or toe cap (class I or II), depending on their medical prescription. The garments – certified medical devices – were used by the patient as part of their recommended lymphoedema treatment following the instructions for use provided by the manufacturer.

Since correct fitting and handling is very important, measurement and fitting was only performed the onsite study coordinators or by selected staff members at the medical supply store/clinic who were trained by contracted onsite study coordinators in advance. The contracted onsite study coordinators also standardised the measurements (tape measure) and provided training in handling of the gloves and toe caps.

The study was conducted between October 2015 and March 2016 at 21 medical supply stores in Germany and two clinics in Norway. Whereas the recruiting was initiated by two contracted onsite study coordinators, further site management was supported by a certified contract research organisation. The completed questionnaires were collected by the medical supply shop/clinic and the data analyses was performed by a contracted research organisation.

Patients had to meet certain inclusion criteria and were not enrolled in the study if meeting any exclusion criteria (see the following section).

The following performance parameters and patient perceptions were defined:

- ♦ Lymphoedema symptoms before and after wearing the seamless JOBST Elvarex Plus compression garment for 14 days
 - ♦ Patient's opinion regarding the product characteristics of the seamed compression, previously worn by the patient (experience of the patient), and the seamless JOBST Elvarex Plus garment after 14 days
 - ♦ Patient's opinion regarding the functionality of the hand or toes while wearing the seamed compression garment, previously worn by the patient (experience of the patient) and the seamless JOBST Elvarex Plus compression garment after 14 days
 - ♦ Patient's quality of life before and after wearing the seamless JOBST Elvarex Plus compression garment for 14 days
 - ♦ Patient satisfaction after 14 days of wearing the seamless JOBST Elvarex Plus compression garment in comparison to their previously worn seamed garment
- To capture the patient's opinion on product characteristics

and wearing experience, as well as aspects concerning the quality of life of the patients linked to toe cap or glove wear, a questionnaire was developed combining questions concerning the product characteristics of the products with relevant QoL questions of a validated questionnaire (Keeley et al, 2010). According to Keeley et al, the quality of life aspects linked to a patient's hand oedema as well as of toe cap or glove wear, were assessed using a 10-point semantic differential scale based on the validated questionnaire by Keeley et al (2010). The setup of the questionnaire was conducted in close cooperation with an experienced lymph therapist.

Criteria

Inclusion criteria

- ◆ Age ≥ 18 years
- ◆ Men and women indicated for compression therapy of a lymphoedema of the hand or foot with a flat-knit compression product
- ◆ Last medical prescription for compression garments for the same extremity within 6 months prior to inclusion
- ◆ Experience of use of a seamed compression garment within the same compression class as the newly prescribed compression garment and worn on the same extremity for at least 5 days per week and for at least 6 hours per day
- ◆ Willingness of the patient to wear the test product for at least 5 days per week and at least 6 hours per day
- ◆ Patient was mentally and physically able to take part in the study
- ◆ Signed informed consent

Exclusion criteria

- ◆ Ischaemia (e.g. advanced peripheral arterial occlusive disease)
- ◆ Decompensated heart failure
- ◆ Untreated septic venous inflammation
- ◆ Severe form of thrombosis (phlegmasia cerulea dolens)
- ◆ According to the instruction for use, patients were made aware that wearing compression garments may lead to problems in the following cases:
 - Immobility (e.g. after being bedridden)
 - Skin inflammation (skin infection) in the extremity indicated for compression treatment
 - Wet dermatoses of the extremity indicated for the compression treatment
 - Known intolerance/allergies to materials of the compression garment
 - Relevant sensory disorders of the hands or feet (e.g. relevant polyneuropathy of diabetes mellitus)

Study schedule

The study duration for each patient was approximately 4 weeks including 3 appointments: at the first appointment informed consent, demographic data such as age and sex, history of lymphoedema and criteria on patient suitability were recorded. Measurement of hand and feet circumferences

were taken and the patient filled in the first questionnaire, Q1, assessing his/her previous experience of garments with a seam. At the second appointment, the JOBST Elvarex Plus garment as well as the second questionnaire, Q2, was distributed. After checking the proper fit of the JOBST Elvarex Plus garment, the observation period of 14 days started where the patients wore the compression garment for at least 5 days per week and at least 6 hours per day. The third appointment was merely arranged if required by the patient, e.g. to reassure them of the correct fit of the garment or to address any questions regarding the handling of the product. If the appointment took place, the completed second questionnaire, Q2, was collected. Otherwise, the patient was asked to send it to the medical supply store or clinic by post.

Ethical considerations

This study was approved by the ethics committee 'Freiburger Ethikkommission International' and conducted based on the principles of the Declaration of Helsinki. Informed consent was received from all patients. Patients could withdraw their consent at any time without providing any reasons.

Statistical analyses

Statistical analyses were carried out by using the Statistical Analysis System 9.3 (SAS Institute Inc., North Carolina). The analysis was performed for all patients who completed the 14-day observation period and returned the second questionnaire within the agreed deadline. All recorded data and responses from the questionnaire were evaluated descriptively. Continuous variables were presented as mean \pm standard error (SE). Percentage values were used to summarise nominal and ordinal data.

A Wilcoxon signed-rank test was performed to detect differences in the mean score between the previously worn garment with a seam and the JOBST Elvarex Plus garment. A p-value of ≤ 0.05 was considered to be statistically significant.

