

# RESULTS OF AN OBSERVATION STUDY IN 102 LEG ULCER PATIENTS WITH A NEW TWO-COMPONENT-SYSTEM (TCS)\*

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## Introduction :

An innovative new short stretch compression system, Two-Component-System (TCS)\* was developed.

## Materials & Methods :

A multicentre (7), international post marketing surveillance study (PMS) to prove the usability in daily routine. On 102 patients with non-infected leg ulcers with or without oedema TCS\* was used over 2 weeks. In one center the interface pressures were measured over 1 week (B1-position, PicoPress).



**Fig 1:** TCS may be applied in a figure of eight or in a spiral technique with a 50% overlap of the layers, as shown here. Photograph of a patient treated by A. Collarte, Tissue Viability Department, Central London Community Healthcare NHS Trust, St Charles Community Hospital, London, United Kingdom.

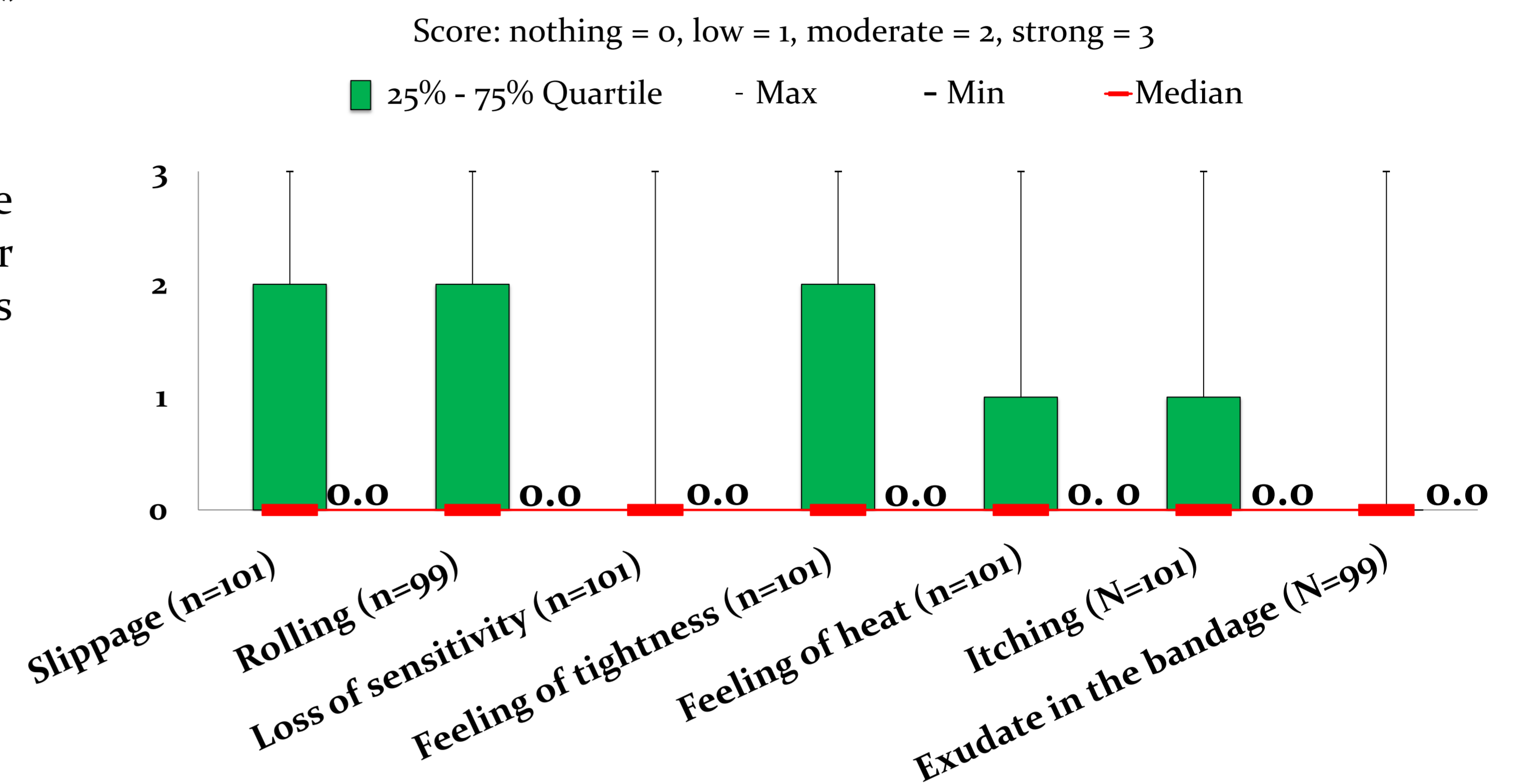
## Results :

