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Tissue Viability

Effect of a new compression garment on adherence: results of a patient satisfaction survey

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Effect of a new compression garment on adherence: results of a patient satisfaction survey

ABSTRACT

Traditionally, knee-high compression stockings apply a slightly higher pressure at the top band to keep them in place. However, some patients find this uncomfortable, which can affect adherence. The Jobst Opaque SoftFit stocking contains a silicone yarn in the top band, which is designed to keep it in place without exerting extra pressure. A survey was undertaken to determine if the SoftFit stocking was more acceptable to patients than the compression stockings they had worn previously, and to identify its effects on the symptoms of chronic venous disease (CVD).

Patients with CVD living in the community were recruited from four federal states in Germany. They wore the test stocking for 7 days. Data collected on days 1 and 7 compared their perceptions of the test stocking with those of the conventional compression stockings worn previously. The results showed that, compared with the previous stockings used, the majority of patients considered the test stocking to be more comfortable at the top band and more likely to stay in place, while many no longer experienced some of the clinical symptoms of CVD such as heavy legs, pain in the legs and itching or dry skin.

Key words: Compression stockings ■ Concordance ■ Adherence ■ Comfort ■ Chronic venous disease

Chronic venous disease (CVD) develops when the blood pressure in the veins is increased (venous hypertension) and the return of blood to the heart is impaired. Many factors can impair venous drainage, the most common being incompetence of the valves in the veins, which results in reflux or retrograde blood flow. Valves can become ineffective for reasons including degenerative changes, pre-existing weakness, direct injury, phlebitis, damage resulting from deep vein thrombosis or excessive venous distension due to hormonal changes. Once one valve becomes damaged, the local high pressure and subsequent dilatation of the veins can lead to secondary valve failure. Venous hypertension can also occur if there is dysfunction of the calf muscle pump, as blood will not be effectively drained from the lower limb.

Early signs of venous hypertension include skin changes such as spider/thread veins, ankle flare and varicose veins, as these are indicative of damage to the superficial veins. Venous hypertension also increases capillary infiltration, resulting in the release of excess fluid into the interstitial spaces (oedema). If the venous disease is not managed promptly, severe varicose veins and, possibly, skin breakdown/ulceration can occur. There is also a risk of chronic oedema. The CEAP system (clinical, etiology, anatomy, pathophysiology) (Eklof et al, 2004) is used to classify the various stages of CVD (*Table 1*).

Continuous compression therapy plays an essential role in the management of CVD. Graduated compression significantly improves the venous return (World Union of Wound Healing Societies, 2008) and reduces capillary filtration (Partsch and Junger, 2006). Compression hosiery is often worn in the early stages of CVD (C0–C4) to alleviate symptoms such as skin changes and oedema (Ashby et al, 2014) and to avoid ulceration. It is also worn after a venous leg ulcer has healed (CEAP stage C5) to prevent a recurrence. Both compression bandaging and hosiery are used to treat active ulceration (Ashby et al, 2014). However, an innovation has been the use of a four-layer bandage kit (Jobst Comprifore, BSN medical), which is applied initially to reduce acute oedema; once this has been achieved and the limb size has stabilised, a two-layer graduated compression stocking (Jobst Ulcercare, BSN medical) is used. An advantage of the four-layer bandage system is that it can accommodate the changes in limb size that occur as the oedema decreases; meanwhile, the graduated stocking has been shown to be effective in treating venous leg ulceration (Brambillla et al, 2013).

When selecting compression hosiery, it is vital that a holistic assessment is undertaken and the patient is involved in the decision-making process. Poor patient concordance and adherence to treatment will result in persistent or a recurrence of symptoms (Moffatt et al, 2009). Reasons for patient non-adherence to use of compression stockings include:

- Unwillingness to tolerate any restrictions, caused by the stockings, inability to perform everyday activities
- Discomfort caused by tightness, particularly around the band, and concerns that this can impair the blood circulation
- Poor fit
- Legs become too hot (Raju et al, 2007).

