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Interrater and intrarater reliability of the Semmes Weinstein aesthesiometer to assess touch pressure threshold in burn scars

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Abstract:

Burn scars are frequently accompanied with sensory deficits often remaining present months or even years after injury. Clinimetric properties of assessment tools remain understudied within burn literature. Tactile sense of touch can be examined with the Touch Pressure Threshold (TPT) method using the Semmes Weinstein monofilament test (SWMT). There is in recent research no consensus on the exact measurement procedure when using the SWMT.

The aim of this paper was to determine the interrater and intrarater reliability of TPT within burn scars and healthy controls using the 'ascending descending' measurement procedure. We used the newly developed Guidelines for Reporting Reliability and Agreement Studies (GRRAS) as a basis to report this reliability study. In total thirty six individuals were tested; a healthy control group and a scar group.

The interrater reliability was excellent in the scar group (ICC= .908/SEM= 0.21) and fair to good in the control group. (ICC= 0.731/SEM= 0.12). In the scar group intrarater ICC value was excellent (ICC= 0.822/SEM= 0.33). Within the control group also an excellent intrarater reliability (ICC= 0.807/SEM= 0.27) was found.

In conclusion this study shows that the SWMT with the 'ascending descending' measurement procedure is a feasible and reliable objective measure to evaluate TPT in (older) upper extremities burn scars as well as in healthy skin.

1. Introduction

Burn scars are frequently accompanied with sensory deficits like pain, pruritus and hyposensibility, often remaining present months or even years after injury [1–3]. The prevalence of paresthetic sensation was found above 70% in patients one year or more post burn [1]. The modalities of touch, two-point discrimination, warming and vibration are all significantly reduced post burn [4]. The underlying pathophysiology of these impairments in body functions is unclear [5,6]. Destruction of nerve fibres or nerve receptors, surgical interventions (e.g. skin grafting) and hypertrophic scarring may contribute to the loss of sensation in healed burn scars [3]. Besides local anatomical changes, modifications in the central nervous system may play a role in the diminished sensation post burn [5].

Objective as well as subjective outcome measures are available to evaluate scars during rehabilitation. Pain, pruritus and typical scar characteristics (e.g. colour, thickness,...) in burn patients can be subjectively assessed with different scar scales (e.g. Patient and Observer Scar Assessment Scale, Vancouver Scar Scale) and psychometric values have been fully documented [7–10]. Diminished sensibility can be measured objectively. However, sensory changes do not appear to have been routinely measured as outcomes in burns patients, which is surprising since sensation has been included as one of the core domains for burns outcome assessments [11]. The assessment of sensibility has been investigated since the 1960s but clinimetric properties of assessment tools remain understudied in burn literature [11] and predominantly focussed on correlation between sensation and anatomical properties of (grafted) skin [5,6,12,13].

Testing tactile sensibility can include pressure perception, two point discrimination, point localization, vibration, etc. [14]. Tactile sense of touch can be examined with the Touch Pressure Threshold (TPT) method. Pressure perception is relatively constant with aging and

changes between gender seems negligible [14]. Cutaneous pressure is received by the Merkel and Meissner mechanoreceptors present near the surface of the skin (epidermis/dermis). The Semmes Weinstein monofilament test (SWMT) is the most popular method for assessing TPT [5,14,15].

The SWMT is available in different kits. The mini-kit (with five monofilaments) is considered the minimum for screening normal versus abnormal sensory status. The SW complete kit, consisting of 20 sequentially graded thickness monofilaments is used to accurately categorize loss of function and to detect first signs of recovery [14].