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\*\* 0.0 = ‘nothing’ [Fig 2]. The technical assessment (easy to use, movement of the ankle was sufficient, very thin and no problems for shoes, comfortable) was rated with a total mean\*\* of 2.0 = ‘very good’ [Fig 4]. The potential for oedema reduction was evaluated with ‘very good’ to ‘good’ (total mean\*\* = 2.3) [data not shown]. The quality of life (feeling of well-being in general, during night or day and the working ability, normal social life conditions, joy of life, wearing comfort and very thin (no problem for shoes) from the perspective of the patient) was rated with ‘very good’ [Fig 3]. Skin alterations were rated with ‘nothing’ [Fig 5]. The bandage system showed an excellent Static Stiffness Index (SSI) - directly after application SSI = 18, after 1 week SSI = 16.5 [Fig 6].

## Conclusion :

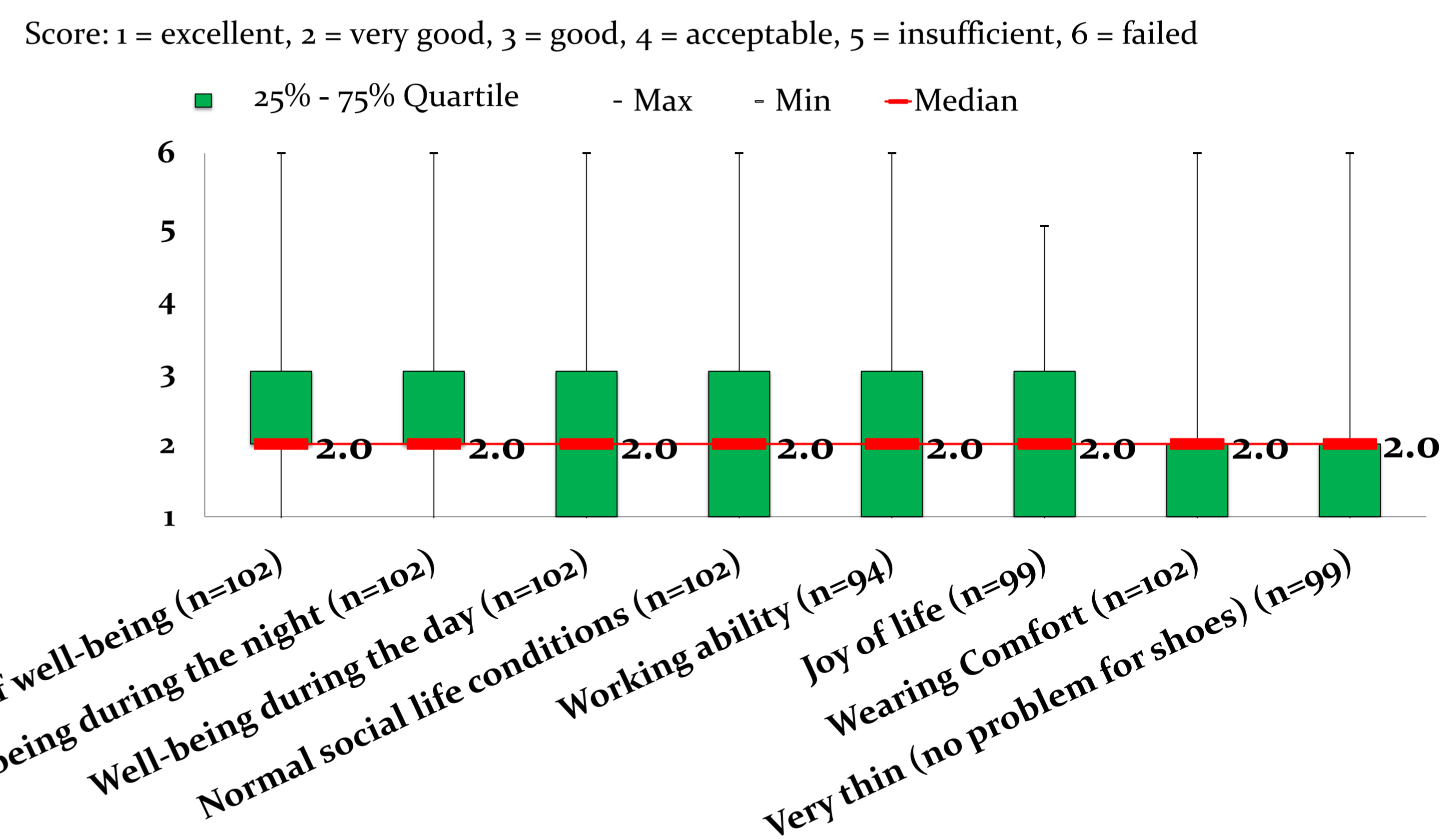
TCS\* is very well tolerable, safe and comfortable, with adequate therapeutic pressure for treating leg ulcers with or without oedema.

