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ABSTRACT

This prospective, single-centre, observational study set out to evaluate the clinical performance and safety of JOBST Relax®, a custom-made compression garment, when worn by a series of patients with lymphoedema during resting hours and at night. Patients were recruited after undergoing complete decongestive therapy (CDT) and wore the night-time compression garment for 21 days as part of their compression therapy regimen. Questionnaires were used to capture their views on parameters such as the garment's comfort, ease of use, fit, ability to avoid excessive heat and perspiration, its effect on their quality of life and their overall satisfaction with it. Occurrences of erythema, skin rash, skin dryness and pain were also evaluated. Ninety-one patients completed the study. Most perceived the night-time compression garment to be 'very good' or 'good' in terms of its ease of use and comfort, its ability to control their oedema and its effect on their quality of sleep. The prevalence of erythema, skin rash, skin dryness and pain was reduced when compared with baseline. Patients also reported that the night-time garment reduced their dependence on others and improved their quality of life. Overall, most rated their satisfaction with the garment as 'very good' or 'good'. Patients reported a high level of satisfaction with both the garment and the comfort associated with it when wearing it frequently.

KEY WORDS

• lymphoedema • night-time compression garment • quality of sleep • self-management • tolerability

Lymphoedema is caused by the accumulation of lymph due to an imbalance between the production and transport of interstitial fluid. Although lymphoedema is not curable, it can be managed with manual lymphatic drainage, compression therapy, exercise and skin care (International Society of Lymphology, 2013). After completing an intensive initial treatment phase designed to reduce lymphoedema volume as much as possible, patients progress onto long-term maintenance (Toccafondi et al, 2017).

For many patients, the key outcome that they are aiming for is self-management. Those who establish routines for self-management can normalise life with lymphoedema and assume ownership of it, which will lead to improved control (Jeffs et al, 2016). Not surprisingly, empowering patients through the use of personalised treatment plans that encourage self-management is a standard of practice for lymphoedema services (International Lymphoedema Framework, 2006). Compression garments play a key role in the maintenance phase, although optimal results will depend on the patient's ability to adhere to and use them properly (International Society of Lymphology, 2013).

Although various compression garments for lymphoedema have been described in various articles (Nazarko, 2015; Wigg and Lee, 2015; Whitaker, 2016a), none of these refer to garments specifically designed for use at night (Whitaker, 2016b). In some patients, it is necessary to maintain continuous compression to prevent a recurrence of oedema (International Lymphoedema Framework, 2012). A study on patients with lymphoedema following breast cancer treatment revealed that failure during the maintenance phase is common. However, this risk is significantly reduced by combining day and night compression therapy (Vignes et al, 2011). Compression at night, such as in the form of self-bandaging, can supplement day-time compression.

Despite this, there is limited published evidence on the efficacy of night-time compression. A study involving 94 patients with chronic lymphoedema, most of whom had the condition in the leg (n=63, 67%), revealed the benefits of night-time compression, as well as several drawbacks and unmet needs (Whitaker, 2016b). However, most patients (n=84, 89%) experienced increased swelling overnight when they did not wear night-time compression. The main reasons cited for not using compression at night included tiredness, increased sensation of heat and stable oedema. Patients who used night-time compression reported reduced swelling, improved pain management and better sleep (Whitaker, 2016b). Over 80% of patients using night-time compression experienced a maintained or reduced level of oedema. Despite these benefits, patients also indicated that night-time compression devices could be improved; suggestions included a device that felt less tight, did not slip or dig, did not feel hot at night and could be applied more easily (Whitaker, 2016b).

JOBST® Relax is a compression garment specifically designed for night-time use (Moffatt, 2017). (For the purposes

of this article, it is referred to hereafter as the night-time compression garment.) It was formulated to address the patient complaints about night-time compression garments described by Whitaker (2016b). As it is a custom-fit and flat-knit garment, it stays in place and so maintains a consistent pressure gradient. Its textured surface is designed to induce a micromassage effect and thus stimulate lymph flow. A monofilament spacer layer provides cushioning and can adapt to various sleeping positions. The night-time compression garment contains breathable Coolmax yarns that stop it from becoming too warm when the patient is sleeping (Whitaker, 2017). Several case studies, conducted in diverse clinical settings and published in a supplement, have provided preliminary clinical evidence on the clinical performance of and patient satisfaction with this night-time compression garment (British Journal of Community Nursing, 2017). The present study aimed to systematically assess the clinical performance and safety of the night-time compression garment during resting hours or at night in a larger sample of patients, all of whom had stage II arm or leg lymphoedema.