Patient concordance with use of compression stockings will not only help achieve treatment outcomes, but will also improve quality of life and reduce healthcare costs. Traditionally, knee-high compression stockings have applied a slightly higher pressure at the top band to keep them in place above the calf (Hohenstein Textile Institute, Germany – data on file). As all legs are not shaped the same, this can result in different levels of tension in the top band among

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Table 1. The CEAP classification system (by clinical symptoms)

Score		Description
C0		No visible or palpable varicose veins
C1		Telangectasia (thread veins/spider veins/broken veins)
C2	C2A	Varicose veins without any symptoms (asymptomatic)
	C2S	Varicose veins with symptoms
C3		Swollen ankle (oedema) due to varicose veins or hidden varicose veins (venous reflux)
C4		Skin damage due to varicose veins or hidden varicose veins (venous reflux)
C5		Healed venous leg ulcer
C6		Venous leg ulcer

Source: Eklof et al, 2004

wearers, resulting in some individuals finding the stockings uncomfortable to wear. This can be a contributory factor to non-adherence with treatment. To address this, BSN medical has developed a knee-high compression stocking with a band that contains SoftFit silicone yarn, which is designed to keep the stocking comfortably in place without causing constriction or tightness. SoftFit technology comprises silicone yarn, which is knitted into the inner side of the top band. According to the manufacturer, the silicone's high coefficient of friction prevents the stocking from slipping down and thus avoids the need to apply extra pressure at the band to keep it in place. Other stockings are available that have solid silicone bands around the top cuff, but these can add bulk and increase the pressure at the top of the stocking (Hohenstein Textile Institute, Germany: data on file). JOBST Opaque SoftFit is European class 2 and exerts 23–32 mmHg.

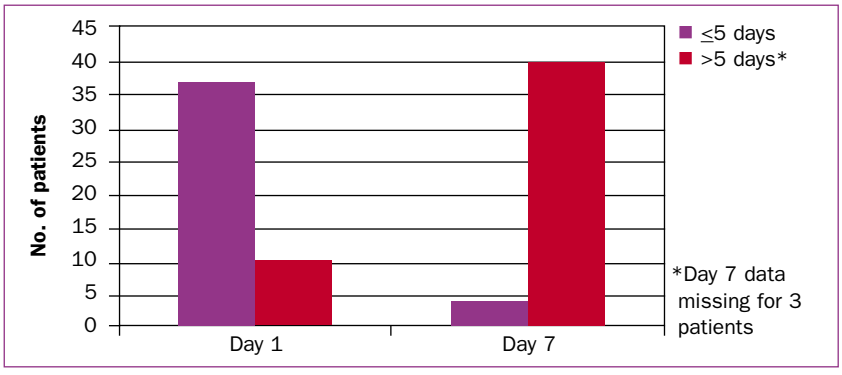

Figure 1. Compression wear times (days)

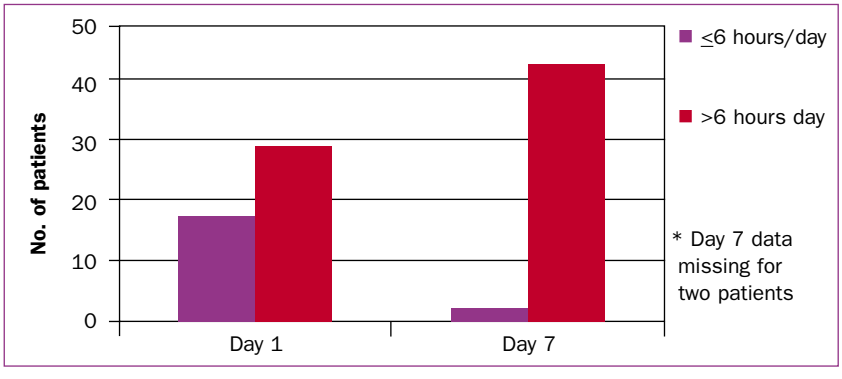

Figure 2. Compression wear times (hours per day)

As far as the author is aware, to date no clinical evaluations have been published on this new technology. A patient survey was therefore undertaken to determine the acceptability of Jobst Opaque SoftFit (hereafter referred to as the test stocking) to patients with experience of wearing compression stockings and to measure if its use resulted in greater adherence to treatment.

