

First results of an observation study in 80 leg ulcer patients with a new Two-Component-System (TCS)*

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Introduction

Compression is the key intervention in the management of venous and lymphatic disease. An innovative new short stretch compression system, Two-Component-System (TCS)* was developed to meet the individual requirements of the patient.



Picture 1: 'Figures of eight' or 50% overlapping (spiral technique), both techniques are applicable. S. Mazzei, Inst. Clinici Zucchi, Monza, Italy.

General Assessment (n = 80; median = 0.4)

Score: nothing = 0, low = 1, moderate = 2, strong = 3

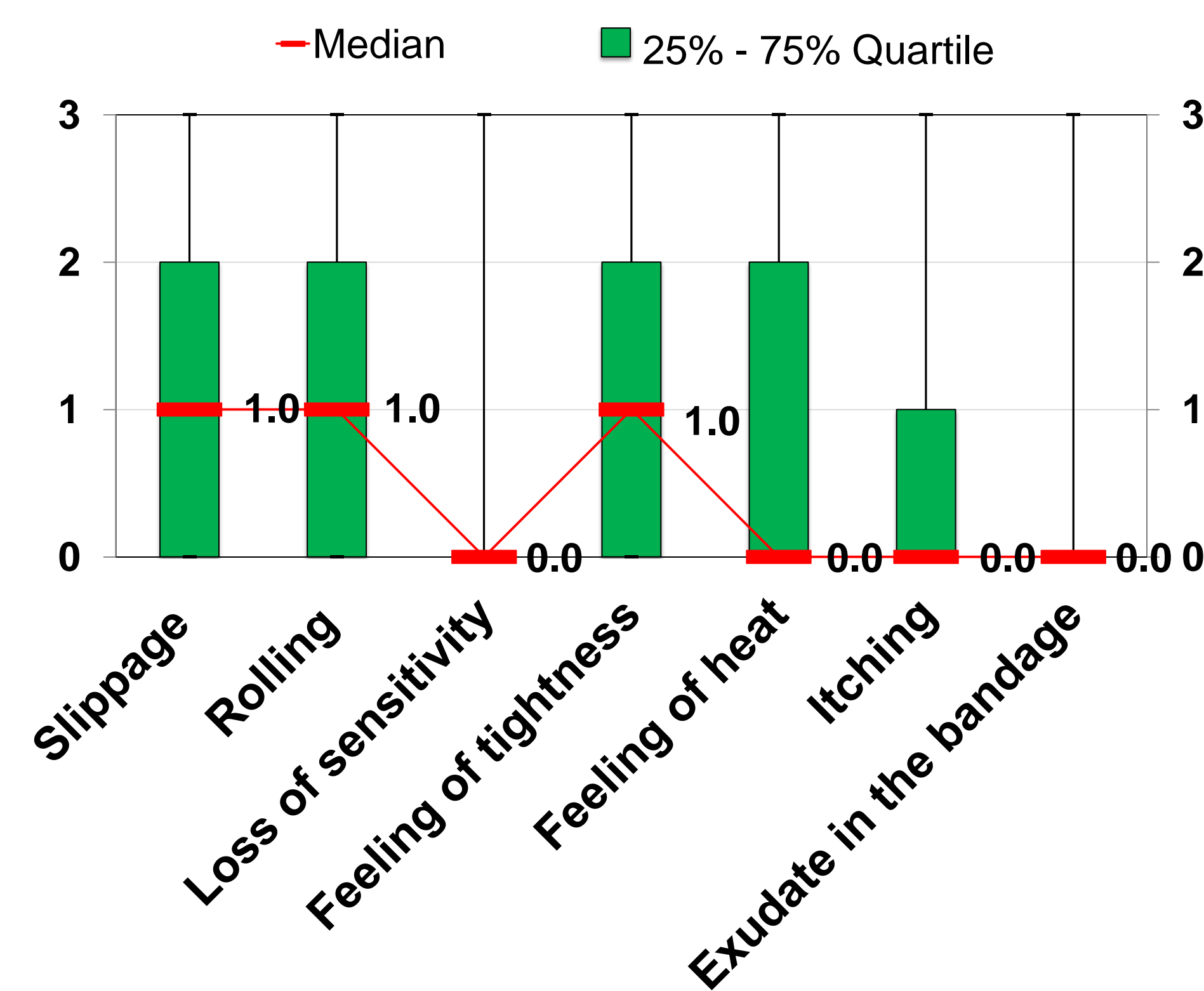


Figure 2: General assessment of the TCS* compression system by the user (number of treated patients n = 80).

