

# RESULTS OF AN OBSERVATION STUDY ON THIRTEEN MIXED OR ARTERIAL LEG ULCER PATIENTS WITH A NEW TWO-COMPONENT-SYSTEM (TCS)\*

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## Introduction :

To prove the usability of an innovative new CE-marked short stretch compression system, Two-Component-System (TCS)\* on mixed (MLU) or arterial leg ulcer (ALU) patients in comparison to venous leg ulcer (VLU) patients this study was conducted.

## Materials & Methods :

In a multicentre (7), international post marketing surveillance study (PMS) on 102 leg ulcer patients with or without oedema treated with TCS\* over 2 weeks the usability of the compression system could be proven. Thirteen (12.75%) of these patients were diagnosed with non-infected mixed or arterial leg ulcers with an ankle brachial index (ABI) generally measured between 0.5 and 0.9. In one center the interface pressures of six mixed ulcer patients were measured additionally over 1 week (B1-position, PicoPress).

### Technical assessment (N=13; median=1.5)

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

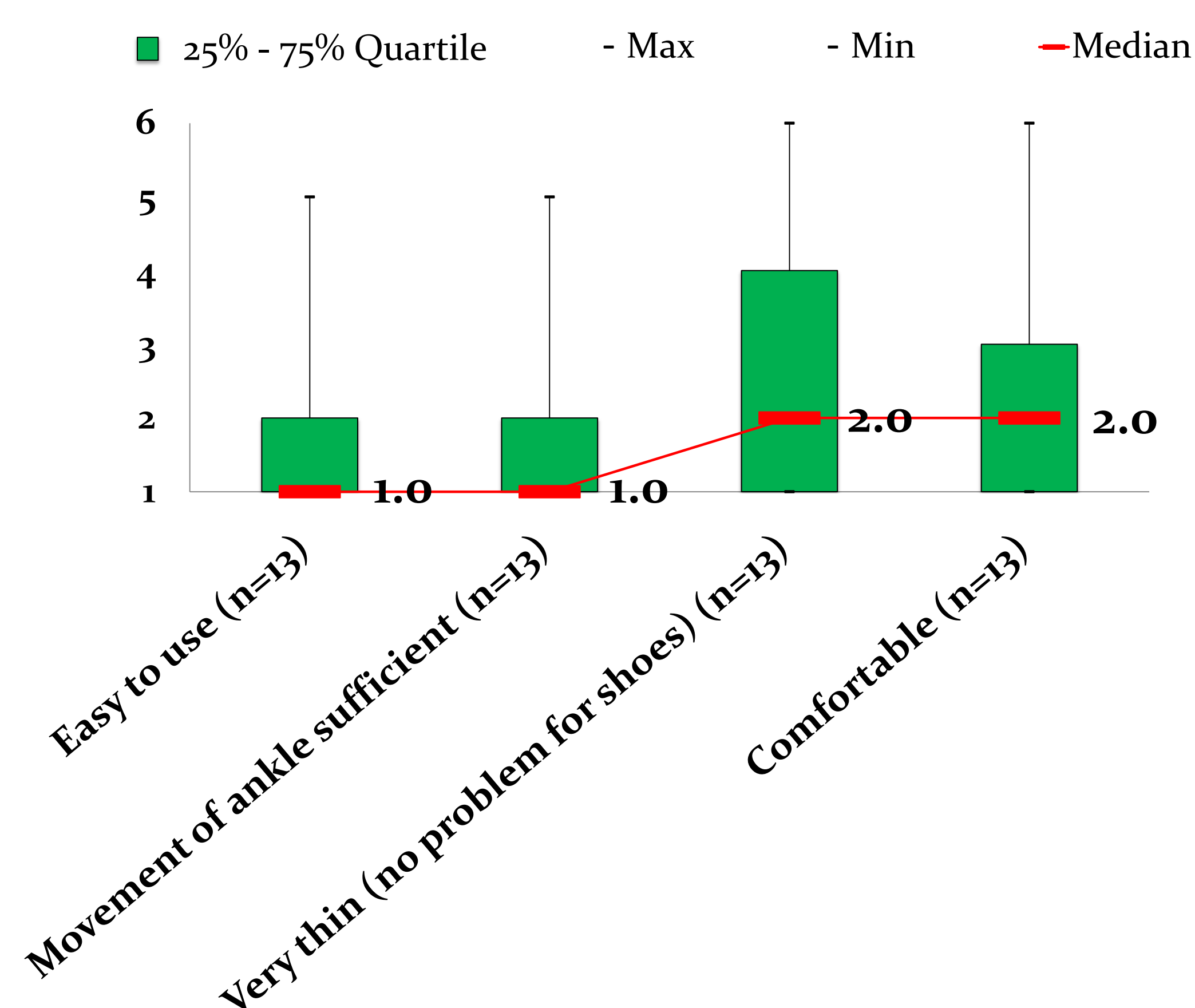


Fig 3: Technical assessment of the TCS compression system applied in a figure of eight or in a spiral technique with a 50% overlap of the layers (N=13).