Method

Patients

Adult patients, aged 18 or over, with CVD (CEAP scores 1–5) from four federal states in Germany were invited to participate in this survey between January and February 2015. All patients were recruited when collecting their prescribed compression stockings from one of the four participating pharmacies (Sanitätshaus). Additional inclusion criteria were:

- Previous experience of wearing compression stockings (for at least 5 days a week and for a minimum of 6 hours a day)
- Willingness to wear the test stocking for at least 5 days and 6 hours a day during the survey follow-up period
- Ability to give written informed consent, as verified by the staff at the pharmacy.

There were no exclusion criteria. All patients had previously undergone a full assessment (in order to receive a prescription), which would have included identification of arterial insufficiency. Ethics committee approval was not required because the stocking was not regarded as a 'study medication'.

Patients were supplied with the test stocking on day 1 and asked to wear it for the next 7 days. They were required to complete a piloted questionnaire at the start of the product evaluation (day 1) and on its completion (day 7), with both including questions about their habits relating to wear, their symptoms of CVD and their general opinions about the compression stockings they had been wearing. The two questionnaires were similar, except the first enquired about their prior experiences of compression stockings, whereas the second focused on SoftFit.

Objectives

The primary objective was to compare differences in the patient acceptability of the test stocking with that of the standard compression stockings used before entry into the evaluation. The secondary objective was to compare differences in clinical symptoms before and after the 7-day follow-up period.

Assessment

The first questionnaire (day 1) asked participants to select from a choice of three answers why they had worn compressions stockings previously.

Both questionnaires asked how many days, and how many hours in the day, the patients had worn the stockings. They also asked the patients to rate whether or not the stockings:

- Improved their quality of life
- Improved their symptoms
- Improved the look of their skin and legs
- Restricted their day-to-day life.

Patients were also asked to score the above in order of importance to them.

In addition, the following symptoms of CVD were evaluated on the basis of the frequency of occurrence:

- Heavy legs
- Feeling of tension in the legs
- Feeling (or sensation of) weight in the legs
- Painful legs
- Itchy/dry skin.

(Here, the term 'heavy legs' is differentiated from a 'feeling of weight' in the legs by being more marked and noticeable to the individual.)

Level of comfort and ease of wear were evaluated on the basis of:

- Fit on the leg, ranging from excellent (stocking fits the leg perfectly) to inadequate (stocking is too wide or too tight)
- Fit of the top stocking band, ranging from excellent (stocking does not constrict) to inadequate (cuts painfully into the skin)
- Ability to stay in place, ranging from excellent (does not slide) to inadequate (slides immediately).

Patients were also asked to assess how often they experienced the following problems when wearing compression stockings:

- Redness
- Itching
- Dry skin
- Cuff cutting into the skin.

Both questionnaires asked the patients to rate how they perceived that the stockings improved their symptoms and affected how their skin felt, on a scale of 1 (excellent) to 6 (inadequate). Finally, the second questionnaire enquired about their overall perceptions of the test stocking and whether they preferred it to the previous stockings used.

Data analysis

It was initially decided to recruit at least 36 patients into the survey, based on the judgement that a minimum of 30 complete questionnaires was required for analysis and that there would be a drop-out rate of 20%. However, once the actual survey was underway, none of the actual patients invited to participate dropped out. All patients who used the test product for the 7-day test period were included in the analysis. All data were analysed in a descriptive manner.