Recent research lacks consensus on the exact measurement procedure when using the SWMT [15]. The 'forced choice' single staircase procedure was described in a reliability study in which 24 plantar hallucuses of 24 healthy subjects were assessed. In this study forced choice trials were used that consisted of the presentation of a stimulus and a blank in random order. The test session began with the presentation of the monofilament that induced a pressure of 4.5 g/mm^2 , followed by or preceded by a blank. If out of the five successive stimuli an incorrect response occurred from the participant, the next trial was presented with a more stiff monofilament two steps higher. This process was continued until five successive correct responses were made, which they then defined as the first staircase reversal. If five correct responses were obtained at the initial 4.5 g/mm^2 , the next lower stimulus was presented in a similar fashion. Once the first staircase reversal was determined, either the 'two-down one-up' rule (2D) or the 'three-down one-up' rule (3D) was tested. In the 2D procedure, correct stimulus detection was required on two successive trials (each trial consisted of the presentation of a stimulus and a blank in random order) before the next lower pressure was presented. In the 3D procedure, three correct successive trials were required. In both instances, a single miss resulted in the presentation of the next stronger monofilament. A threshold was defined as the mean of all the stimulus levels at which a reversal occurred in the included reversal pairs. The 3D rule and the 2D rule as described by Tracey et al. were compared and with four reversal pairs the 3D approach appeared more

reliable ($r > .90$) [15]. The 'yes no' procedure and also the 'forced choice' were described in a review by Mueller et al. in a diabetic population. The 'yes-no' procedure instructs the patient to say "yes" each time the application of a SW monofilament is felt. Five to ten trials are taken at each site and the patient needs to respond to 80% of the trials to be graded a given value at that site, if not the patient is tested with the next higher monofilament [16]. In the 'forced choice' procedure the SW monofilament is applied during one of two intervals (in the count of either "one" or "two"). The patient is then asked whether they felt any sensation after the first or second interval. Weinstein introduced the average of an 'ascending descending' procedure to determine the TPT [14]. In a study on tactile, thermal and pain sensibility in burned patients the 'ascending descending' procedure was used to determine TPT in 121 subjects with upper limb scars 18 months after burn injury [5]. Likewise, in another burn study, in which 15 patients with grafted skin (10 months after grafting) were tested to evaluate TPT, this 'ascending descending' procedure was described [6]. Besides in the burn population, this 'ascending descending' procedure was also used in patients with chronic neuropathic pain [17,18]. This 'ascending descending' procedure is clinically being used to measure TPT in post burn evaluations in Oscare, an after-care and research centre for burns and scars in Belgium, hence this procedure was chosen to evaluate in this study.

The clinimetric properties of the SWMT have been evaluated and quantified in other populations [5,19], there is however limited evidence on reliability of the different procedures within burns. The aim of this paper was to determine the interrater and intrarater reliability of the SWMT within burn scars and healthy controls using the 'ascending descending' procedure to evaluate TPT as described by various authors [5,6,15,17,18,20]. We used the newly developed Guidelines for Reporting Reliability and Agreement Studies (GRRAS) as a basis to report this reliability study [21]. This study is part of a larger comprehensive study in which the effects of physical treatment modalities in burn scars are being examined.

2. Methods

2.1. Subjects

A convenient sample (a sample drawn without any underlying probability-based selection method) of burn patients were recruited at Oscare, Organisation for Burns, Scar After-care and Research, situated in Antwerp, Belgium. The start of enrolment was November 2012 and the completion date was the 1st of March 2013. This study focused exclusively on burn scars in the upper extremities, hands excluded. To verify the eligibility, the burn patients and control subjects were contacted by phone and invited to the after-care centre. Inclusion criteria were: patients aged between 18 and 70 years, burn scars on the upper extremities, resulting from second or third degree burns, Caucasian skin type, three months or more after discharge from the burn unit. Exclusion criteria were as follows: scars only on the hands or other than upper extremities, patients with disorders affecting sensory function (e.g. diabetes, neurological diseases).

All participants signed informed consent and the protocol was approved by the ethics committee (MEC: 009; OG 031 Ethics committee of ZNA Antwerp E.C. approval n° 4130).