Supine, standing pressure and SSI at start and day 7

25% Quartil = Q.25 - Max - Min 75% Quartil = Q.75 - Median

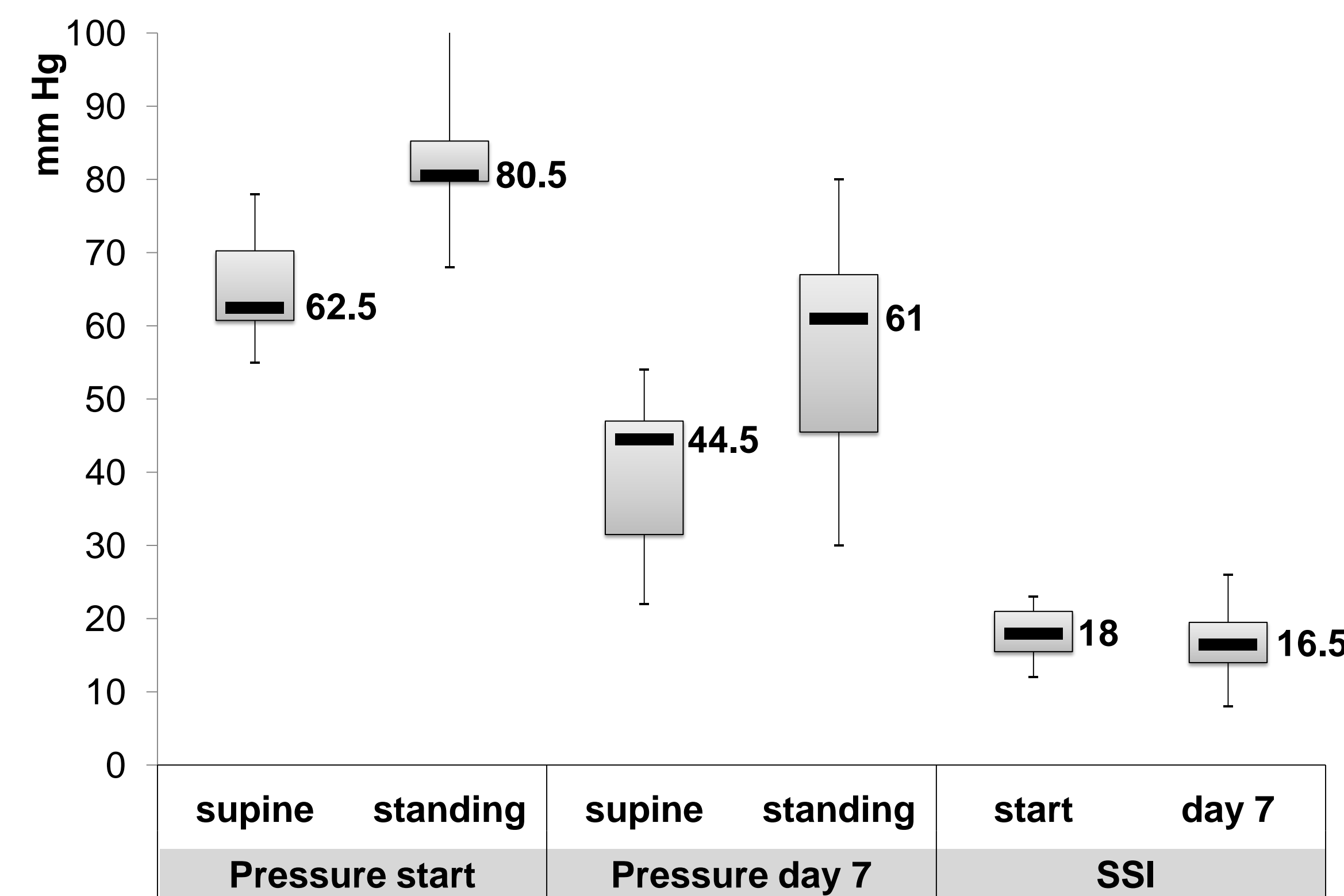


Figure 3: Supine and standing pressure, SSI (static stiffness index) at start and day 7 measured on B1-position, with PicoPress over 1 week.

Skin alterations (n = 80; median = 0.0)