Results

Forty-seven patients were enrolled into this survey.

Baseline data

The mean age was 36 years (range 20–88 years). No other demographic information was collected. Asked why they had wore stockings before entry into the survey, the majority of patients stated that it was for symptom relief and to prevent symptoms worsening (n=26 and n=27 respectively). Only 10 patients said it was to promote successful treatment.

Acceptability

Comparative results of the questionnaires given on days 1 and 7 showed that patients wore the test stockings for longer

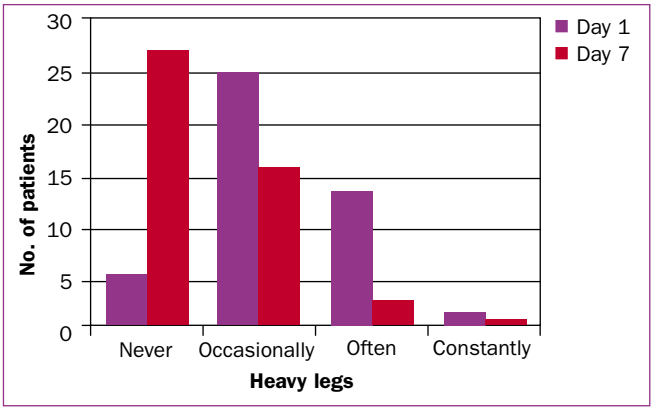

Figure 3. Frequency of occurrence: heavy legs

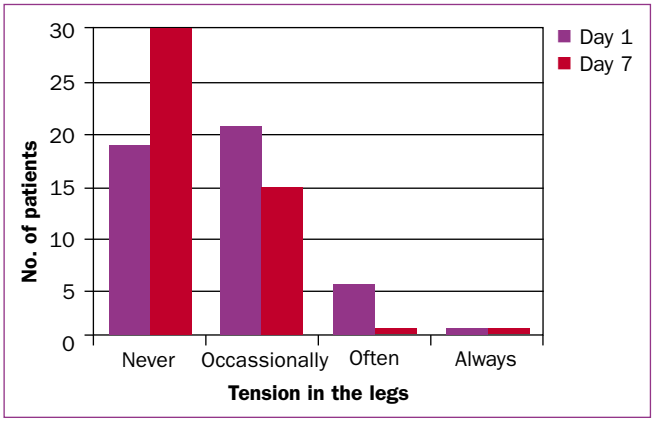

Figure 4. Frequency of occurrence: tension in the legs

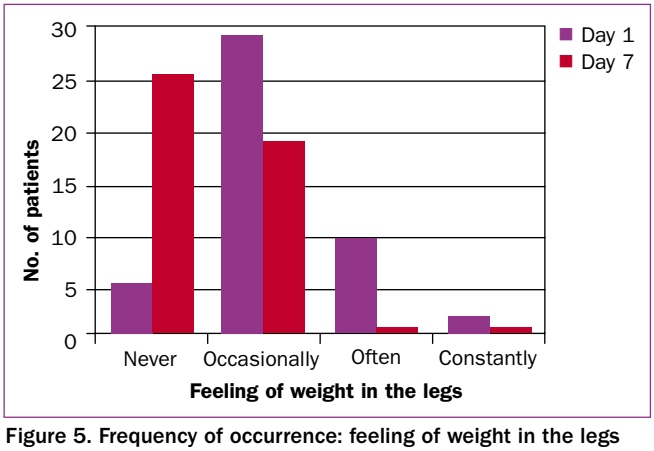

Figure 5. Frequency of occurrence: feeling of weight in the legs

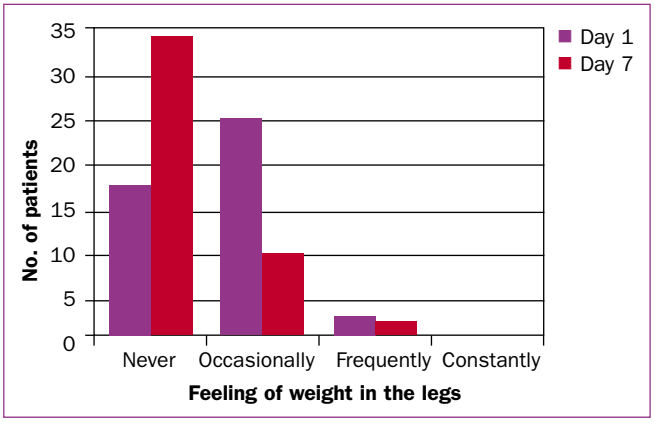

Figure 6. Frequency of occurrence: pain in the legs

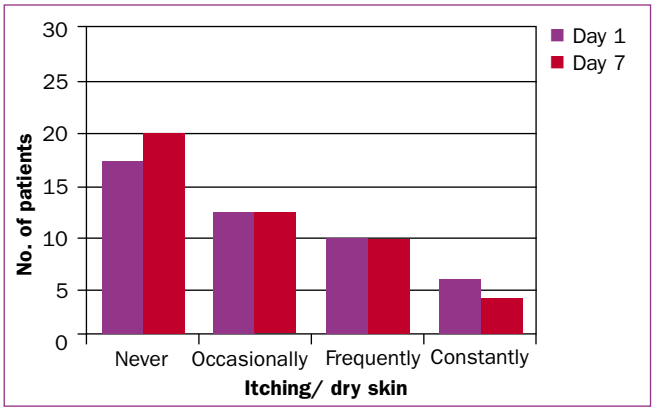

Figure 7. Frequency of occurrence: itching/dry skin

periods compared with the conventional stockings. Only 10 patients (21%) had worn their conventional stockings for more than 5 days before entry, whereas 9 (19%) and 31 patients (66%) indicated that they wore the test stockings for 6 and 7 days of the evaluation, respectively (*Figure 1*). Similarly, patients were much more likely to wear the test stockings for more than 6 hours a day than they had the conventional stockings: 29 (62%) vs 43 (91%) (*Figure 2*).

Effect on symptoms of CVD

Results for the closed-ended questions on quality of life, symptoms and day-to-day activities were broadly similar at the start and end of the evaluation. In terms of quality of life, 41 (87%) and 38 patients (81%) reported an improvement on days 1 and 7 respectively, while slightly more reported an improvement in symptoms on day 1 compared with day 7: 44 (94%) vs 39 (83%). Sixteen patients (34%) reported an improvement in the appearance of the skin on their legs on day 1 compared with 14 (30%) on day 7, while 8 patients (17%) indicated on day 1 that the previous stockings used had restricted their day-to-day life compared with 6 (13%) for the test stocking on day 7. The patients graded two of the four parameters—ability of the stocking to improve their quality of life and to improve their symptoms—as most important to them.

While the patients reported little difference in the overall severity of CVD symptoms during the follow-up period, the findings showed there was a marked improvement in the frequency with which they occurred. Compared with baseline, there was an increase in the number of patients who reported they never experienced a particular symptom during the 7-day evaluation period, with the most marked difference being for heavy legs (+21 patients), followed by feeling of weight in the legs (+20 patients), pain (+16 patients), tension in the legs (+11 patients) and itching/dry skin (+2 patients). Full details are given in *Figures 3, 4,5,6,* and 7.