Results

Patients

A total of 143 patients were enrolled. Of those, 10 patients dropped out due to less-than-ideal fit of the compression garment (n=3), withdrawal of consent due to non-oedema related health issues (n=2) and failure to return the second questionnaire by the agreed deadline (n=2). Moreover, one patient withdrew her consent without stating a reason, one patient died due to non-oedema-related health issues, and for one patient it turned out after inclusion that she did not fulfil the inclusion criteria entirely. A total of 133 patients completed the study and were eligible for statistical analyses. Of those, 98 (73.7%) patients were treated with compression gloves and 35 (26.3%) patients with compression toe caps. Neither any incidents nor any adverse effects associated with JOBST Elvarex Plus were reported.

Demographic data and lymphoedema anamnesis

Demographic data of the 133 patients were collected at the first appointment (Table 1). In both groups (glove and toe cap), the vast majority of patients were female (glove: 88.8%; toe cap: 77.1%). The mean patient age was 60.2±1.2 years for compression gloves and 56.1±2.8 years for toe caps.

The majority of lymphoedema patients treated with compression gloves developed their lymphoedema in the context of a malignant disease (81.6%) (Table 1). Conversely, most patients treated with a compression toe cap suffered from primary lymphoedema (57.1%). On average, the lymphoedema was present for 6.9±0.7 years in hand oedema patients and for 12.8±2.2 years in foot oedema patients with a similar duration compression therapy in both groups (5.2±0.5 years and 5.5±1.0 years, respectively).

Patients rate fit of compression garment to be more important than outer appearance

First, the patients' needs were collected by asking the patients to rate the overall importance of given product characteristics for gloves and toe caps by assigning scores on a scale from 1 ('not important at all') to 6 ('extremely important') (Table 2). The vast majority of assessed product characteristics for gloves and toe caps was considered to be very important to the patient (mean score ≥5 for nearly 80% of the addressed characteristics). Merely the appearance (inconspicuousness, worn out look) was found to be of a lower importance (mean score between 3.4 and 4.8), with a tendency to be more relevant for gloves than for toe caps.

KEY POINTS

- ◆ Patients rated proper fit of a compression glove or toe cap to be very important to not cause pressure marks or restrict the mobility of fingers
- ◆ Patients also rated product characteristics that refer to the fit of the garment to be better for JOBST Elvarex Plus garments than for garments with a seam.
- ◆ Typical lymphoedema-related signs of discomfort and medical conditions were reported to occur less frequently when wearing a JOBST Elvarex Plus garment compared to a garment with a seam.
- ◆ Over 80% of patients were more satisfied with the wearing comfort of JOBST Elvarex Plus garments compared to seamed garments.
- ◆ Limitations of hand and foot functionality were reported to be less pronounced and patient's rated their quality of life to be less effected by their lymphoedema when wearing JOBST Elvarex Plus garments compared to seamed garments.

For patients treated with compression gloves and based on the average scores for all addressed product characteristics, it was most important that the glove does not cause any uncomfortable pressure marks (5.9±0.05) and that it restricts the mobility of the fingers as little as possible (5.9±0.04).

Likewise, patients treated with compression toe caps found it most important that the garment does not cause any uncomfortable pressure marks (5.9±0.05). Based on all average scores it was equally important that the glove/toe cap adapted well to the shape of the hand/foot and fingers/toes (5.8±0.05/5.8±0.10) as well as that the toe cap allowed for wearing closed shoes (5.8±0.07).

Table 1. Demographic data and lymphoedema anamnesis

	Glove outcomes (n=98)	Toe cap outcomes (n=35)
Sex		
Female, n (%)	87 (88.8%)	27 (77.1%)
Male, n (%)	11 (11.2%)	8 (22.9%)
Age		
Age in years, mean ± SE	60.2±1.3	56.1±2.8
Underlying disease¹		
Cancer, n (%)	80 (81.6%)	6 (17.1%)
Unspecified disease (surgically treated) or injury, n (%)	7 (7.1%)	7 (20.0%)
Other disease, n (%)	8 (8.2%)	3 (8.6%)
Primary lymphoedema, n (%)	5 (5.1%)	20 (57.1%)
Presence of lymphoedema		
Duration in years, mean ± SE	6.9±0.7	12.8±2.2
Lymphoedema treatment with compression garment		
Duration in years, mean ± SE	5.2±0.5	5.5±1

¹Multiple answers were possible

CPD REFLECTIVE QUESTIONS

- ◆ What are your patient's expectations of a compression glove or toe cap?
- ◆ Are your patient's expectations met and are they satisfied with their garments? If so, how?
- ◆ Do your patients report to be limited in conducting simple tasks in their daily life when wearing compression gloves and toe caps? If so how?
- ◆ How do your patients' gloves and toe caps affect their quality of life?

Characteristics of JOBST Elvarex Plus compression garment addresses patients' needs

To assess how JOBST Elvarex Plus seamless garments are concordant with patients' expectations when compared with previous garments with a seam, patients were asked to rate how well their garments met defined product characteristics on a scale from 1 ('does not apply at all') to 6 ('applies entirely') (Figure 1, compared with Table 2).