Score: nothing = 0 low = 1 moderate = 2 strong = 3

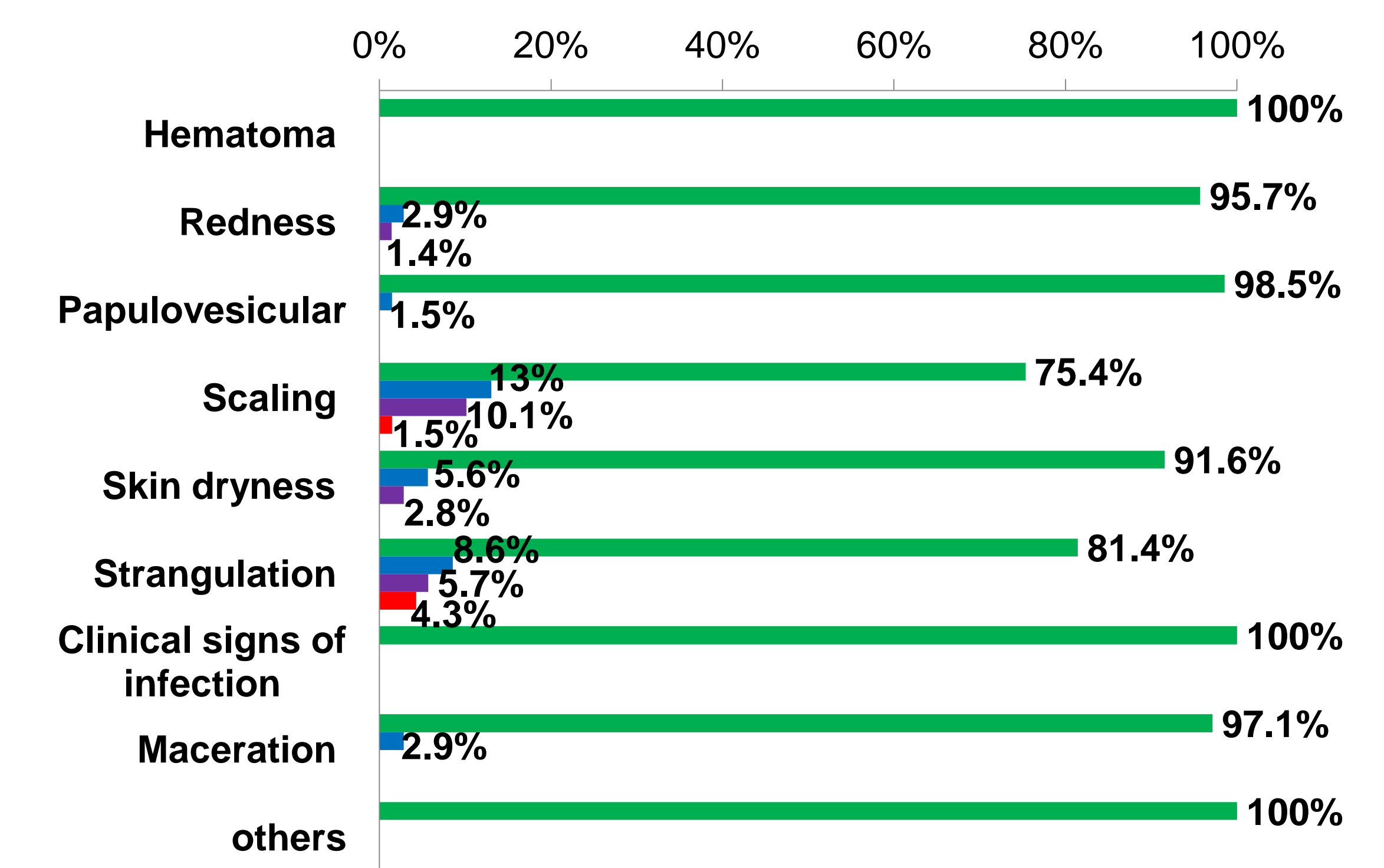


Figure 4: Skin alterations caused by the TCS* compression system (number of treated patients n = 80).

Material & Methods

A multicentric, international observation study (post marketing surveillance study, PMS) with a CE-certified Two-Component-System (TCS)* applied in its instructions of use to prove the usability (ergonomic aspects) in the daily routine as well as the user and patient satisfaction during the treatment with the new compression system. On 80 patients with non-infected leg ulcers or with edema the test system was used over 2 weeks. Additionally in one center the interface pressures were measured on B1-position with PicoPress over 1 week.

Patient - Quality of life with TCS (n = 80; median = 2.0)

Score: 1 = excellent, 2 = very good, 3 = good, 4 = acceptable, 5 = insufficient, 6 = failed