2.2. Material

The Semmes-Weinstein aesthesiometer set (Rolyan Monofilaments, Trademark of Smith & Nephew-copyright 1998) was used for the procedure, since this set can be used to measure recovery of sensibility [14]. This hand held tool consists of a series of 20 flexible calibrated nylon monofilaments of equal length and varying diameters (0.06–1.14 mm). Each of the 20 filaments is assigned a calibration value corresponding to the log of 10 times the strength

required to bend the filament in demi-circle [22,23]. The pressure varies between 0.045g/mm^2 - 447 g/mm^2 (representing the pressure given by the monofilaments with dimensionless values 1.65- 6.65 respectively). The higher the value on the monofilament the more rigid and more difficult it is to bend. By design each filament exerts a specific pressure. Since all filaments bend when the specific pressure is reached, the amount of pressure presented at a given point is a function of the test instrument and not the examiner [24].

2.3. Procedure

The interrater and intrarater reliability was independently examined by two researchers; randomly selected from a pool of researchers and trained according to a pre-defined training protocol. Each researcher performed their measurements separately.

The participants were asked to lie down in a comfortable position supine or prone (depending on the volar or dorsal area to be tested). Participants were asked to close their eyes and to turn their head to the contralateral side. A permanent marker was used to mark the exact spot to test and a picture was taken to establish the location when a retest was done. The measurement location was the same in both groups meaning that every site of the burn patient was matched with the same site in the control subject. Healthy controls were chosen since many patients had bilateral scarring. Environmental factors were reduced to a minimum to keep attention high. Thus all tests were performed in a treatment room with controlled temperature and humidity (temperature: $21\text{ - }23^{\circ}\text{C}$ and relative humidity: 40-60%) with the door closed. Participants stayed in this room and in the same position during the entire test procedure, while the raters separately went in and out of the room.

Before performing the tests and between the tests the patients received instructions on the test procedure. Participants were asked to say “yes” if a touch was felt. The filament was held vertically above the test area and slowly descended, the actual nylon filament was applied to the skin surface perpendicular to the length of the filament until it bowed (this in

about 1.5 seconds), this bow was maintained once per monofilament for approximately 1.5 seconds (and removed in 1.5 seconds) [25]. Measurements were started with the 5.88 monofilament in both groups [18]. As shown in Fig. 1a for the orientation series, measurements started at the 5.88 monofilament, if felt by the participant subsequently the monofilament three steps lower was applied (repeating the next step every time three monofilaments lower) until no perception could be felt. The filament last felt constituted the orientation value [5].

Subsequently six measurements were performed. The ascending series were started three filaments below the orientation value and three filaments above for the descending series (view Fig. 1a and Fig. 1b). All filaments in this range were successively applied for 1.5 s [26] until the subject reported its presence (ascending series) or absence (descending series). Time between stimulus application varied from 5 to 15 s to avoid temporal summation [27].

These steps were repeated 3 times resulting in an “ascending descending ascending descending ascending descending” (ADADAD) series. The threshold was calculated by the mean of the 6 values and considered as the TPT.

For the threshold the labelled units as displayed on the Semmes Weinstein monofilaments were used, not the values converted into grams. The total duration of the tests was about 30 minutes. The data of both assessors were compared to determine interrater reliability. The two measurements of the first assessor were used to investigate intrarater reliability. The two assessors performed their assessments at the same day with a period of rest in between to reduce fatigue. The re-evaluation took place on average 12 days (range: 9-16 days, SD: 2.36 days) later in the burn group and 9 days (range: 7-13 days, SD: 2.14 days) in the control group, depending on the availability of the participants.

2.4. Statistics

Statistical analysis was performed using the SPSS 20 software package for Windows. The interrater and intrarater reliability were based on the measurements of two observers. The Intra-class Correlation Coefficient (ICC) with its 95% Confidence Interval (CI) was calculated to assess the interrater reliability for two observers and the intrarater reliability of one observer. The two-way-random effect model was selected and calculated for absolute agreement of the scores. Fleiss and Shrout classification for reliability coefficients (ICC_{2,1}) was used to describe the degree of reliability [29]. The single measure ICC was used to interpret the results. In the results section the ICC findings are reported based on Rosner [28]. Specifically, an ICC value of less than 0.4 indicates poor reliability while an ICC between 0.4 and 0.75 indicates fair to good reliability. Lastly, an ICC over 0.75 indicates excellent reliability [28].