JOBST Elvarex Plus gloves were rated significantly better when compared to the previous glove for a number of product characteristics (Figure 1) that refer to the previously identified patient needs (Table 2). Superior rating for JOBST Elvarex Plus versus previous glove was observed for product characteristics such as 'fit of cuffs and welts' (5.2±0.14 vs 4.7±0.15, p=0.0057), 'adaptability to the shape of the hand and fingers' (5.1±0.13 vs 4.7±0.14, p=0.0025), 'restriction of the tactile sense of the fingers' (4.2±0.15 vs 3.7±0.16, p=0.0059), and 'restriction of the mobility of the fingers' (4.2±0.16 vs 3.7±0.14, p=0.0218) (Figure 1a).

For patients with toe caps (Figure 1b), the possibility to wear the garment with sandals or comfortable shoes was

rated significantly better when wearing JOBST Elvarex Plus toe caps compared to the previous toe caps (4.9±0.23 vs 4.3±0.27, p=0.0190). For the remaining assessed product characteristics the JOBST Elvarex Plus toe cap was generally rated better with the exception of the two features related to product appearance (Figure 1).

Lymphoedema-related discomfort was reported to occur less frequently when wearing JOBST Elvarex Plus garments compared to seamed garments

To analyse the impact of JOBST Elvarex Plus seamless compression garments when compared with previous garments with a seam on typical signs of discomfort and medical conditions associated with their lymphoedema, patients assessed the experienced effects on a scale from 1 ('never') to 6 ('always') (Figure 2). Patients treated with compression gloves with a seam rated, on average, the 'restriction of motion', 'sensation of heaviness', and 'dry skin' to be the most present factors of all addressed discomfort/medical conditions (Figure 2a). These limitations were found to occur less frequently as indicated by lower mean score values when wearing a JOBST Elvarex Plus glove versus the previous glove (motion restriction: 2.8±0.13 vs 3.6±0.19, p<0.0001; heaviness: 2.4±0.13 vs 3.3±0.19, p<0.0001; dry skin: 1.9±0.12 vs 3.1±0.19, p<0.0001), respectively. Altogether, all addressed discomfort/medical conditions occurred less frequently when wearing a JOBST Elvarex Plus glove, whereby the largest effect was observed for dry skin.

Patients treated with compression toe caps with a seam rated, on average, 'pressure marks due to cuffs and welts', 'dry skin', and 'pressure marks between toes' to be the most limiting of all addressed discomfort/medical conditions

Table 2. Importance of compression garment features for the patient

The garment should...	Glove outcomes (n=98)	Toe cap outcomes (n=35)
...not cause any uncomfortable pressure marks	5.9±0.05	5.9±0.05
...restrict the mobility of fingers/toes as little as possible	5.9±0.04	5.3±0.22
...adapt well to the shape of hand/foot and fingers/toes	5.8±0.05	5.8±0.10
...allow wearing closed shoes	N/A	5.8±0.07
...have well-fitted cuffs and welts	5.8±0.06	5.6±0.13
...restrict the tactile sense of fingers as little as possible	5.8±0.06	N/A
...keep perspiration under the garment low and be breathable	5.8±0.06	5.5±0.19
...equally distribute the compression pressure	5.8±0.06	5.5±0.19
...be easy to don and doff	5.6±0.09	5.4±0.18
...restrict the mobility of the wrist as little as possible	5.6±0.08	N/A
...allow wearing sandals/comfortable shoes	N/A	5.1±0.25
...not look worn after being used for a short time	5.5±0.10	4.8±0.24
...be inconspicuous	3.8±0.20	3.4±0.31
...be available in fashionable colours	3.6±2.08	3.1±1.79

Values are presented as mean ± SE. Scale ranges from 1 ('not important at all') to 6 ('extremely important'). N/A = not applicable