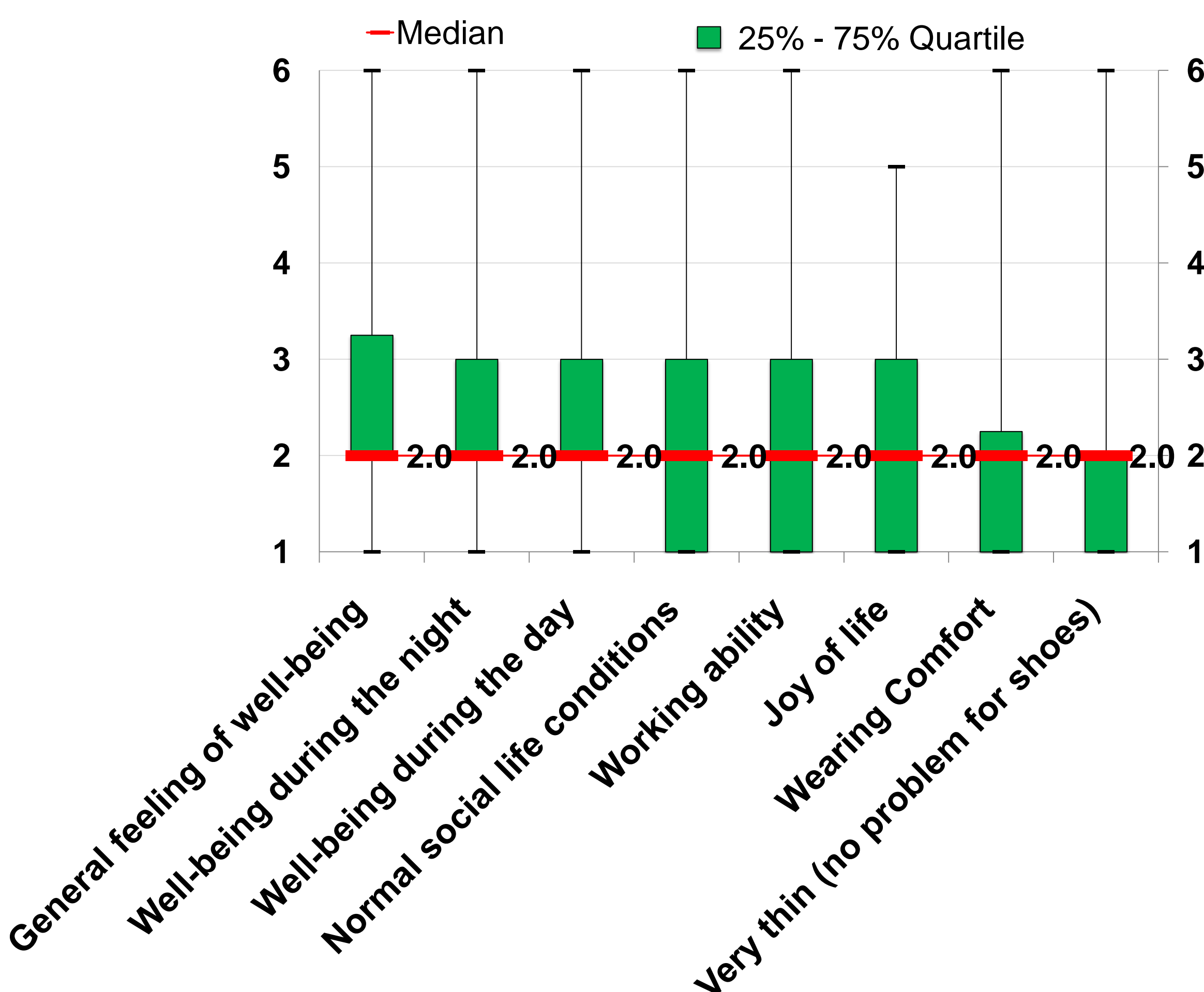


Figure 5: Quality of life for the patient with the TCS* compression system (number of treated patients n = 80).

Results

The Two-Component-System (TCS)* showed in the general assessment (slippage, rolling, loss of sensitivity, feeling of tightness, feeling of heat, itching, exudate in the bandage) very good results – mostly rated between nothing and moderate, with a total mean** of 0.4 = low to nothing. The evaluation of the technical assessment (easy to use, movement of the ankle sufficient, very thin and no problems for shoes, comfortable) was mostly assessed from excellent up to good, with a total mean** of 2.0 = very good. The total mean** of the quality of life evaluation was 2.0 = very good. General feeling of well-being and well-being during night and day were mostly rated with very good up to good, normal social life conditions working ability, joy of life with excellent up to good and the wearing comfort with excellent to very good. In personal comments the users rated TCS* with 2.0 = very good, especially with regard to its potential for edema reduction. With respect to possible side effects like skin alterations (hematoma, redness, papulovesicular, scaling, skin dryness, strangulation, clinical signs of infection, maceration or others) the results were consistently very good (from 'nothing' to 'low'). The total mean** of the side effect evaluation was 0.0 = nothing. In one center the interface pressure of the patients was measured – directly after application and after one week wearing time. The bandage system showed directly after application and after 1 week an excellent Static Stiffness Index (SSI): 16.5 to 18. No skin alterations occurred. The bandage system was very well tolerated.

* Rosidal® TCS, Lohmann & Rauscher International GmbH & Co KG, Rengsdorf, Germany

** median

Technical Assessment (n = 80; median = 2.0)

Score: 1 = excellent, 2 = very good, 3 = good, 4 = acceptable, 5 = insufficient, 6 = failed