To objectively identify reliability it is suggested to combine ICC (which represents a relative measure of reliability) with the Standard Error of Measurements (SEM), which is the standard deviation (SD) of the difference between mean scores at baseline and follow-up (d) divided by the square root of two ($SEM = SDd/\sqrt{2}$). This quantifies the variability of the difference scores and is referred to as the typical error of differences [29] and the SEM percent change (SEM%). The SEM% was defined as $(SEM/\bar{x}) \times 100$, where \bar{x} is the mean for all observations from test session 1 and 2.

The SEM estimates the measurement error across repeated measurements for a group of individuals, while the SEM% indicates measurement error independent of the units of measurement [30]. The mean difference scores between the two raters (MD inter) and between the two observations of the first rater (MD intra) were compared statistically using a one sample t-test. The within subsequent test differences was likewise tested in both groups

using the paired t-test. MD inter is derived by calculating the mean of the differences between each pair of the two raters' observations. MD intra is derived by calculating the mean of the differences between each pair of the two observations of the first rater.

3. Results

3.1. Participants' characteristics

Participants were Caucasian, older than 18 and younger than 65, and in their after-care phase of treatment (with mature scars). The control group, (participants without scars) was age (4 years deviation maximum) and gender matched with the burn group. Eighteen burn patients and eighteen age and gender matched healthy participants volunteered to take part in this study. In total, thirty six people were tested by two raters. In each group more men (n=13 or 72%) than women (n=5 or 28%) were included and equal numbers of upper arms and lower arms were tested. The participants' characteristics of the burn group are illustrated in Table 1. In the burn group the major cause of the injury was thermal. Scar age was on average 83 months and average age of the participants was 43 years (range between 21-60 years, SD: 12.42 years). The age and gender paired-matched healthy participants were on average 43 years old (range between 21 and 63 years (SD: 12.18 years)).

The mean TPT was significantly higher ($p < 0.001$) in the scar group (e.g. results from rater 1: $4.53 \pm \text{SD } 0.75$) than in the healthy controls (e.g. results from rater 1: $3.19 \pm \text{SD } 0.67$) as illustrated in Table 2. The mean values as well as the reliability are presented with dimensionless values as indicated on the monofilaments (not between values converted into grams).

3.2. Reliability of the ADADAD procedure performed with the SWM

3.2.1. Interrater reliability

As presented in Table 2 the interrater reliability was excellent in the scar group (ICC= 0.908/SEM=0.212) and fair to good in the control group. (ICC=0.731/SEM= 0.121). As shown in Fig. 2 the TPT values of rater 1 and rater 2 are close to one another and were not significantly different in the burn scar group.

3.2.2. Intrarater reliability

Results of the reliability analysis are summarized in Table 3. In the scar group intrarater ICC was excellent (ICC= 0.822/SEM= 0.329). Within the control group also an excellent intrarater reliability (ICC= 0.807/SEM= 0.269) was found. As shown in Table 3 the intrarater reliability was lower in the healthy group (than in the burn group). In Fig. 2 the values of the different measurements are presented. In the control group (as shown in Fig. 2) the second measurement of the first rater was significantly higher ($p < .001$).

4. Discussion

This study was set out with the aim of assessing the interrater and intrarater reliability of the 'ascending descending' procedure of the SWMT. It is to our knowledge the first reliability study examining TPT within the burn population. Since sensation has been included as one of the core domains for burns outcome assessments [11], it underlines the importance of evaluating hyposensibility after burn injury, thus assisting in the search for adequate treatments to improve tactile sensation in burn patients.