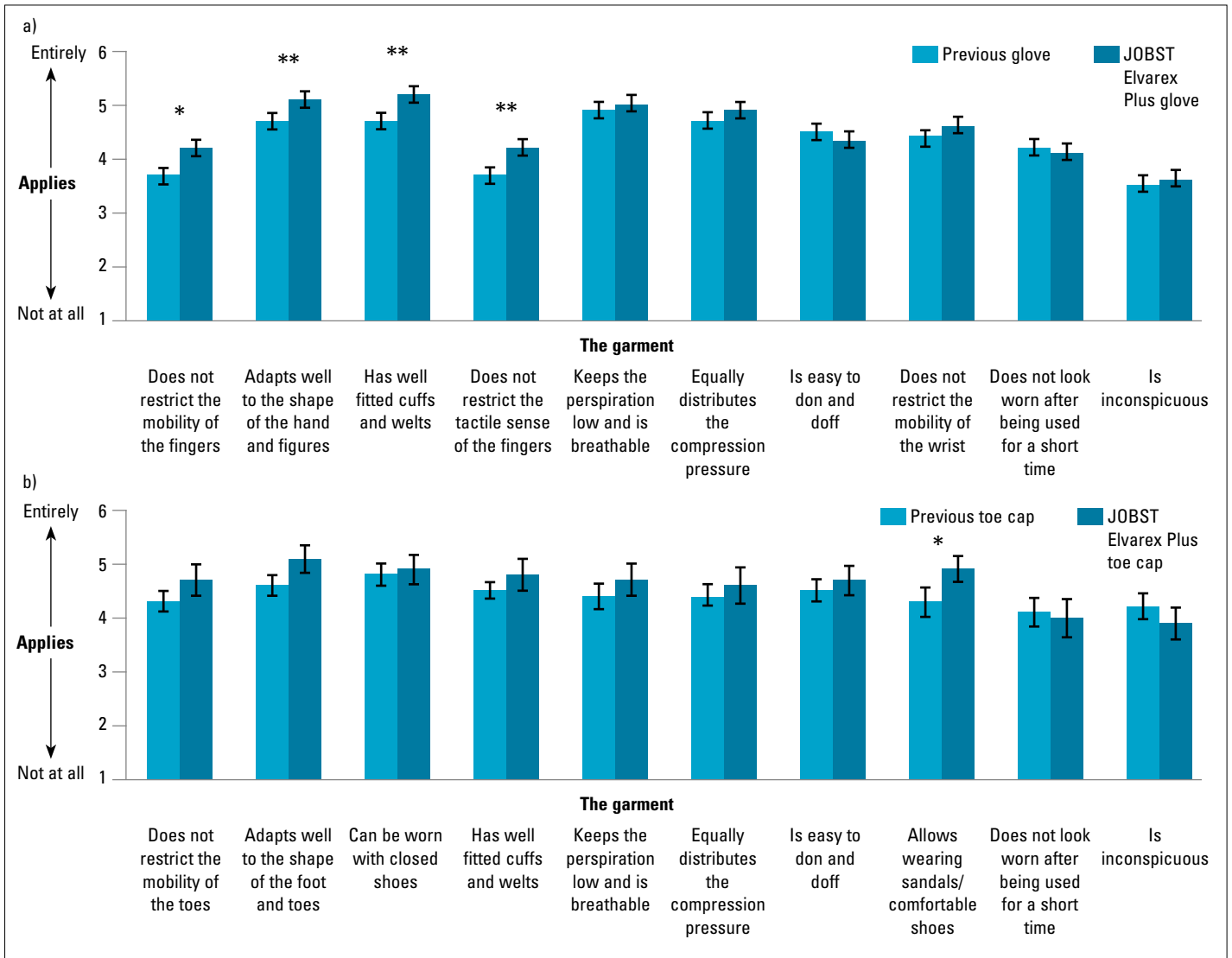


Figure 1. Patient assessment of product characteristics. Patients assessed on a scale from 1 ('does not apply at all') to 6 ('applies entirely') on how well compression a) gloves (n=98) or b) toe caps (n=35) fulfilled specific requirements within the last 2 weeks. Values are presented as mean ± SE. * p<0.05, ** p<0.01

(Figure 2b). These limitations were reported to occur less frequently when wearing JOBST Elvarex Plus toe caps versus the previous toe cap (pressure marks due to cuffs/welts: 2.1±0.23 vs 3.5±0.31, p=0.0010; dry skin: 2.1±0.22 vs 2.8±0.26, p=0.0170; pressure marks between toes: 1.7±0.19 vs 2.8±0.32, p=0.0023). Regarding mean score values, all addressed discomfort/medical conditions, except for swelling/increase of lymphoedema, improved while wearing JOBST Elvarex Plus toe caps with the greatest effect observed for pressure marks due to cuffs and welts.

In addition, patients evaluated their overall satisfaction with regard to the wearing comfort of the tested compression garments (Figure 3). In total, 80.6% of all patients treated with compression gloves stated to be more satisfied with JOBST Elvarex Plus, 14.3% patients were equally satisfied with both products and 5.1% patients were more satisfied with their previous glove. Also 82.9% of the patients treated with compression toe caps were more

satisfied with JOBST Elvarex Plus, 11.4% of them were equally satisfied with both products and 5.7% patients were more satisfied with their previous toe cap.

Reduced limitation of hand and foot functionality when wearing JOBST Elvarex Plus

In order to reveal the impact of compression garments on everyday activities, patients assessed the extent of limitations due to their lymphoedema with respect to specific activities and tasks on a scale from 1 ('not at all') to 6 ('very much') (Figure 4).

All hand lymphoedema patients felt considerably limited in their daily housekeeping, professional practice and hobbies (Figure 4a). The limitation with respect to social events was found to be less present (meaning a lower mean score value). When wearing a JOBST Elvarex Plus glove, the extent of these limitations was rated lower versus the