## General Assessment (N=102; median = 0.0)



**Fig 2:** 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=102).

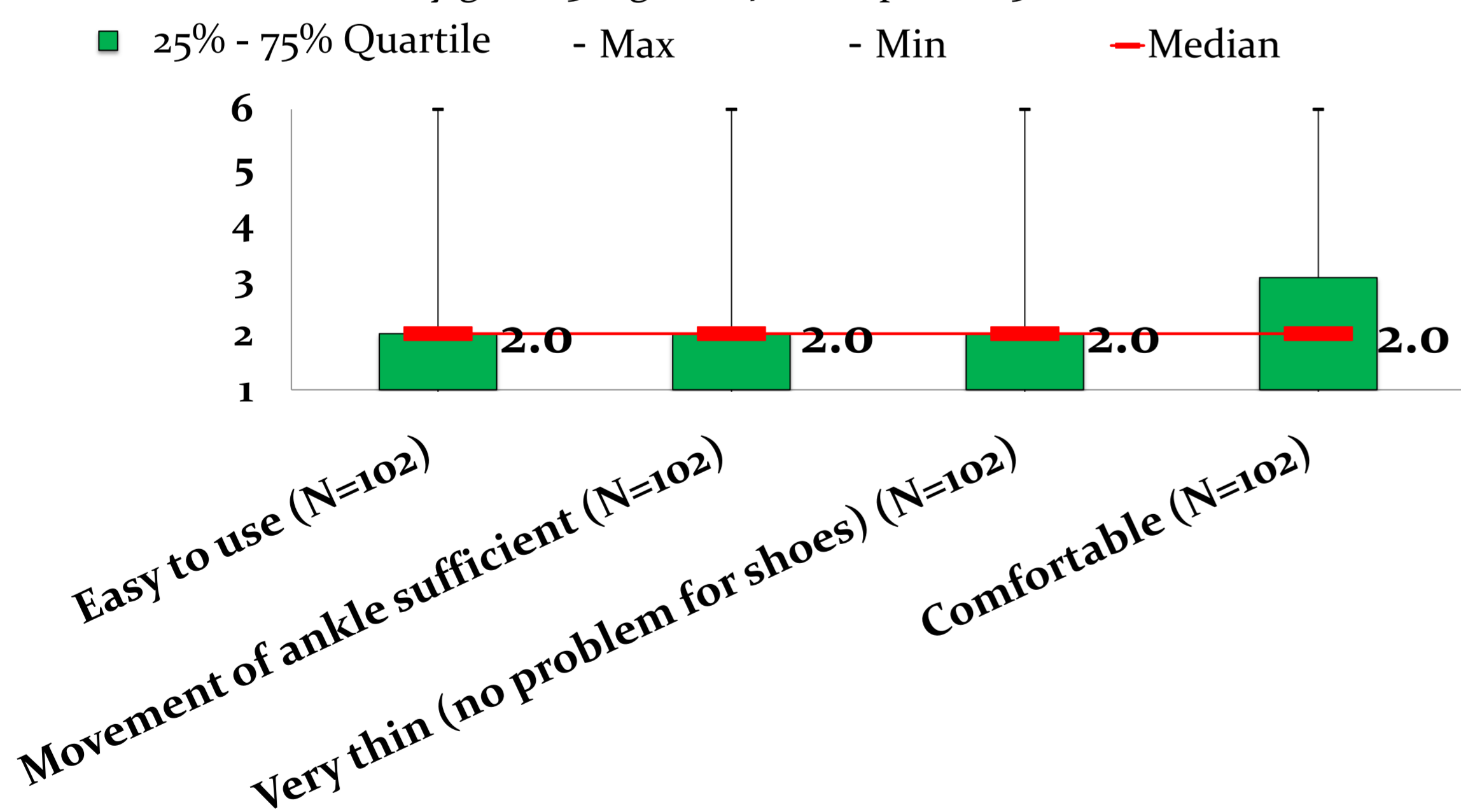
## Patient - Quality of life with TCS (N = 102; median = 2.0)