The current study found high ICC values for both interrater and intrarater reliability using the 'ascending descending' procedure in the scar group (ICC inter: 0.908/ intra: 0.822) and control group (ICC inter 0.731/ intra: 0.807). In addition the SEM and SEM% were calculated

and found to be low. In the scar group the SEM% were 4.67% and 7.32% for the interrater and intrarater reliability, respectively. In the healthy group the SEM% for interrater reliability was 3.69%, intrarater SEM% was 7.95%. For the interrater reliability the ICC values of the healthy group were significantly lower compared to the scar group. A possible explanation for lower reliability and higher variability in the retest values in the control group might be the smaller intervals between two consecutive monofilaments with smaller diameter (representing lower pressure in grams) in the lower part of the aesthesiometer. In the upper part of the aesthesiometer the pressure difference between two consecutive monofilaments is higher and probably more easily detectable [14]. The mean TPT was significantly higher ($p < 0.001$) in the scar group (4.53) than in the healthy controls (3.19), these results are consistent with those of other studies [6,31] and suggest that a lack of pressure perception might persist for several years after burn injury [3].

This procedure shows merit although a few reflections have to be made. Patients were recruited in a burn after-care centre. The mean scar age was rather old, on average 83 months. Since a convenience population was used the reader is cautioned against generalizing these findings to populations with less mature scars. In the selection of patients only upper extremity burn scars were included, because innervation density on the arms is different than on the soles of the feet. Generalization of these findings to other body regions needs to be done with caution. The study of Tracey et al. [15] investigated overall young people, in contrast to this study where the age of the subjects ranged between 21 to 60 years old. Although it has been stipulated that there is limited influence of age in TPT [32], with aging a reduction of Merkel and Meissner mechanoreceptors follows, and the number of myelinated peripheral nerve fibers diminishes [15,33]. A study investigating the variation of pressure perception in the index finger of various healthy age groups (between 19 and 88 years) revealed that threshold values were higher in elderly and more variation was noted with older age [33]. Further studies on the effect of age are therefore recommended. In spite

of the rather high mean age and scar age, a strength of this study was the good match between the scar and the control group.

Due to pragmatic reasons the test and retest for the inter-rater reliability was performed on the same day, for the intrarater reliability the time varied between nine and twelve days. Other authors examined test-retest reliability with an average of seven days between measurements [15].

The 'ascending descending' procedure takes about ten minutes and subjects need to stay focused and immobilized during the whole procedure. Environmental stimuli (e.g. noise, heat, light changes,...) were reduced to a minimum by testing in a quiet closed room with only the subject (prone or supine position) and rater present, still these effects might have some influence on these findings.

Previous authors have described the 'ascending descending' procedure as too time-consuming for clinical practice [14], nevertheless it takes about 10 minutes to administer and with limited education on the procedure a rater can perform the test. In previous studies on TPT the measurement procedures in many cases differ from one another or the exact measurement procedure is not fully described. In contrast to earlier research a strength of this present study is the description of the 'ascending descending' test procedure. In the SWMT there is a slight gradation of pressure between two filaments and since the 'ascending descending' procedure is used in this study it seems less possible for the patients to know the order of presentation. These factors reduce the possibility of error and might explain the reliability of this procedure.

Further investigation could evaluate different test procedures (e.g. 'yes – no', 'forced choice',...) in order to determine the most reliable and feasible procedure. Ameliorating tactile sensation is often a goal during scar after-care treatment. Since the TPT measurement is being used (e.g. in Oscare) in the after-care settings to evaluate sensibility changes over time and evaluate the effect of treatment, in future research the

responsiveness of the SWMT should be investigated in the burn population. Each one of the 20 filaments are labelled so as to give a linear scale of perceived intensity which exerts a specific, repeatable force between 0.86 gram and 448 grams. These forces were converted into a logarithmic function by the manufacturers (Labelled units on the monofilaments= Log^{10} (10 x force in milligram)). For further research a good recommendation would be to use a force transducer to measure the exact force of each monofilament. Weinstein et al described that the values in grams are not reliable to use in statistical analysis [32].