Method

This was a prospective observational study conducted between November 2017 and May 2018 in a single clinic (Földiklinik GmbH & Co. KG) in Hinterzarten, Germany. Potential subjects were identified and recruited during regular clinic visits. Patients attending this clinic are advised to self-bandage at night, making this the predominant benchmark against which the effects of the night-time compression garment could be assessed.

Ethics

The study was approved by the Freiburger Ethikkommission international ethics committee and conducted in accordance with the principles of the Declaration of Helsinki. All of the participants provided written informed consent to participate and were free to withdraw from the study at any time without giving a reason.

Inclusion and exclusion criteria

Eligible patients were aged ≥18 years with stage II lymphoedema on the lower or upper extremities for which a daytime flat-knitted compression garment was indicated. To be included, they had to have received inpatient treatment at the clinic and have progressed to the maintenance phase; they also required experience with daytime compression therapy on the affected extremity (previous wearing period was 5 days per week, ≥6 hours per day), and had to be willing to wear the night-time garment at least 5 days per week. Finally, they had to be physically and mentally able to participate in this study and to provide written informed consent.

Exclusion criteria were: arterial insufficiency; deep vein thrombosis; decompensated heart insufficiency or acute heart failure; untreated cancer; very deep skin folds; untreated septic phlebitis; phlegmasia cerulea dolens (severe form of deep venous thrombosis); missing or very impaired or severe peripheral neuropathy; a known sensitivity to one or more night-time compression garment's components.

Study protocol

Four study visits were required, involving four appointments. First, patients provided written informed consent, after which they completed a questionnaire which enquired about the compression garments they had used previously and the duration/type of lymphoedema present. They were then measured for the custom-made night-time compression garment, which they received 2–3 days later, when they were shown how to apply it. As proper fit and handling of the compression garment are critical, the medical staff at the clinic carefully assessed that it fitted properly. The observation period of 21 days began at this point. At ±day 21 after the first application of the garment, each patient completed a second questionnaire that enquired about the garment's performance, its safety parameters and their satisfaction with it, and elicited lymphoedema-specific data on their quality of life (QoL). The QoL questions were based on validated tools (Keeley et al, 2010), although it should be noted that the questionnaire was not designed to achieve a comprehensive assessment.

Performance and safety criteria

After the 21-day observation period, the patients assessed the performance and safety of the night-time compression garment using Likert and similar rating scales. Performance criteria included fit, wearing comfort, heat, perspiration, quality of sleep, effect on daytime compression in the morning, patient satisfaction with the garment and lymphoedema-specific QoL. Safety criteria included the presence of skin erythema, rash, dryness, itching, unpleasant pressure marks and pain. Patients also reported wearing times. No comparative measurements were undertaken during the follow-up period.

Data analysis

Data were analysed by an independent consultant (http://www.econ-epi.eu/, ECON-EPI, Hamburg, Germany). Continuous variables were described as the absolute number of observations and mean±standard deviation (±SD). Percentages and frequencies were used to describe nominal or ordinal variables.

Results

A total of 94 patients were recruited into the study. Two patients withdrew from it (one withdrew consent and the other did not receive the garment in time). One patient was aged under 18 years and so were excluded. Therefore, 91 patients were included in the analysis.

Baseline patient demographics and disease characteristics

The majority of the sample (n=79, 86.8%) were female. Mean (±SD) age was 57 (±13.9) years. Mean (±SD) duration of lymphoedema was 11.5 (±10.0) years. The majority of patients (n=62, 68.5%) had secondary lymphoedema, mostly in their legs (*Table 1*).