### Skin alterations (N=13; median = 0.0)

■ nothing = 0 ■ low = 1 ■ moderate = 2 ■ strong = 3

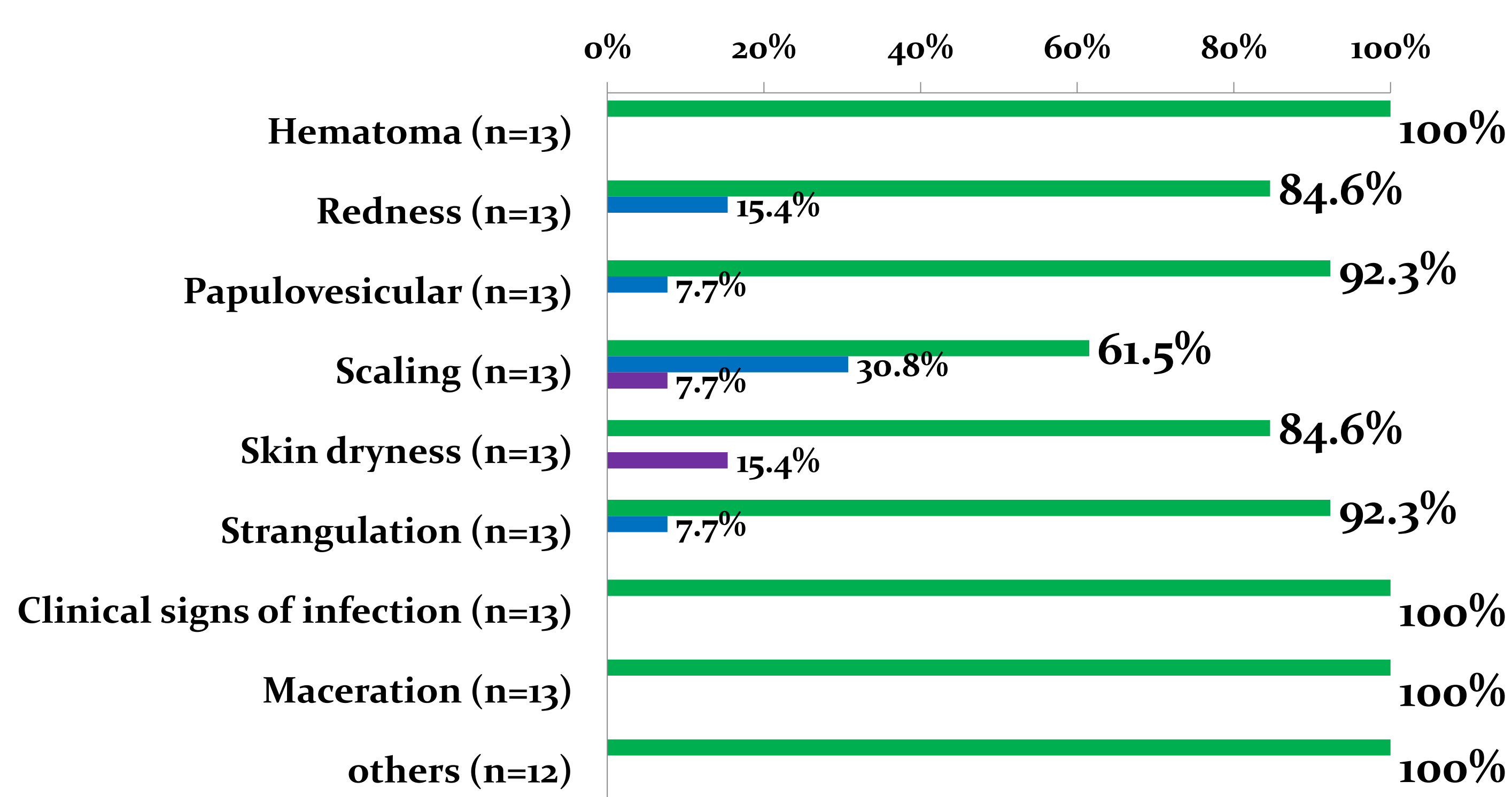


Fig 4: Skin condition during the study period when using the TCS compression system applied in a figure of eight or in a spiral technique with a 50% overlap of the layers (N=13).