Establishing a relation between hyposensibility and functional status (e.g. hand function) and quality of life in patients with burn scars would be interesting to affirm whether these deficits influence human functioning. Future studies should focus more on evaluating the effect of therapeutic interventions on skin sensation (and pain and pruritus) taking into account patient factors (e.g. age, scar age), injury factors (e.g. cause of burn, burn depth, surgical intervention). Recent studies have investigated the above mentioned effects with vacuum massage [34], manual scar massages [35] and found promising results.

In conclusion this study shows that the SW aesthesiometer with the 'ascending descending' measurement procedure is a feasible and reliable objective measure to evaluate TPT in (older burn) upper extremities scars as well as in healthy subjects. Further research with a larger sample size, various body location and different scar ages is needed to support present findings.

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Legends for tables and figures

Fig. 1a-c show how the assessment of the TPT is performed

Fig. 2 Scatter plot of the Touch Pressure Threshold (TPT) values in the control group and scar group

Table 1: Participants' characteristics

Table 2: Results of the interrater reliability analysis

Table 3: Results of the intrarater reliability analysis

Fig. 1a-c show how the assessment of the TPT is performed

Fig. 1a First step is the determination of the orientation series (orientation value: **O**) starting at the 5.88 monofilament, if felt by the participant subsequently the monofilament three steps lower was applied (repeating the next step every time three monofilaments lower) until no perception could be felt. The filament last felt constituted the orientation value.

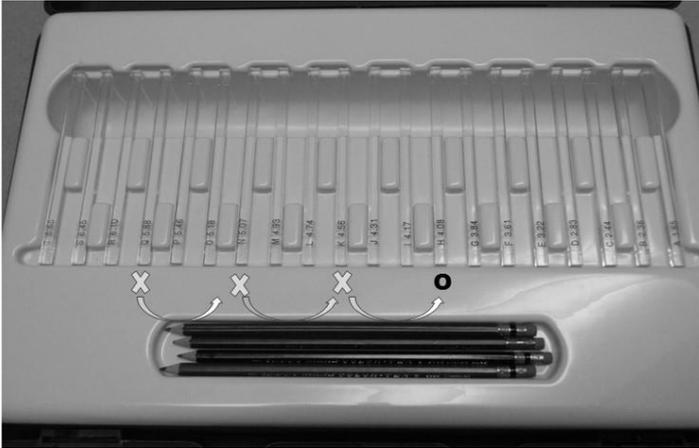


Fig. 1b The second step in the assessment of the TPT. The ascending series starting 3 steps below the orientation value (**O**) all filaments in this range are successively applied for 1.5 s

until the first monofilament was felt **X** (this value is registered).

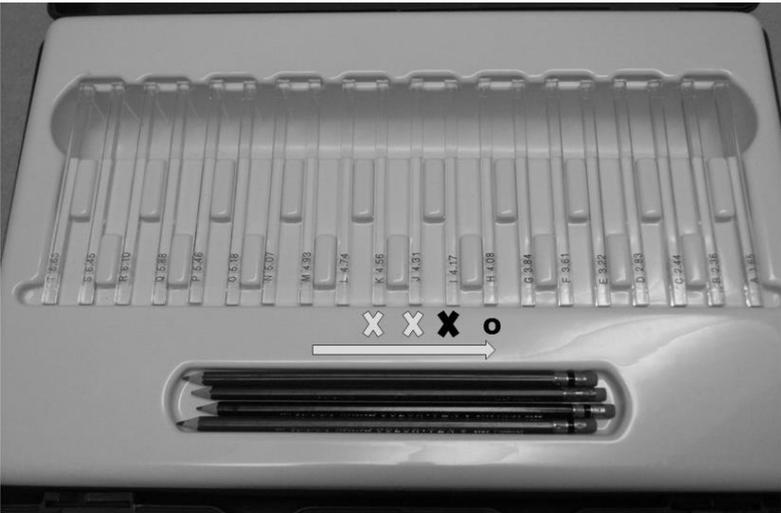


Fig. 1c The descending series starting 3 steps above the orientation value (O) all filaments in this range are successively applied for 1.5 s until the subject reports its absence (the value of the last felt monofilament X is registered). These steps (Fig. 1b and 1c) were repeated 3 times resulting in an “ascending descending ascending descending ascending descending” (ADADAD) series.