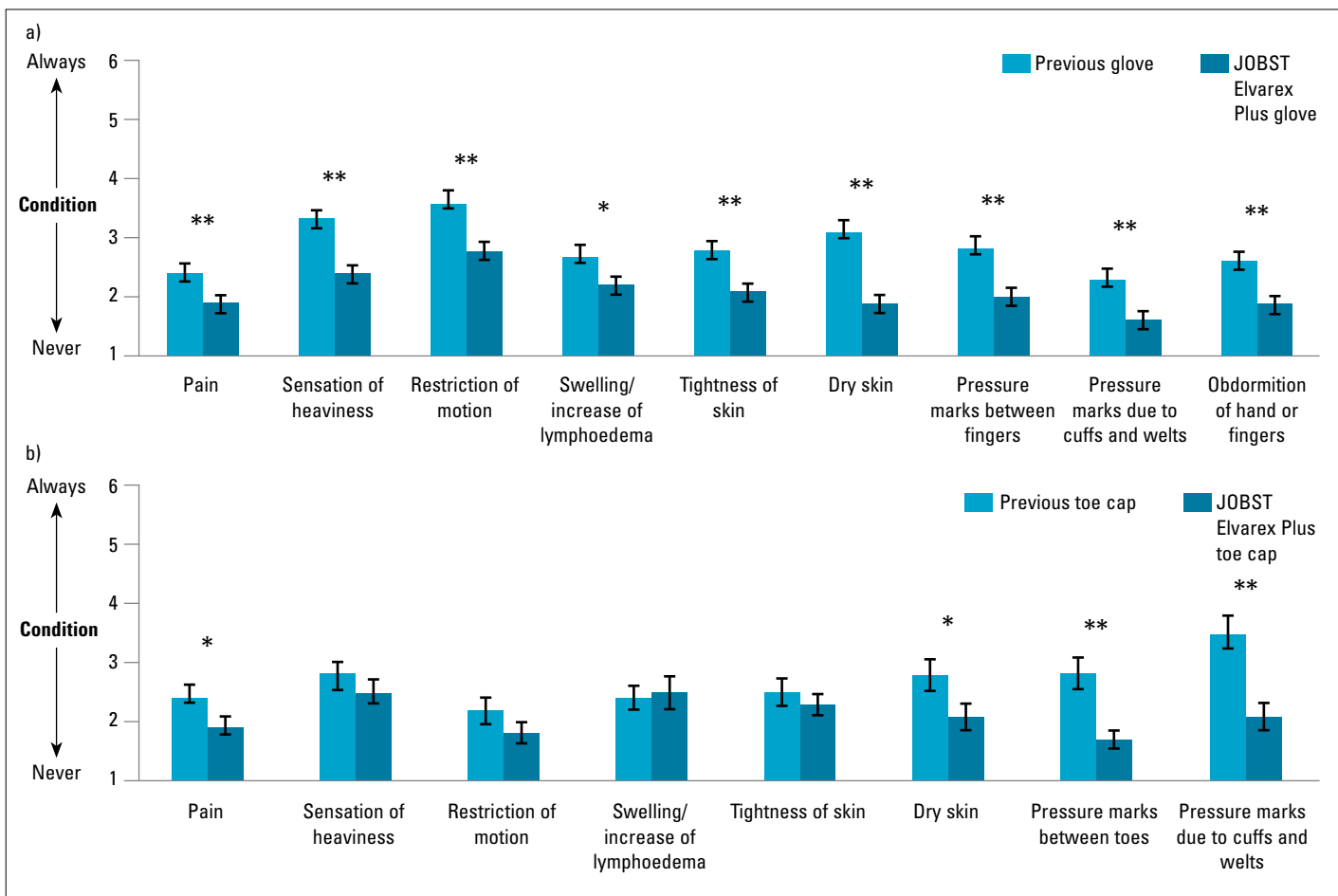


Figure 2. Positive impact of JOBST Elvarex Plus on discomfort/medical conditions. Patients rated on a scale from 1 ('never') to 6 ('always') on how often they experienced discomfort/medical conditions associated with lymphoedema when wearing compression a) gloves (n=98) or b) toe caps (n=35) within the last 2 weeks. Values are presented as mean ± SE. * p<0.05, ** p<0.01

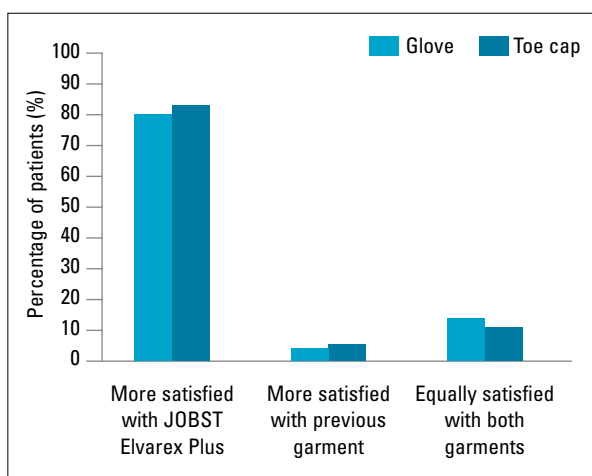


Figure 3. Patient satisfaction regarding wearing comfort in favour of JOBST Elvarex Plus. N=133 patients evaluated their satisfaction with the wearing comfort of JOBST Elvarex Plus garments without a seam in comparison to compression garments with a seam

previous glove (daily housekeeping: 3.4±0.14 vs 4.5±0.15, p<0.0001; professional practice: 3.3±0.20 vs 4.4±0.22, p=0.0001; hobbies: 3.1±0.17 vs 4.0±0.17, p<0.0001; social events: 2.1±0.16 vs 2.6±0.17, p=0.0036).

In general, experienced impairments of the foot caused by compression toe caps were much lower. Nevertheless, patients reported similar improvements in functionality (meaning lower mean score values) when wearing the JOBST Elvarex Plus garment versus the previous toe cap (hobbies: 1.8±0.21 vs 3.1±0.30, p=0.0002; professional practice: 1.6±0.24 vs 2.6±0.32, p=0.0070) (Figure 4b).

Regarding specific daily tasks, patients treated with seamed compression gloves felt most limited with respect to writing/using a computer, opening/closing buttons and eating (Figure 4c). These, as well as all other restrictions, were rated to be significantly lower when wearing a JOBST Elvarex Plus glove versus the previous glove (writing/computer use: 2.7±0.17 vs 4.1±0.20, p<0.0001; opening/closing buttons: 2.6±0.15 vs 3.6±0.20, p<0.0001; eating: 2.5±0.17 vs 3.6±0.18, p<0.0001).