**Fig 3:** 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=102).

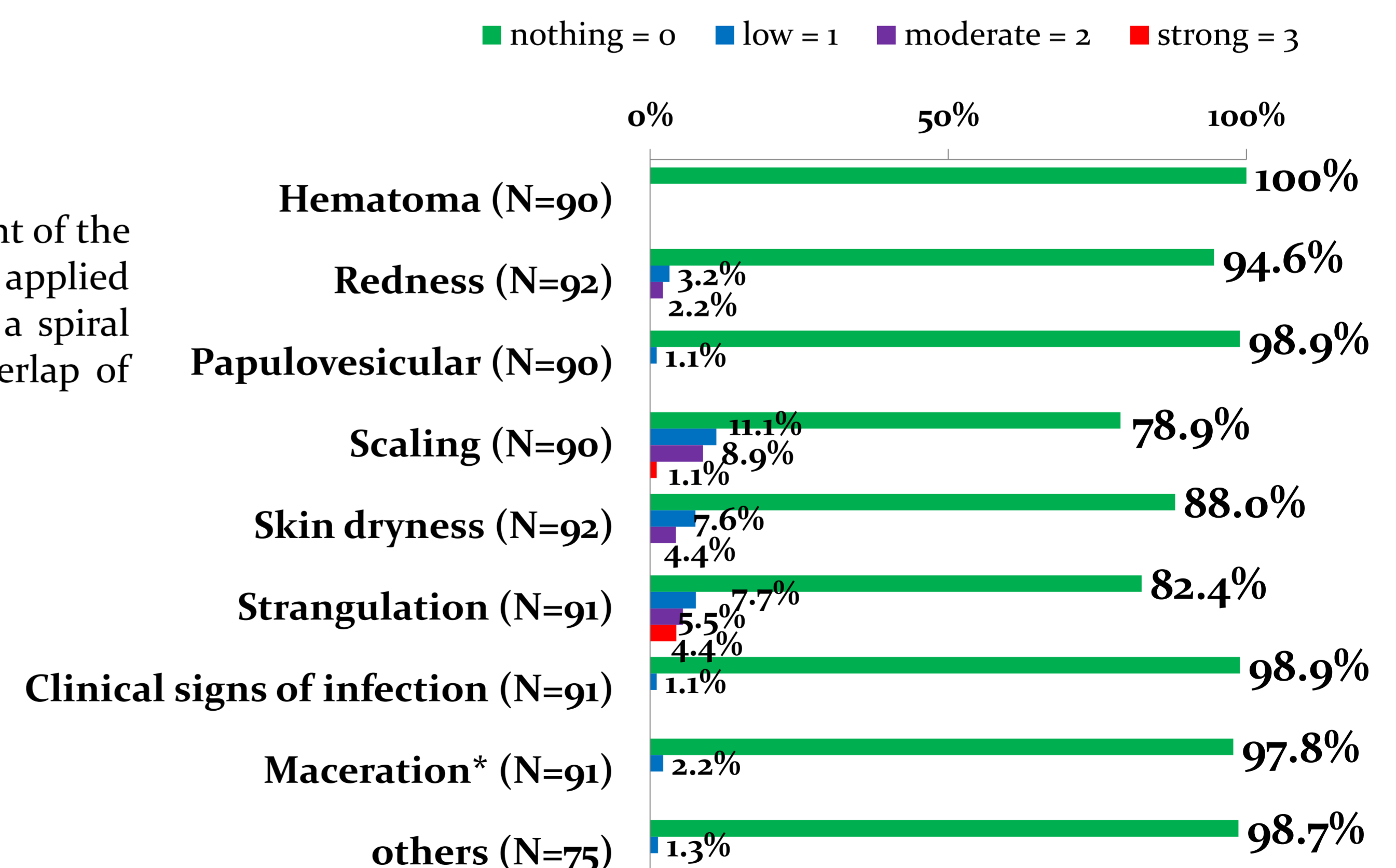
## Technical Assessment (N = 102; median = 2.0)