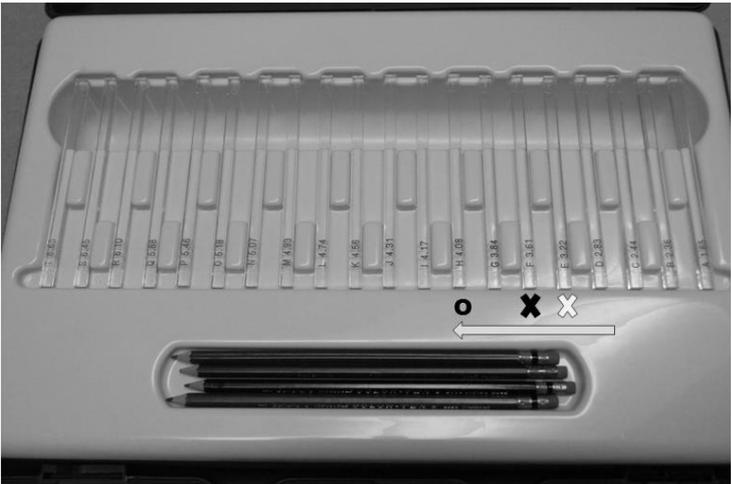


Fig. 2 Scatter plot of the Touch Pressure Treshold (TPT) values in the control group and scar group