Previous use of compression

Eighty-nine patients (97.8%) had worn day-time compression before entering the study. They had been wearing

Table 1. Demographic data and lymphoedema-specific parameters

	Total sample (n=91)
Female	79 (86.8%)
Age (years), (mean±SD)	57.0±13.9
Duration of lymphoedema (years) (mean±SD)	11.5±10.0
Type of lymphoedema	
• Primary • Secondary • Obesity-associated	25 (27.5%) 62 (68.5%) 2 (2.2%)
Location of lymphoedema (affected extremity)*	
• Right leg • Left leg • Right arm • Left arm	36 (39.6%) 48 (52.7%) 11 (12.1%) 16 (17.6%)

All values are n (%) unless otherwise indicated
** Some patients were affected on more than one location*

Table 2. Patients' previous experience with day and night-time compression

	Total sample (n=91)
Used day-time treatment before entering the study	**89 (97.8%)**
• Years of daytime treatment (mean±SD)	10.5±9.2

• Type of day-time treatment used previously:*
  • Compression garment
  • Self-bandaging
  • Other type of daytime treatment
	
	89 (100.0%)
	13 (14.6%)
	0 (0.0%)

Used night-time treatment before entering the study	**42 (46.2%)**
• Years of night-time treatment (mean±SD)	9.7±7.9

• Wearing behaviour:**
  • At least three times a week
  • Less than three times a week
  • Irregularly (no wearing routine)
	
	21 (50.0%)
	7 (16.7%)
	13 (31.0%)

• Type of night-time treatment used previously:*
  • Compression garment
  • Self-bandaging
  • Other type of day-time treatment
	
	11 (26.2%)
	34 (81.0%)
	4 (9.5%)

** Patients supplied more than one answer*
*** Data are missing for one patient, thereby reducing this subset to 41 patients*

day-time compression for a mean (±SD) duration of 10.5 (±9.2) years. Compression garments were worn predominantly during the day. As stated above, patients who attended the Földi Clinic were advised to self-bandage at night. A total of 42 patients (46.2%) had worn night-time compression previously for a mean duration of 9.7 (±7.9) years. Of these patients, 21 (50%) wore compression at night at least three times/week, seven (16.7%) wore it less than three times/week and 13 (31%) wore it irregularly. Self-bandaging was the predominant method of compression worn at night time (n=34, 81%) (*Table 2*).

The night-time compression garment

During the observation period, patients wore the night-time compression garment for a mean (±SD) of 24.5 (±9.1) days (range: 19–72). All patients wore it on most nights each week (6.5±0.8 nights/week) for 7.9 (±0.9) hours per night. Fifty-two patients (57.1%) also wore the night-time compression garment during resting hours in the evening for 5.3 (±1.7) days per week, as well as for 2.6 (±1.3) hours per day (*Table 3*).

Ease of use and comfort

Patients rated the garment's ease of use and comfort highly. Fit, wearing comfort and breathability were deemed 'good' or 'very good' by at least 86 patients (94.5%). Appearance, donning and doffing were rated as 'good' or 'very good' by at least 77 patients (85%). The full results are given in *Figure 1*. Only 30 patients (33%) used a donning aid.

Twenty-five patients reported applying body lotion before donning the garment. None of these patients said that the lotion affected the garment (data are missing for two patients) (*Table 3*).

Sensation of heat and perspiration

Seventy-eight patients (85.7%) and 79 patients (86.8%) rated the night-time compression garment as 'good' or 'very good' in terms of avoiding heat generation and perspiration, respectively. Full results are given in *Figure 2*. Only six patients (6.6%) occasionally removed the garment at night because of a sensation of heat and perspiration.

Tolerability

The night-time compression garment was associated with a marked reduction in the occurrence of erythema on the skin compared with baseline. More patients did not experience erythema when wearing the night-time compression garment (n=75, 82.4%) compared with before the study (n=21, 23.1%). In addition, there were notable reductions in the prevalence of skin rash, skin dryness and pain during the study period (*Table 4*). Most patients did not experience itching (n=70, 76.9%) or pressure marks (n=78, 85.7%) while wearing the night-time compression garment (*Figure 3*) (no baseline data were collected on these parameters).

Quality of sleep

Patients rated their quality of sleep while wearing the night-time compression garment on a five-point scale ranging from 'very good' to 'very poor.' Eighty-nine patients (97.8%) reported that their quality of sleep was either 'very good' or 'good' when wearing the garment at night (*Figure 4*). Eighty-six patients (94.5%) stated that, compared with what they had experienced before first wearing it, the quality of the sleep associated with the night-time compression garment was 'very good'/'good' (*Figure 4*). Most patients (n=82, 90.1%) described their ability to handle their day compression the next morning as 'very good'/'good' (*Figure 4*).

A subgroup analysis was performed on the 42 patients who had worn night-time compression before entering the study. Of these, 41 (97.6%) said the quality of sleep experienced with the night-time compression was 'very good' or 'good' compared with what they had experienced with their previous night-time product.

