

SUMMARY OF SELECTED RESULTS

The impact of VenoTrain soft on quality of life and leg problems in CVI patients

INTRODUCTION

Chronic venous insufficiency (CVI) is a condition with a high prevalence rate that affects the lower extremities in particular and can result in restricted quality of life (1, 2, 3).

Compression is commonly used as the basic treatment to prevent venous congestion and the disruption of the pressure conditions in the veins that is associated with it (4). Based on a defined resting pressure exerted from the outside, adapted compression stockings normalize flow conditions in the affected extremities, thus reducing CVI-related leg problems CVI (2, 4).

The objective of this study was to identify how wearing VenoTrain soft impacts quality of life in CVI patients who have been wearing compression stockings for many years. The short version of the validated and internationally recognized Freiburg Life Quality Assessment for chronic venous disease (FLQA-VS-10) was used, which measures condition-specific and health-related quality of life in patients with chronic venous disorders.

METHODS

Study design

- Non-controlled interventional study, longitudinal study
- Wearing duration: 28 days (Ø 12.2 h/day)
- Retrospective, weekly assessment of quality of life, CVI-related leg problems and comfort
- Baseline: start of the study, day of first survey

Patients

- 31 patients with CVI (16 women, 15 men)
- CEAP: C2 n=8; C3 n=12; C4 n=11
- Mean age: 63

MCS

- VenoTrain soft (Ccl 2, AG thigh-high stocking)

Measurements

- Quality of life assessment using the FLQA-VS-10 questionnaire (10 = no restrictions whatsoever; 50 = major restrictions)
- Survey of subjective CVI symptoms using visual analog scales (1 = no symptoms; 10 = most severe symptoms)
- Participants' self-reported evaluation of the compression stockings

RESULTS

1. CVI-associated quality of life

Even after wearing the VenoTrain soft for one week, a significant improvement in the quality of life became evident, which continued to increase over the course of the study (Fig. 1). At the beginning of the study, participants indicated a value of 15.2, which decreased significantly to 12.5 after four weeks of wearing the product.

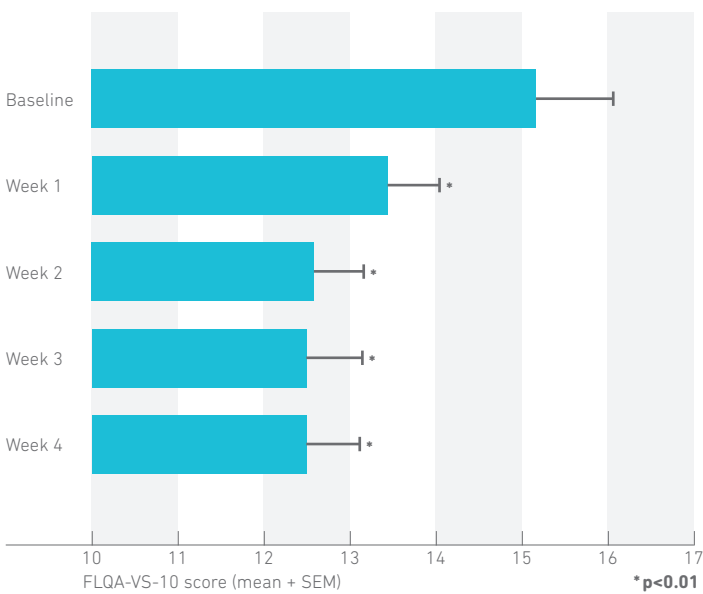


Fig. 1: CVI-associated quality of life

Significant improvement in CVI-associated quality of life even after one week

2. Subjective CVI symptoms

There was a reduction in symptoms after four weeks of wearing the product for all parameters surveyed (Fig. 2). After 28 days of wearing the product, pain perception decreased by 48.5%, heavy legs by 52.9%, swollen feet by 56.6%, feelings of tension in the legs by 41.6%, tingling in the legs by 25.7%, itching by 34.4% and sore muscles by 36.1%, compared with the baseline values.

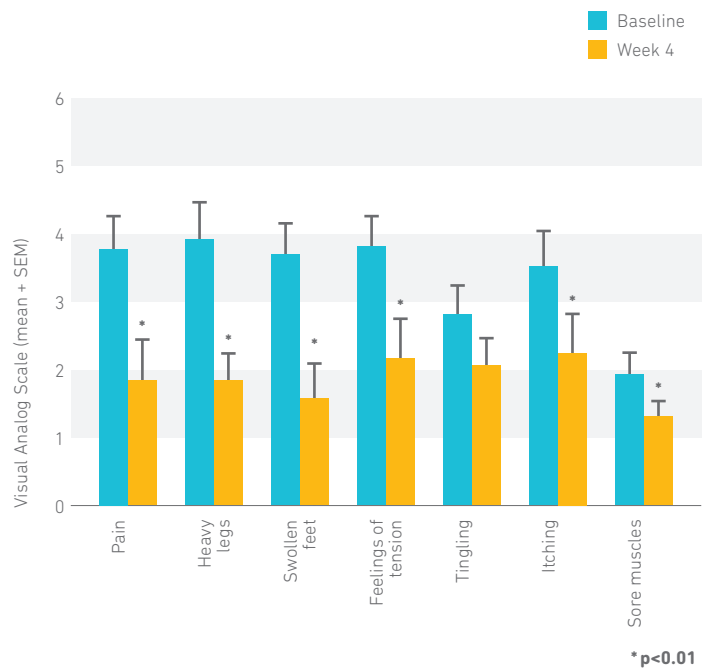


Fig. 2: Patients' CVI symptoms

Significant and clinically relevant reduction of typical CVI symptoms

More than 50% reduction of heavy legs and swollen feet

Even one week of wearing the VenoTrain soft resulted in a significant and clinically relevant reduction in leg pain (Fig. 3). This effect increased over the wearing period and resulted in a pain reduction of 1.6 points on a 10-item visual analog scale after four weeks.