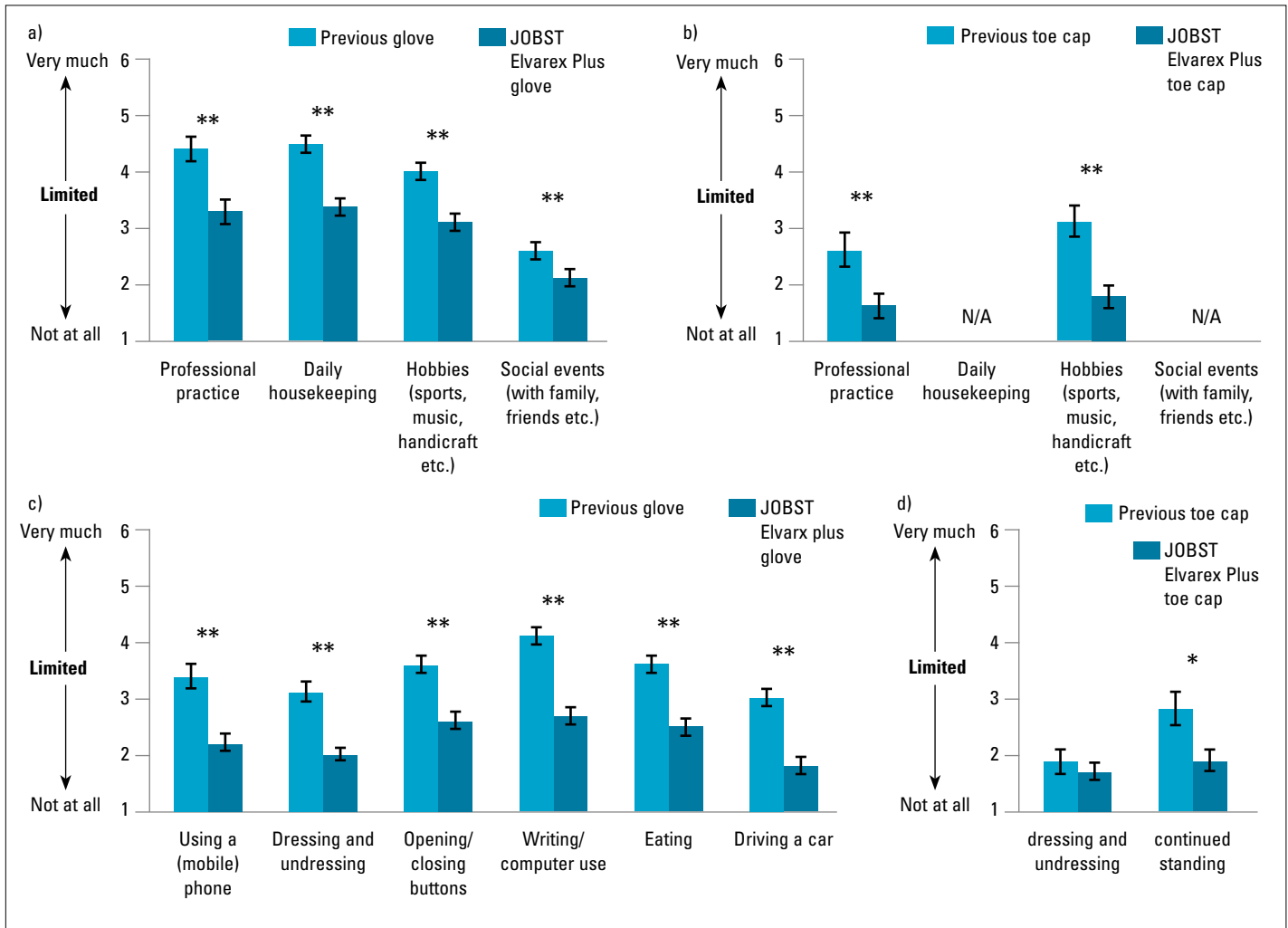


Figure 4. Less limitations regarding daily activities and tasks when wearing seamless JOBST Elvarex Plus. Patients assessed on a scale from 1 ('not at all') to 6 ('very much') on how much they were limited with respect to everyday activities when wearing compression a) gloves (n=98) or b) toe caps (n=35) and tasks when wearing compression c) gloves (n=98) or d) toe caps (n=35) by their lymphoedema within the last 2 weeks. Values are presented as mean±SE. * p<0.05, ** p<0.01, N/A = not applicable

The impact of toe caps on everyday tasks was less dominant (Figure 4d). Still, patients assessed the ability for continued standing significantly better when wearing a JOBST Elvarex Plus toe cap in comparison to their previous toe cap (1.9±0.22 vs 2.8±0.31, p=0.0162).

Overall, the extent of limitations regarding hand and foot functionality, considering all addressed everyday activities and tasks, were, considering mean score values, rated in favour of JOBST Elvarex Plus garments without a seam.