Of the entire sample, 69 patients (75.8%) reported that the night-time compression garment helped managed their oedema 'a lot' or 'a great deal'. Of the subgroup of 42 patients who had worn night-time compression products before entering the study, 33 (78.6%) reported that the current night-time compression garment helped manage their oedema 'a lot' or 'a great deal'; 26 of these patients (61.9%) reported that the previous night-time product had improved their oedema to the same degree (*Figure 5*). Most of the patients in this subgroup (34, 81.0%) had self-bandaged before entering the study.

Effect on quality of life

The night-time compression garment had a positive impact on disease-specific QoL parameters, compared with baseline. The largest improvement related to the overall effect of lymphoedema on QoL: 49 patients (53.8%) reported that the disease affected them 'a lot' or 'a great deal' at baseline, compared with 38 patients (41.8%) at the study end. Similarly, the percentage who reported they were 'not at all dependent' on others for support because of their lymphoedema increased from a baseline of 36% to 51% at the end of the study. There was also a reduction in the percentage of patients who felt 'a lot' or 'a great deal' of unattractiveness due to lymphoedema (48% at baseline vs. 41% at end of study) (*Table 5*).

Overall patient satisfaction

Eighty-six patients (94.5%) rated the night-time compression garment as 'good' or 'very good'. Only one patient rated satisfaction as 'fair' and one patient as 'very poor' (*Figure 5*). This patient was used to wearing very strong compression during the day as a result of combining a class 2 and a class 3 compression garment.

Discussion

These results demonstrate the performance and tolerability of the night-time compression garment. Most of the patients commented that the new garment was comfortable, easy to use and more tolerable than the product(s) they had worn before entering the study. In addition, patients experienced a good quality of sleep during the observation period, and the quality of sleep they reported at the end of the study had improved when compared with that experienced before its start. Disease-specific QoL also improved when compared with baseline, and, based on the questionnaire, was associated with a reduced dependence on others. Importantly, patients who had worn night-time compression previously commented that their oedema was better controlled compared with the period before they entered the study.

In the author's experience, patients with lymphoedema are non-adherent to night-time compression therapy. It is possible that this is due to the discomfort and inconvenience of night-time compression products (Whitaker, 2016b). In this study, the entire sample wore the night-time compression for means of 6.5 days per week and 7.9 hours per night. Patient adherence to the night-time compression garment was therefore higher than would be expected for compression bandages. This was probably due to the better tolerability and comfort observed with the garment.

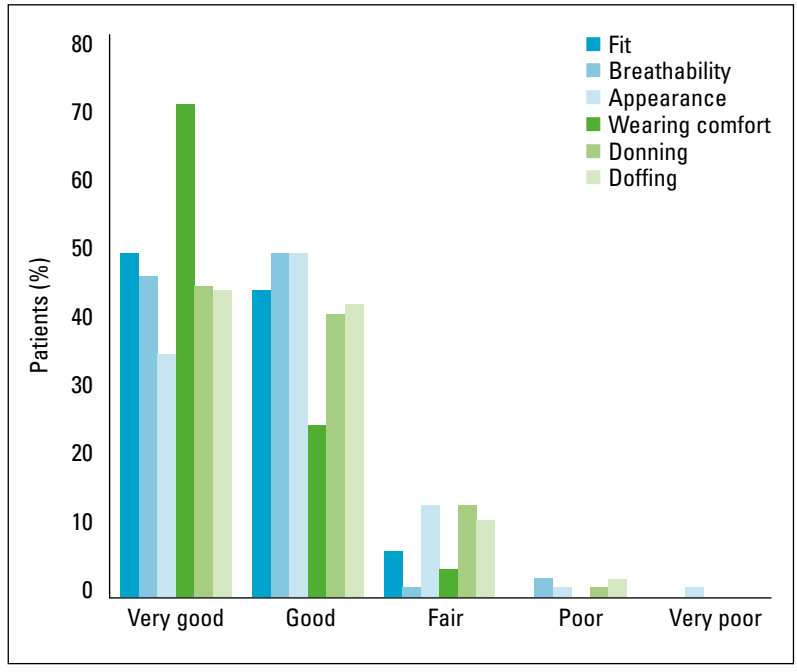

Figure 1. Patients' perspectives on the properties of the night-time garment and its ease of use