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



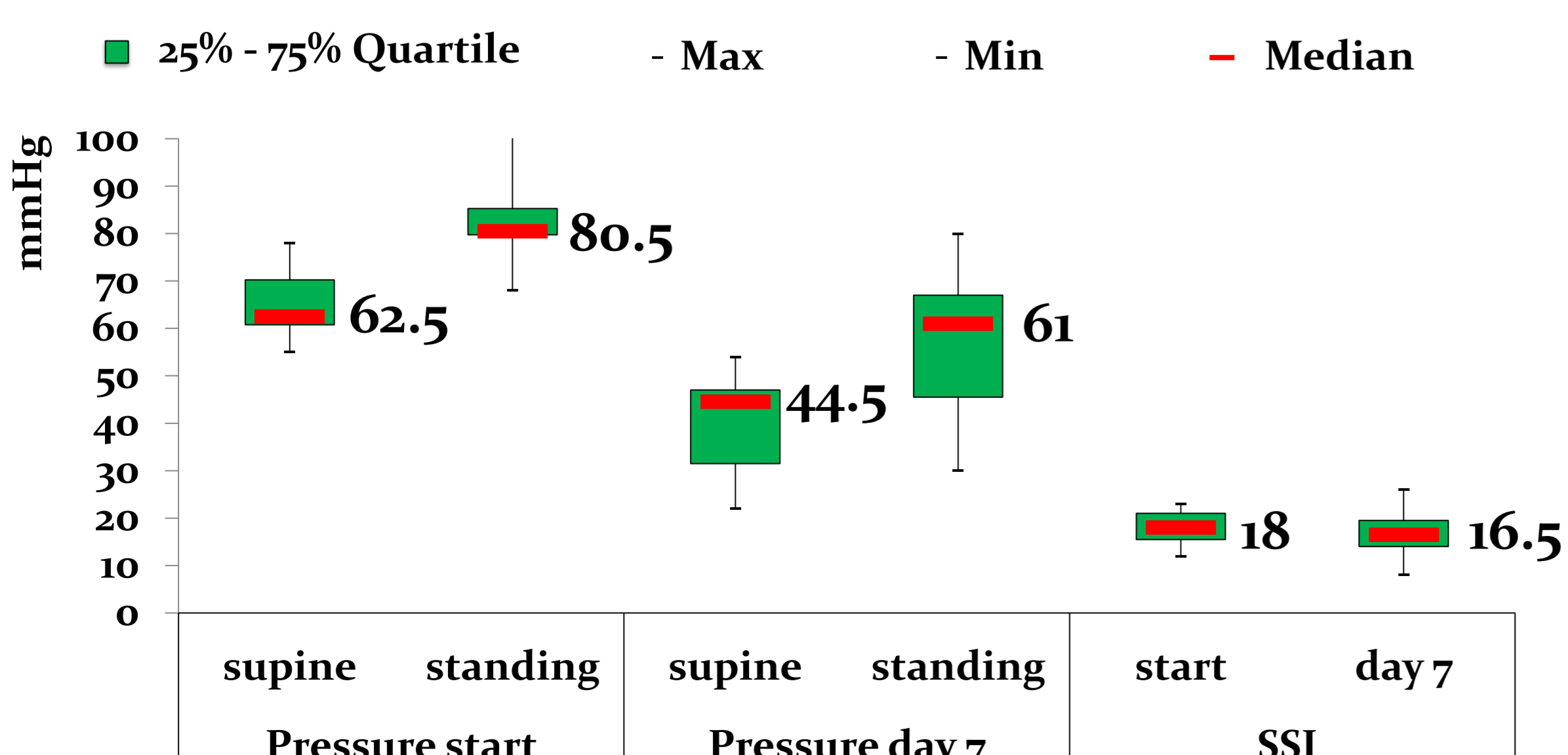
**Fig 4:** Technical assessment of the TCS compression system applied in a figure of eight or in a spiral technique with a 50% overlap of the layers (N=102).

## Skin alterations (N=102; median = 0.0)



**Fig 5:** 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 = 102).

## Supine, standing pressure and SSI at start and day 7 (N= 12)



**Fig 6:** Interface pressure in supine, while standing and SSI (static stiffness index) measured at day 0 and at day 7 (N = 12).