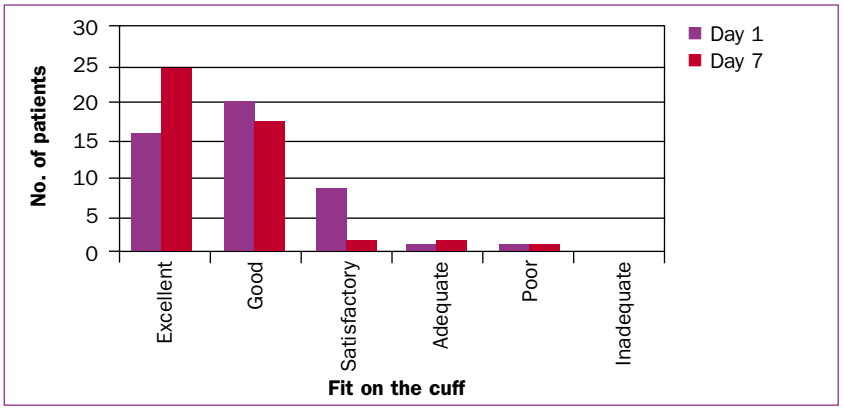

Figure 8. Rating for fit on the cuff

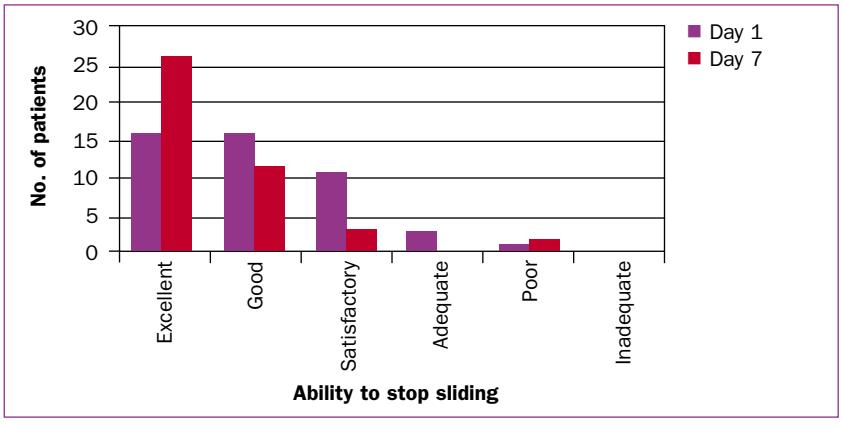

Figure 9. Ratings for ability to stay in place

Perceptions of the test stocking

When asked to score how effectively the compression stockings improved symptoms, most patients rated them as excellent or good on both days 1 and 7 (37 (79%) vs 36 (77%), although more patients regarded the test dressing as excellent on day 7 (14 (30%) vs 4 (9%) for day 1). (Almost all of the remaining scores were 'satisfactory' for both time points.) The same pattern was observed when the patients were asked to rate how the stockings felt against their skin, with 38 (81%) and 36 (77%) reporting this as excellent or good on days 1 and 7 respectively, but with five more patients reporting scores of excellent on day 7 than at baseline (14 (30%) vs 9 (19%)).

Comparative results for the compression stockings

The main parameters assessed were fit (on the leg and cuff) and ability to avoid slippage. Similar numbers rated the fit on the leg as excellent or good on days 1 and 7 (41 (87%) vs 42 (89%)), although markedly more patients gave scores of excellent on day 7 (25 vs 15). However, there were bigger differences in favour of the test stocking for fit on the band and ability to stay in place. For fit on the band, more patients gave scores of either excellent or good on day 7 than on day 1 (42 (89%) vs 36 (77%)), while there were also more 'excellent' scores (n=9) on day 7 (25 (53%) vs 16 (34%) (*Figure 8*). The difference was even more marked for ability to stay in place, with 41 patients (87%) rating this as excellent or good on day 7 compared with 32 (68%) on day 1, and 12 more patients (26%) rating it as excellent on day 7 (*Figure 9*).

The frequency of occurrence of symptoms of reddening, itching and the presence of dry skin was similar before and after the evaluation. However, there was an increase in the number of patients whose stocking band did not cut into the skin during the 7-day evaluation period (25 (78%) vs 34 (72%)). Full results are given in *Table 2*.