Quality of life is less affected by lymphoedema when wearing JOBST Elvarex Plus garments

In addition to specific everyday activities and tasks, the general influence of lymphoedema on the patients' quality of life was analysed. Patients rated the current impact of their lymphoedema on QoL on a scale from 1 ('not at all') to 10 ('very' or 'very much') (Figure 5). A significant effect of lymphoedema on the patient's QoL was observed for hand

oedema patients (Figure 5a). At the same time, a slightly less pronounced impact was observed for foot oedema patients (Figure 5b). In both cases, the quality of life was significantly less affected by the lymphoedema when wearing JOBST Elvarex Plus garments versus the previous glove (5.1±0.27 vs 6.5±0.26, p<0.0001) and versus the previous toe cap, respectively (4.4±0.45 vs 5.7±0.46, p<0.0004).

Patients are more satisfied with JOBST Elvarex Plus than with compression garments with a seam

Finally, patients evaluated their overall satisfaction with JOBST Elvarex Plus in comparison to their previous garments (Figure 6). In total, 77.6% of all patients treated with compression gloves stated to be more satisfied with JOBST Elvarex Plus, 15.3% patients were equally satisfied with both products and 5.1% patients were more satisfied with their previous glove (Figure 6). For 2.0% of patients, the overall assessment on patient satisfaction was missing.

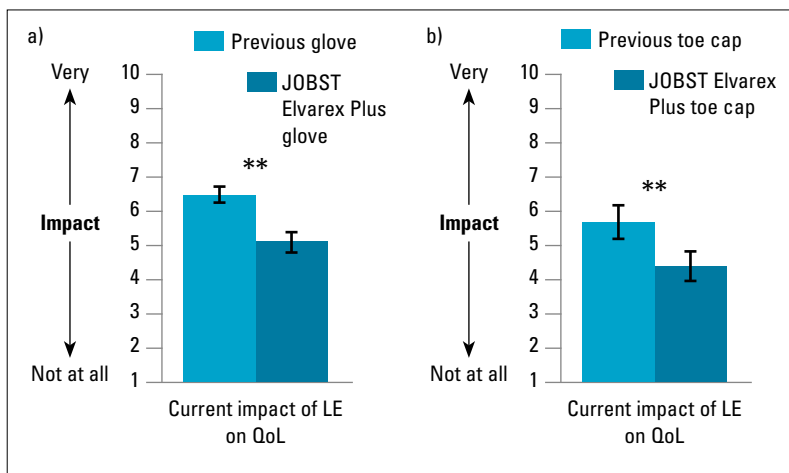


Figure 5. Lymphoedema has less impact on quality of life when wearing JOBST Elvarex Plus. Patients assessed on a scale from 1 ('not at all') to 10 ('very') the current impact of their lymphoedema on their quality of life when wearing compression a) gloves (n=98) and b) toe caps (n=35) within the 2 weeks observation period. Values are presented as mean±SE. ** p<0.01

Likewise, 71.4% of the patients treated with compression toe caps were more satisfied with JOBST Elvarex Plus, 22.9% of them were equally satisfied with both products and 5.7% patients were more satisfied with their previous toe cap.

Discussion

This multicentre study aimed to gain a better understanding of the effect of different flat-knit compression garments (with a seam as well as the 3D flat-knitted JOBST® Elvarex Plus without a seam) have on the life of lymphoedema patients.

The study focused on parameters such as (a) lymphoedema symptoms, (b) product characteristics, (c) functionality of the hands or toes when wearing the compression garment, (d) quality of life and (e) patient satisfaction.

Empirical data were collected in order to gain further insights into patients' views that may be crucial for the

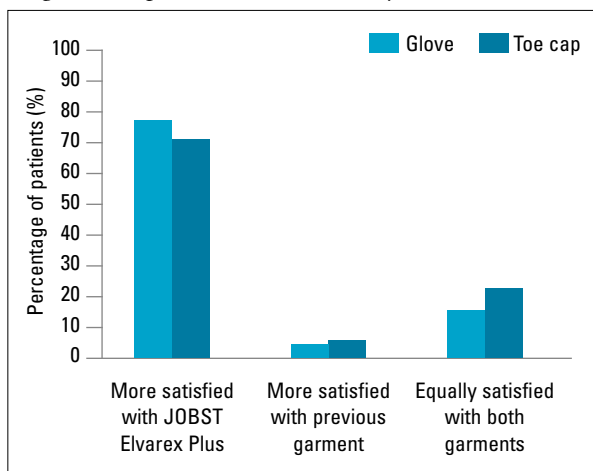


Figure 6. Higher patient satisfaction with JOBST Elvarex Plus compared to compression garments with a seam. N=131 patients evaluated their overall satisfaction with JOBST Elvarex Plus garments without a seam compared to previously worn compression garments with a seam

successful and long-term treatment of lymphoedema patients with compression garments. This approach was considered appropriate as the patients' perception is a critical indicator for the patients' compliance.

To our knowledge it was the first study comparing the patient's opinion on flat-knitted compression garments without a seam with flat-knitted garments with a seam.