### General Assessment (N=13; median = 0.3)

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

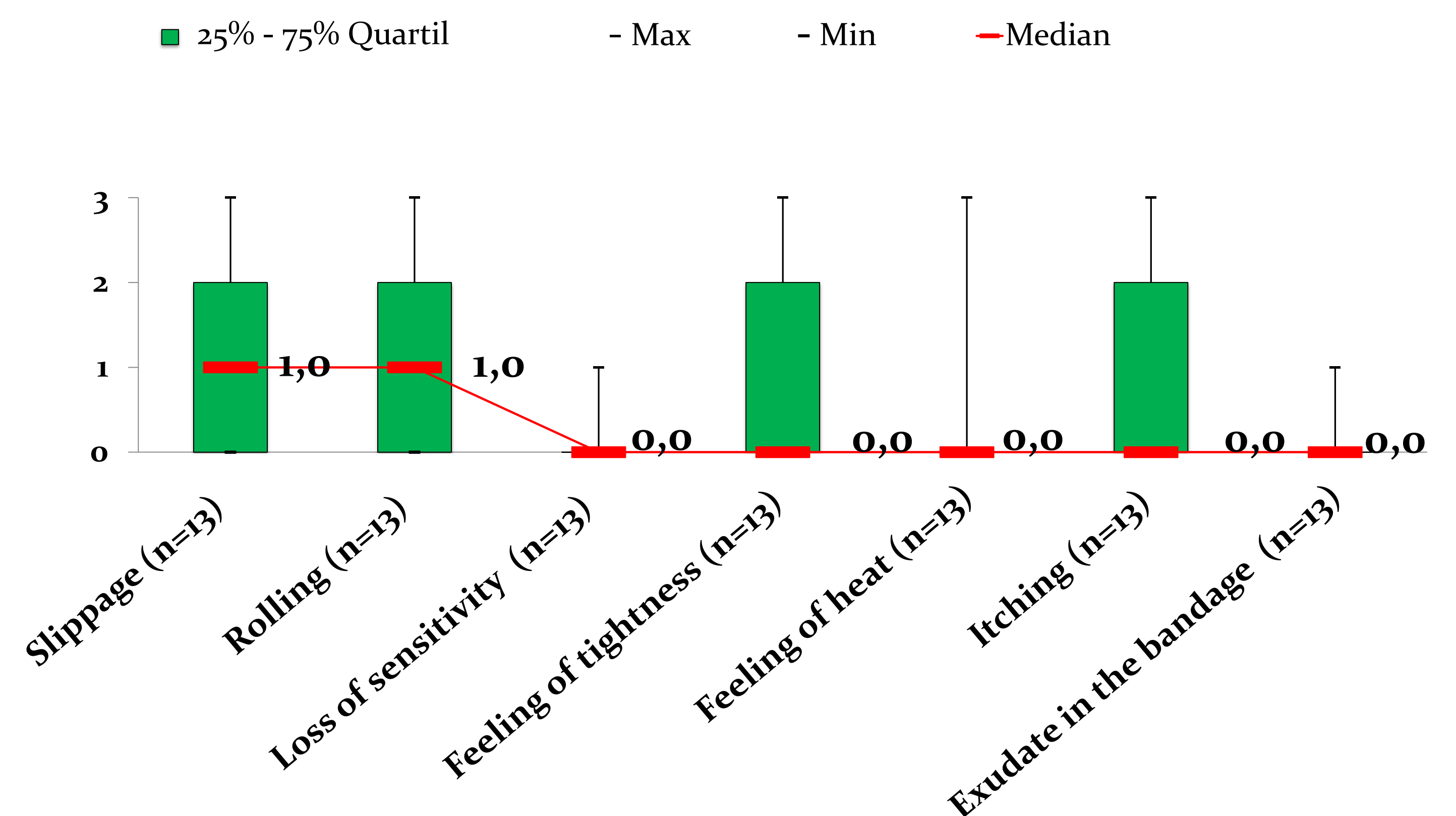


Fig 1: General assessment of the TCS compression system applied in a figure of eight or in a spiral technique with a 50% overlap of the layers (N=13).