Table 3. Wearing periods and habits associated with the night-time compression garment

	Total sample n=91
Wearing period (days) of the night-time garment*	24.5±9.1
No. of nights the garment was worn each week**	6.5±0.8
No. of hours the garment was worn each night**	7.9±0.9
Styles of night-time compression garment: • Arm garment with hand • Arm garment without hand • Knee-high garment • Thigh-high garment	 22 (24.2%) 1 (1.1%) 4 (4.4%) 64 (70.3%)
Compression class: • Class 1 (15–20 mmHg) • Class 2 (20–30 mmHg)	 23 (25.3%) 68 (74.7%)
Use of the night-time during resting hours: §,| • Yes • No	 52 (57.1%) 31 (34.1%)
No. of patients who wore the night-time garment during resting hours:| .^ • Days per week • Hours per day**	52 (57.1%) 5.3±1.7 2.6±1.3
Use of body lotion before donning the night-time garment: • Changes in product characteristics if body lotion was used: & • Yes • No • No recognised changes	25 (27.5%) 0 (0.0%) 10 (40.0%) 13 (52.0%)

All values are mean±SD unless otherwise indicated.
** Data are missing for one patient*
*** Data are missing for one patient from each category*
§ Data are missing for eight patients
\| Resting hours were in the evening while the patient was awake
^ Data are missing for one patient
& Data are missing for two patients

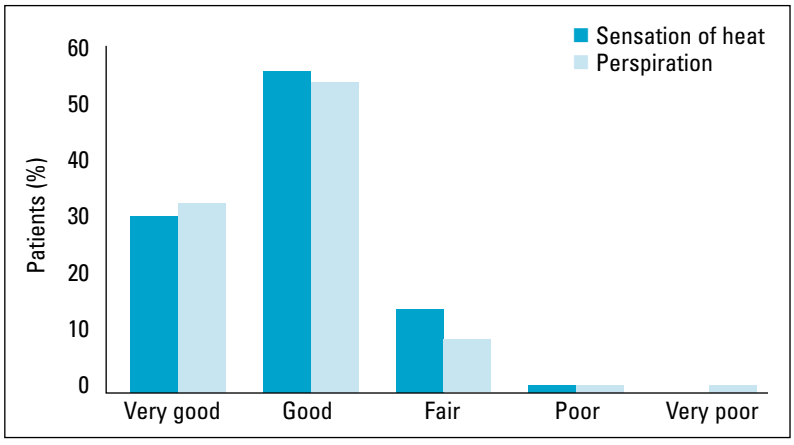

Figure 2. Patients' perspectives on the ability of the night-time garment to avoid sensation of heat and perspiration at night

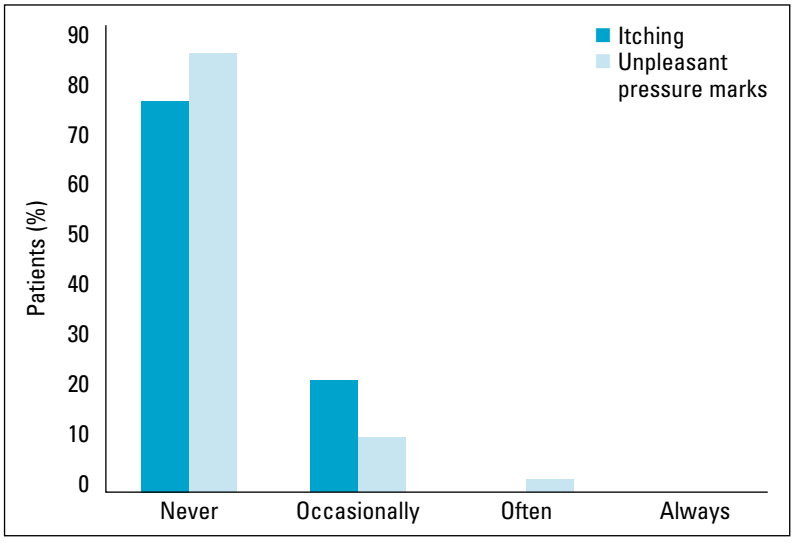

Figure 3. Occurrence of itching and unpleasant pressure marks observed with the night-time garment

Due to the time required to apply compression bandages, patients with lymphoedema who might benefit from night-time compression may choose not to wear it. In the author's experience, it takes trained and experienced patients approximately 45 minutes to apply and doff (including rolling up the bandage the next morning) a single leg, increasing to 90 minutes for both legs. It takes an experienced patient 25 minutes to self-bandage an arm. In contrast, the investigator observed that patients were able to don the night-time compression garment within 1–2 minutes.