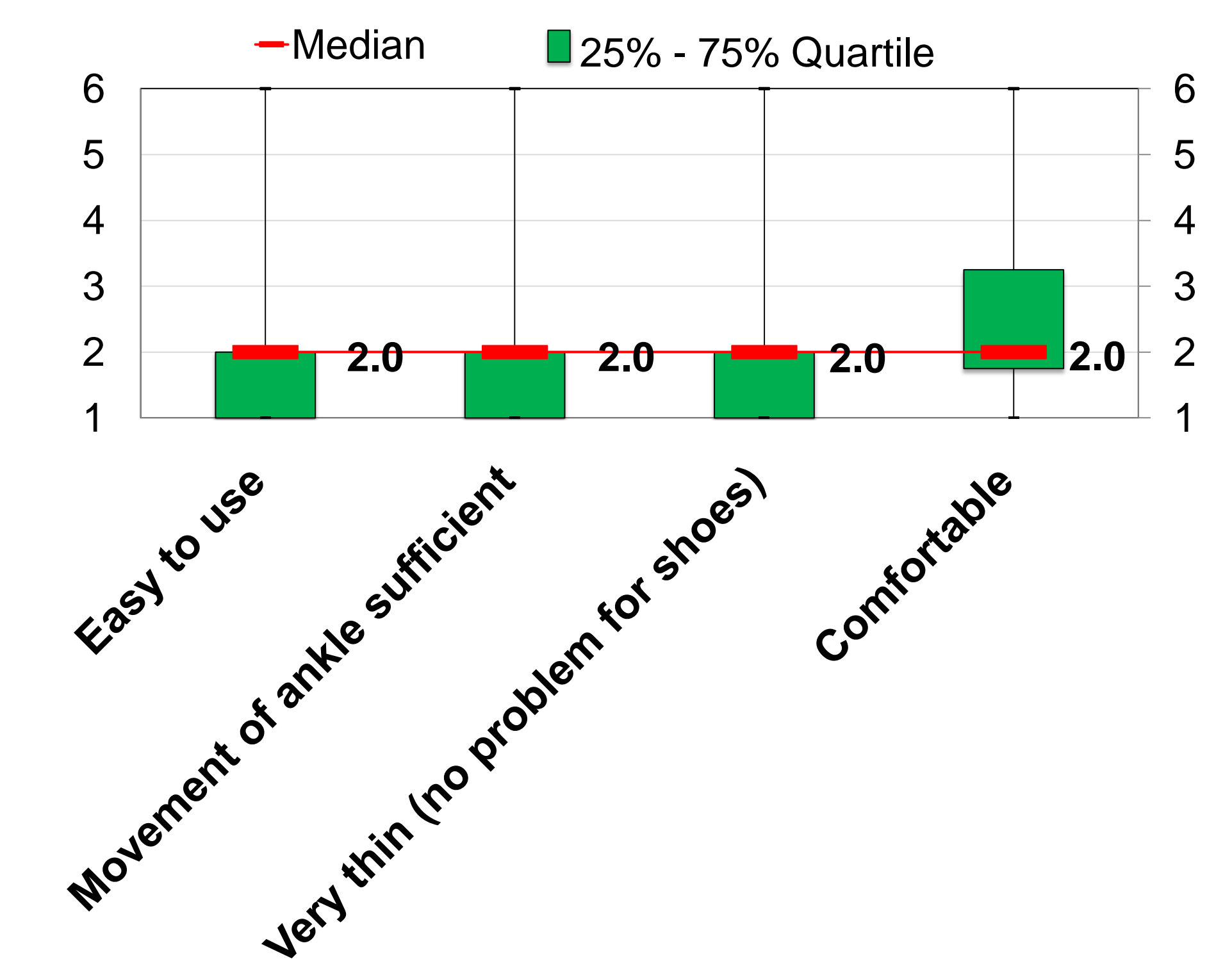


Figure 6: Technical assessment of the TCS* compression system by the user (number of treated patients n = 80).

Conclusions

These first results demonstrate, the Two-Component-System (TCS)* is a very good tolerable, safe and comfortable bandage system with adequate therapeutic pressure for treating leg ulcers as well as edema. The observation study is ongoing.