In this study, the majority of lymphoedema patients were female with secondary lymphoedema, and were treated with compression gloves (Table 1). Also 80.6% of patients (data not shown) suffered from breast cancer, which is the predominant cancer in women worldwide (World Health Organization, 2016). Arms/hands are commonly affected by cancer treatment-related secondary lymphoedema (Karadibak and Yavuzsen, 2015; Caffo et al, 2003; Engel et al, 2003; Voogd et al, 2003). Due to the tremendous negative impacts of lymphoedema on patients' overall health-related quality of life, lymphoedema is feared by breast cancer patients as the most unfortunate outcome from their cancer treatment (Fu and Kang, 2013). The results of this study show that the fit of the garment without causing pressure marks or restriction of motion is, on average, the most important aspect for the patients (Table 2). However, these patients' needs are often not sufficiently addressed by the currently available compression garments, which is supported by the observation that patients often present to therapists with ill-fitting garments frequently reporting them as being uncomfortable and therefore intolerable (Lee and Wigg, 2013). This drawback leads to a reduced adherence, negatively affecting the success of lymphoedema management (Lee and Wigg, 2013). The patients evaluations in this study indicate that JOBST Elvarex Plus gloves without a seam may close this product gap as they fulfil two major requirements, which are good adaption to the anatomical shape and as little motion restriction as possible, and this is significantly better than the gloves with a seam (Figure 1a and 2a). The same trend was observed for toe caps (Figure 1b and 2b). Pain and other medical conditions/discomfort were reported less frequently, from both patients with gloves and toe caps, when wearing JOBST Elvarex Plus garments without a seam (Figure 2a and 2b). Specifically, the lower occurrence of pressure marks (between fingers/toes and due to cuffs/welts) was rated significantly better for both the JOBST Elvarex Plus gloves and toe caps (Figure 2a and 2b). The resulting very positive rating of the wearing comfort of JOBST Elvarex Plus garments compared to garments with a seam is in line with these results (Figure 3). A study that aimed to identify the different types of adverse effects of compression therapy revealed that rubbing of sleeve seams may cause pain and even ulcers between the thumb and forefinger, demonstrating that the avoidance of pressure marks and damage is also mandatory from a clinical perspective (Vignes and Arrault, 2009).

Moreover, lymphoedema-related medical conditions and discomfort such as 'sensation of heaviness', 'swelling/increase of lymphoedema' and 'tightness of skin' were reported to occur less often when wearing JOBST Elvarex Plus gloves

(Figure 2a). In a cross-sectional study, it was demonstrated that breast cancer patients with lymphoedema already suffer from pain (45.2%), heaviness (71.4%), swelling (100%), or tightness (71.4%) in the affected arm (Fu et al, 2015). Since the patients reported less compression garment-related problems when using compression garments without a seam, the application of these products may help to reduce compression-related problems. This is of major importance because lymphoedema-associated pain and symptoms can lead to disability and psychological distress that negatively impacts the patient's daily life (Burckhardt and Jones, 2005; Fu and Rosedale, 2009; Fu et al, 2013; Reddick et al, 2005).

According to patient's rating, JOBST Elvarex Plus garments improve the hand and foot functionality, and reduce limitations in general daily activities (professional practice, housekeeping, hobbies, social events) and specific tasks (making phone calls, dressing/undressing, opening/closing buttons, writing/computer use, eating, driving, continued standing) (Figure 4). In lymphoedema management, reducing functional impairment is part of a multidisciplinary therapy approach, including physical exercise, in order to improve the patient's independence and self-management in daily activities, reduce their need for caregivers, and improve their QoL. In accordance with the identified improvements associated with the use of JOBST Elvarex Plus garments, the patients reported a significantly reduced impact of their lymphoedema on their QoL (Figure 5), resulting in a higher overall satisfaction with seamless JOBST Elvarex Plus garments (Figure 6).

The observed advantages of JOBST Elvarex Plus garments are meaningful as they may deliver perceptible benefits to the patient in their daily life, which could positively influence the patient's compliance to compression therapy. It is known that a high level of compliance is a prerequisite for a better therapy outcome (Jin et al, 2008). Moreover, evidence is arising that patients who are actively engaged in their own health care have better experiences and contribute to positive treatment outcomes and economic objectives (Hibbard and Greene, 2013). Therefore, tailored interventions that facilitate the individual's level of engagement (e.g. by improving patients' mobility to do regular exercise) enable better therapy results.

Conclusions

In summary, this study demonstrates that anatomically adapted JOBST Elvarex Plus compression garments adequately address patient needs and increase patient satisfaction. The extent of the limitations that lymphoedema patients evidently face can be reduced, leading to a positive effect on patients QoL. This may allow for a better adherence, thereby enabling improved therapy outcomes.

Limitations

The present study covered merely a period of 14 days in the patients' lives, addressing only a choice of factors influencing a patient's quality of life. Hence, the collected data should be interpreted carefully and future studies are needed to confirm the results. A bias of the observations is potentially given as the study didn't include a direct control group

but instead a historical control based on remembering the patients experiences with previously worn compression garments. Regarding the patients' evaluation, there is no validated or consented threshold for the scale used in this study. In some cases mean differences for the assessed features between the previous and the JOBST Elvarex Plus garment may seem small. However, the Disease Activity Scale 28 (DAS28) – a validated scale from 2 to 10 in rheumatoid arthritis, considering an improvement of 1.2 points as significant – provides an indication that improvements of more than 0.6 on a scale from 1 to 6 as observed in the present study may be considered relevant improvements for the patients as well (Mease et al, 2005).

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Acknowledgments: The author would like to thank the patients who participated in the study, the contracted onsite study coordinators, the contract research organisation and BSN medical GmbH providing seamless compression gloves and toe caps

Declaration of interest: The author received educational grants and support by different compression device suppliers (Bauerfeind, Medi, Jobst, Juzo, Galderma, Novacor AG, Eurocom, Marpinion, Lymphologicum) including BSN medical GmbH

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