Drawbacks with other night-time compression garments reported by patients include discomfort, skin reactions and a sense of heat or perspiration (Whitaker, 2016b). In the author's experience, many patients experience an intense feeling of heat under a compression garment when wearing it in bed, resulting in them taking it off. In this study, very few patients reported skin reactions with the night-time compression garment when compared with baseline. Only six (7%) removed the garment due to heat or perspiration (on some days).

Some patients experience sleep disturbance when wearing compression products at night (Whitaker, 2016b). In this study, patients reported that the quality of their sleep was 'good' or 'very good' when wearing the night-time compression garment, and indicated that it had improved when compared with baseline.

Many patients reported a major improvement in their lymphoedema in the next morning. According to the investigator, this was mostly characterised by a reduced sensation of tension and heaviness in the affected limb, although this was not measured. Patients with leg lymphoedema subsequently found it much easier to put their shoes on. It is worth noting that night-time compression in general will have this effect (Whitaker, 2016b). The key factor influencing adherence to a night-time compression garment is comfort. Patient adherence to self-bandaging before going to bed can be very poor.

Patients who had never worn compression at night stated that, due to the good wearing comfort experienced with the night-time compression garment and the short time required to don it, they would consider wearing it when resting and at night. Taken together, the garment's convenience and tolerability may improve patient adherence to night-time compression therapy.

This study has several limitations. Patients were recruited after completing decongestive lymphatic therapy and thus constituted a homogenous patient population that was optimally decongested and had limited complications, which positively influenced their QoL. However, these factors are a prerequisite for assessing parameters such as comfort, fit and quality of sleep, as patients with uncontrolled oedema may have difficulties in specifically assessing the performance of their compression garment. Another limitation is the study's non-comparative design, as the night-time compression garment was not directly compared with any other products that

Table 4. Occurrence of lymphoedema-specific problems with compression garments

	Baseline data				End of evaluation			
	Never	Occasionally	Often	Always	Never	Occasionally	Often	Always
	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)
Erythema	21 (23.1)	47 (51.6)	17 (18.7)	6 (6.6)	75 (82.4)	14 (15.4)	0 (0.0)	2 (2.2)
Skin rash*	53 (58.2)	32 (35.2)	4 (4.4)	0 (0.0)	87 (95.6)	4 (4.4)	0 (0.0)	0 (0.0)
Skin dryness**	12 (13.2)	40 (44.0)	24 (26.4)	13 (14.3)	62 (68.1)	24 (26.4)	2 (2.2)	1 (1.1)
Pain	23 (25.3)	47 (51.6)	18 (19.8)	3 (3.3)	84 (92.3)	6 (6.6)	1 (1.1)	0 (0.0)

** Baseline data are missing for one patient*
*** Baseline and endpoint data are missing for two patients*

can be used to achieve compression at night. It is also possible that there were other reasons, beside the use of the garment, for the improvements observed in lymphoedema-related QoL.

Patients' self-reported outcome and wearing times and were not assessed by a health professional at the end of the follow-up period. This was due to practical reasons as the patients do not live near the specialist centre and repeat visits would be costly and inconvenient for them. This is a general issue affecting other studies in lymphology. Generally, patients visit their lymphoedema specialist once a year.

Future research should focus on comparing the night-time compression garment with the most common alternative night-time compression regimen (self-bandaging) and note the effects on QoL. Data collection that allows health economic modelling would also be useful.

Conclusion

This study demonstrated that the night-time compression garment was well tolerated by this patient sample, who found it comfortable and conducive to sleep. Due to its ease of use and tolerability, the garment appears to improve adherence to night-time compression for lymphoedema and increase patients' ability to self-manage this condition. This can potentially improve both patient outcomes and quality of life.