To conclude the outcome of this patient survey, patients

Table 2. Frequency with which compression stockings caused problems on the skin: day 1 versus day 7

	Never		Occasionally		Often		Always	
	Day 1	Day 7	Day 1	Day 7	Day 1	Day 7	Day 1	Day 7
Reddening	42 (89%)	40 (85%)	5 (11%)	5 (11%)	0	1 (2%)	0	1 (2%)
Itching	24 (51%)	24 (51%)	17 (36%)	16 (34%)	4 (9%)	4 (9%)	2 (4%)	3 (6%)
Dry skin*	15 (32%)	17 (36%)	14 (30%)	16 (34%)	8 (17%)	7 (15%)*	10 (21%)	5 (11%)†
Cuff cutting into skin†	25 (53%)	34 (72%)	18 (38%)	11 (23%)	3 (6%)	1 (2%)	1 (2%)	0

*Answers missing from 2 patients †Answer missing from 1 patient

were asked to give their opinion on whether they had changed their 'behaviour' in terms of use of compression stockings. Although only 19 patients (40%) explicitly thought they had improved their behaviour, the results for wear show a more promising change. When asked if they would use the test stocking again, the majority (n=34, 72%) said they would, with the remainder saying no or maybe. Thirty-four patients (72%) also said they preferred the test stocking to standard compression stockings.

Discussion

In order to promote patient adherence to treatment and achieve better healing outcomes, it is necessary to produce compression garments that fit better and are more comfortable to wear. The results of this patient survey show that patients found the Jobst Opaque SoftFit stocking more comfortable to wear compared with the standard compression stockings worn before entry into the evaluation. This is more likely to result in patients continually wearing their stockings, which is in turn likely to improve adherence with treatment and thus achieve better outcomes.

A PubMed search found no other patient surveys on compression stockings against which to compare these results.

This was a simple patient survey and so inevitably has some limitations. The first questionnaire did not elicit full patient demographic data, including gender, history of CVD disease, CEAP score, history of compression stocking usage and the frequency of wear/replacement of the previous stockings, while the follow-up period was short at 7 days. Data were not gathered on CEAP scores as the focus of the evaluation was acceptability of the stockings to the patients, not stocking performance as measured by a change in CEAP score. Similarly, the questionnaire did not identify the previous stockings worn as the intention was to compare the test stocking with as broad a range of stockings as possible, rather than specific brands. However, although this was not recorded, it can be assumed that the previous stockings were in the same class and length as the test stocking. Quality of life was assessed subjectively, and not with a validated quality-of-life tool, as it would have been difficult to include such a detailed tool into the two relatively short questionnaires. The application of the findings to an older patient population is questionable given that the mean age was 36, and the majority of the sample was aged under 60 years. Regarding the question of whether the increase in wear time reported with the test dressing can be attributed to its greater comfort, an inclusion criterion was that patients had to have worn their previous stockings for at least 6 hours a day and 5 days a week. It can therefore be assumed that the patients' decision to wear the test stocking for a longer period of time than they had previously was an independent decision, potentially attributable to its increased comfort. Finally, it must be borne in mind that the findings are based on patient satisfaction ratings, and so cannot be used alone to predict efficacy of the garment. Nevertheless, the survey provides an interesting and useful insight into the ability of SoftFit technology to promote patient adherence.

Conclusion

This patient survey provides preliminary data showing that compression stockings made with SoftFit technology are acceptable to patients and might help promote adherence with treatment. The next step would be to undertake a more long-term evaluation, both of its efficacy as well as tolerability and acceptability of this new compression stocking. However, early signs indicate that this new technology is well received by patients. BJN

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KEY POINTS

- Compression therapy is essential in the management of chronic venous disease symptoms
- Poor patient adherence to compression therapy results in persistence or recurrence of symptoms
- New advances in compression stockings with the introduction of SoftFit technology, may play an important role in improving patient adherence to therapy