### Patient - Quality of life with TCS (N=13; median=2.0)

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

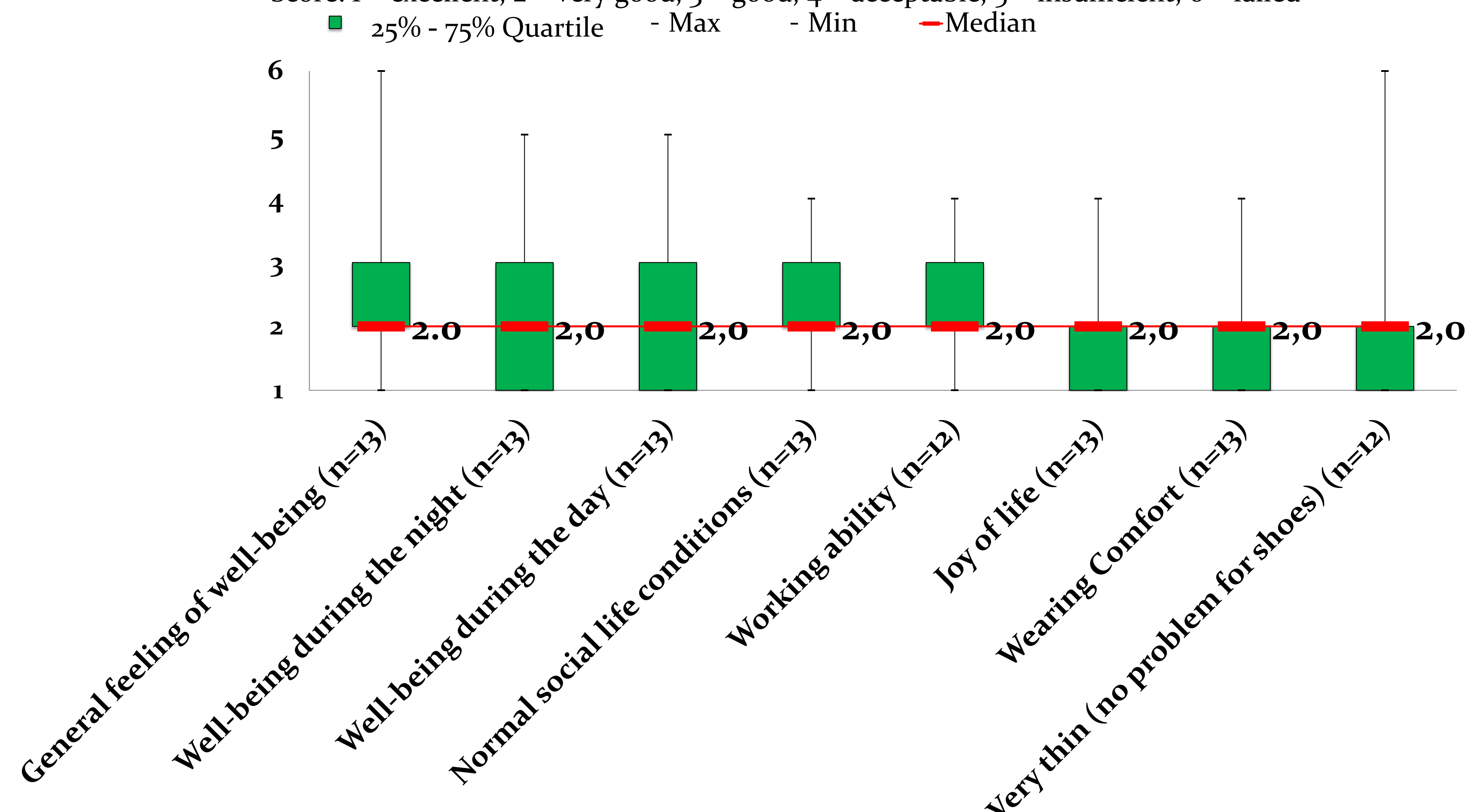


Fig 2: Patient reported quality of life aspects when using the TCS compression system applied in a figure of eight or in a spiral technique with a 50% overlap of the layers (N=13).

## Results :

Comparably for VLU as for MLU or ALU patients the TCS\* showed in the general assessment (slippage, rolling, loss of sensitivity, feeling of tightness, of heat, itching, exudate in the bandage) very good results – total mean\*\* 0.3 = ‘low’ to ‘nothing’ [Fig 1]. Equally very good results has been observed for in the technical assessment of TCS\* (easy to use, movement of the ankle was sufficient, very thin - no problems for shoes, comfortable) [Fig 3], the quality of life evaluation (feeling of well-being in general, during night or day, social life conditions, the working ability, joy of life, wearing comfort and very thin) [Fig 2] and the potential for oedema reduction [data not shown] rated with a total mean\* of 1.5 to 2.0 = ‘very good’. Skin alterations were very rare (except scaling) – total mean\*\* 0.0 = nothing. The bandage system showed for all kind of ulcer patients an excellent Static Stiffness Index (SSI). [data not shown].

## Conclusion :

TCS\* is very well tolerable, safe and comfortable, with adequate therapeutic pressure for treating all kinds of leg ulcers with or without oedema.

\*\* median