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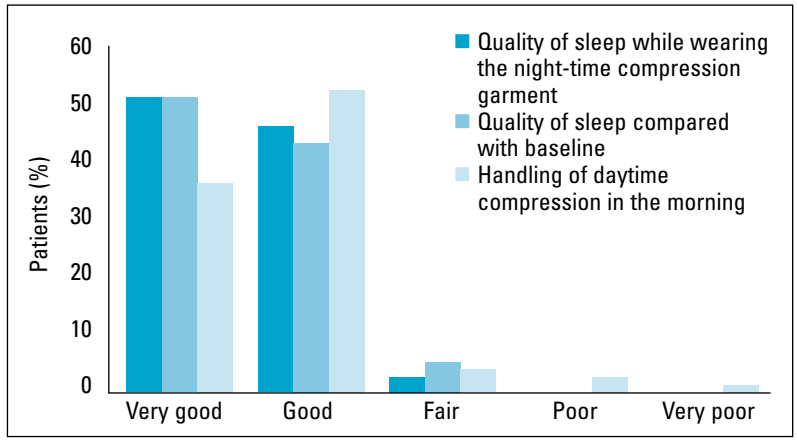

Figure 4. Patient self-reported quality of sleep while wearing the night-time garment and compared with that for the night-time compression worn before entering the study, as well as ability to handle daytime compression in the morning after wearing the night-time compression garment during the study

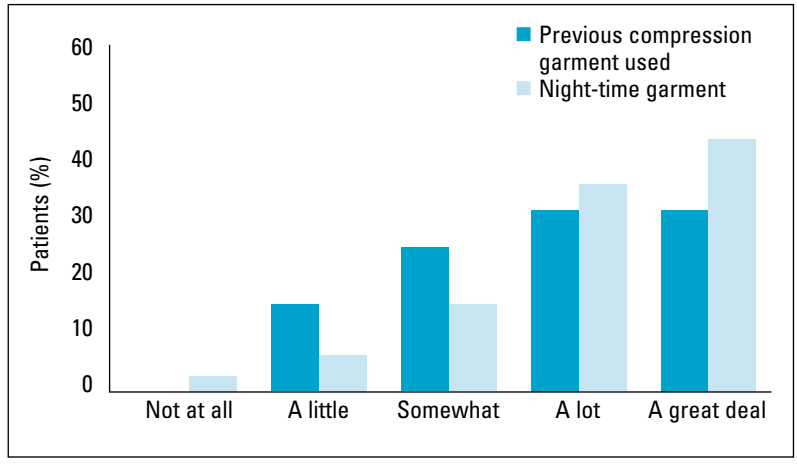

Figure 5. Patient self-reported rating of the ability of the night-time compression garment to control oedema compared with baseline (n=42, this is the subgroup of patients who wore compression at night before entering the study)

Table 5. Effect of the night-time compression garment on quality of life

	Baseline					End of the evaluation				
	Not at all	**A little**	**Somewhat**	**A lot**	**A great deal**	**Not at all**	**A little**	**Somewhat**	**A lot**	**A great deal**
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Lymphoedema affected the patient's quality of life*	1 (1.1)	14 (15.4)	26 (28.6)	22 (24.2)	27 (29.7)	2 (2.2)	19 (20.9)	30 (33.0)	23 (25.3)	15 (16.5)
Dependence on others for help due to the lymphoedema**	33 (36.3)	32 (35.2)	15 (16.5)	6 (6.6)	4 (4.4)	46 (50.5)	21 (23.1)	13 (14.3)	7 (7.7)	4 (4.4)
Unattractiveness due to lymphoedema§	9 (9.9)	14 (15.4)	22 (24.2)	21 (23.1)	23 (25.3)	12 (13.2)	21 (23.1)	20 (22)	20 (22)	17 (18.7)

**Baseline and endpoint data are missing for one and two patients, respectively*
**Baseline data are missing for one patient*
§ Baseline and endpoint data are missing for two and one patients, respectively

KEY POINTS

- Lymphoedema is a condition characterised by swelling caused by accumulation of lymph
- While no curative treatment exists for lymphoedema, the condition can be managed with complex decongestive therapy including manual lymphatic drainage, compression therapy and exercise and skin care
- Optimal therapy outcomes can be achieved by combining day and night-time compression
- Patients may not adhere to night-time compression regimens due to difficulties or discomfort with currently-available compression garments
- JOBST® Relax is a compression garment specifically designed for night-time use and is effective and well-tolerated

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CPD REFLECTIVE QUESTIONS

- Are your lymphoedema patients aware of the importance of night-time compression in managing their condition?
- Do your lymphoedema patients consistently use night-time compression?
- For your patients who do not use night-time compression consistently, what are the reasons for this lack of therapy adherence?