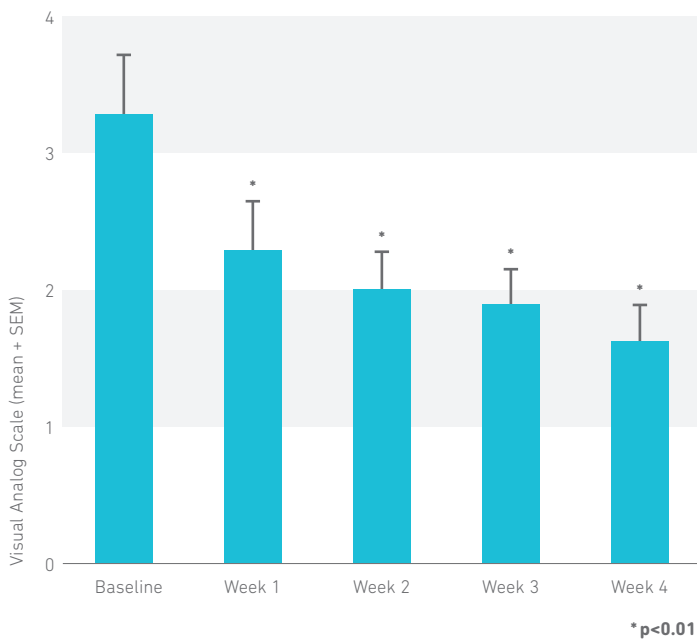


Fig. 3: Patients' pain perception over the course of treatment

Significant reduction of pain in the legs even after one week of wearing the product

3. Patients self-reported evaluation of the compression stockings

For the subjective evaluation of the compression stockings at the end of the study, participants reported whether they noticed "none", "hardly any", "some" or "many" positive changes from wearing the product. The majority of respondents noticed positive changes (Fig. 4). No participant reported no positive changes whatsoever. 84% of patients also rated donning of the stockings as easy, uncomplicated or requiring little effort. Moreover, 93% of patients stated that they would recommend the compression stockings to their friends without reservation.

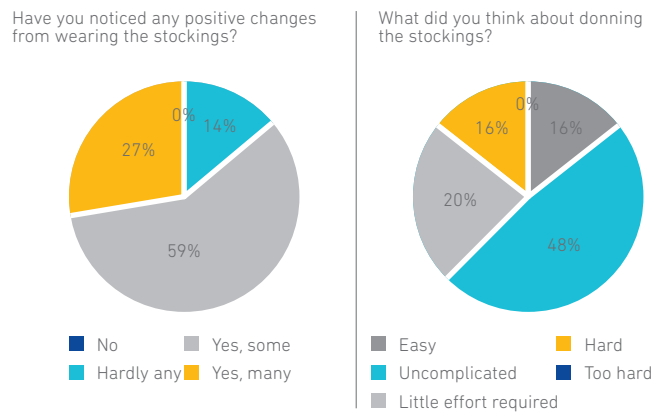


Fig. 4: Subjective evaluation by participants

86% of patients noticed some or many positive changes from wearing the stockings

84% of patients were happy with donning the stockings

93% of patients would recommend the stockings to their friends

SUMMARY

This study showed that even one week of wearing the VenoTrain soft significantly improved quality of life and reduced CVI-associated leg problems in CVI patients who had been using compression products for many years. These findings continued to improve until the end of the 4-week wearing period.

Additionally, the subjective evaluation of the compression stockings revealed that the majority of patients noticed positive changes, they were happy with the compression stockings even after an extended average wearing time of 12.2 hours per day and would recommend them to friends.

The fact that such a significant, positive impact was achieved, even though the participants had experience with compression stockings, may be connected with the comprehensive education of the patients and increased awareness in relation to their own compression therapy. By completing the questionnaire every day, the patients' focus was put on their treatment and allowed them to notice even minor improvements. This may have had a positive impact on adherence because 12 hours is an above-average length of documented wearing time. Compression therapy in particular can only be successful when the patient is properly educated and fully involved. The willingness to wear the required compression stockings increases with the patients' understanding of the treatment and increased awareness of effective self-management (5).

CONCLUSIONS

- VenoTrain soft significantly improves quality of life and CVI symptoms in experienced users of compression garments.
- Patients' treatment adherence is critical to guarantee comprehensive therapeutic success.

Acknowledgments

The study described above was conducted internally at Bauerfeind. It was approved by the relevant ethics committee, meets all requirements of Good Clinical Practice (GCP) and was conducted under the supervision of an external investigator. If you have any questions about any of the study details, please contact medical.affairs@bauerfeind.com.

References

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