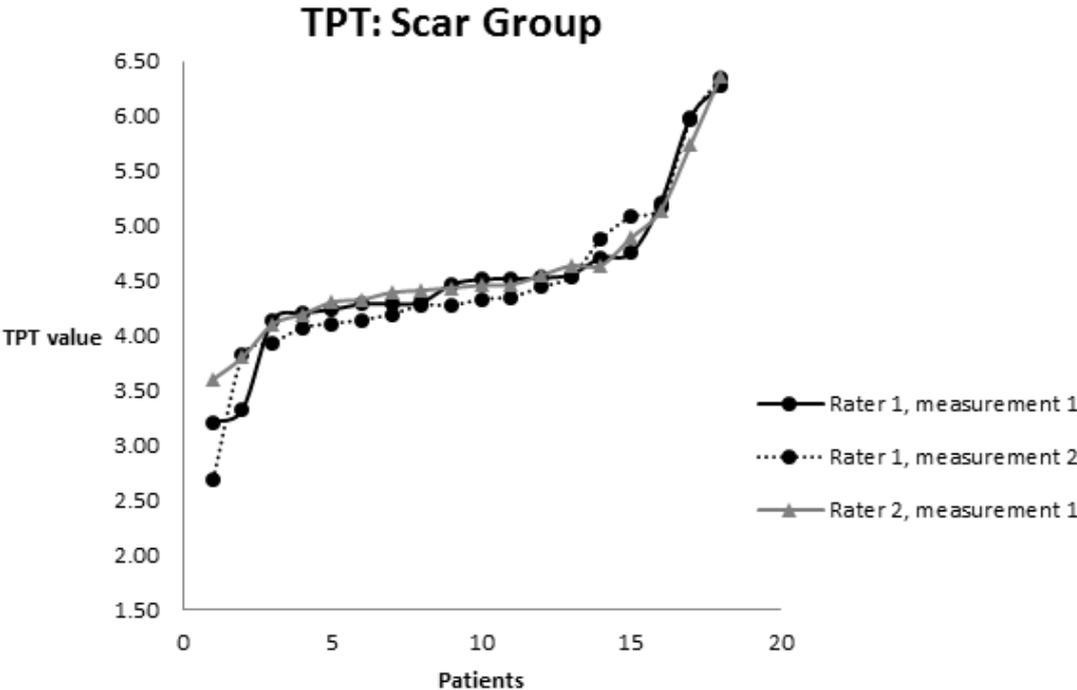
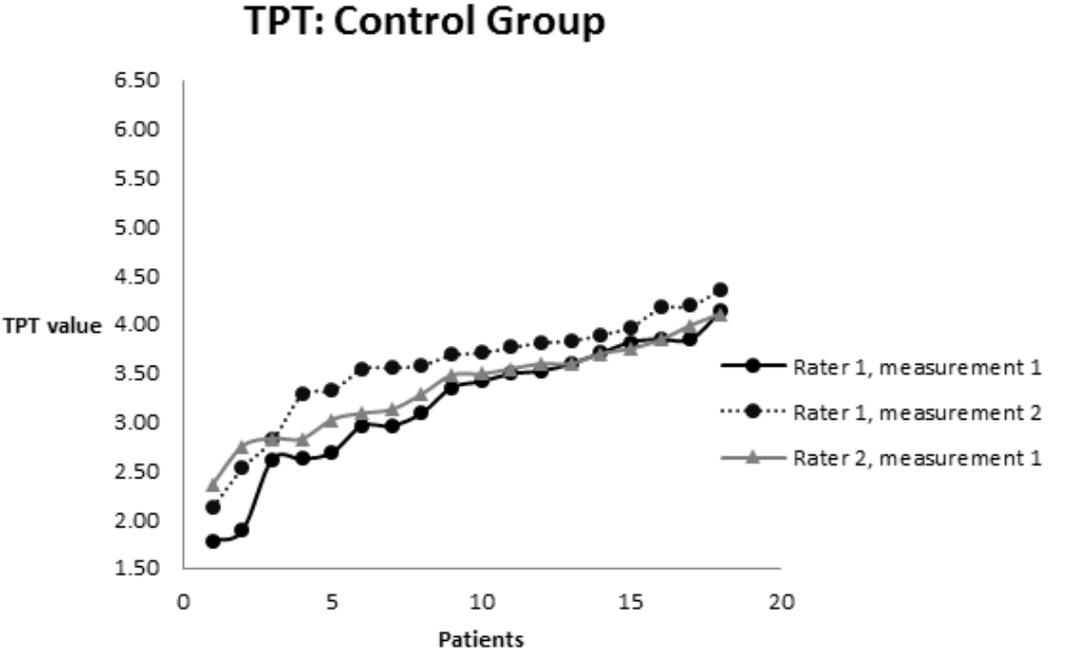


Table 1: Participants' characteristics

Demographic variables scar group	
sex % male-female	72-28
average age in years (range, SD)	43 (21-60, 12.42)
Demographic variables control group	
Average age in years (range, SD)	43 (21-63, 12.18)
Location tested n (%)	
upper arm volar	7 (39)
upper arm dorsal	2 (11)
lower arm volar	8 (44)
lower arm dorsal	1 (6)
Cause of burn n (%)	
Thermal	14 (78)
Chemical	2 (11)
Electrical	2 (11)
Scar age	
average age in months (range, SD)	83 (5-588,129.14)

n: number of participants; %: percentage, SD: standard deviation

Table 2: Results of the interrater reliability analysis

	Rater 1.1 mean (SD)	Rater 2.1 mean (SD)	inter ICC (95%CI)	MD inter (SD)	SEM	SEM%
SCAR	4.53 (.75)	4.58 (.65)	.908 (.771-.964)	.05 (.30)	.212	4.67
HEALTHY	3.19 (.67)	3.36 (.47)	.731 (.414-.890)	.17 (.42)	.121	3.69

SD: standard deviation; ICC: intraclass correlation coefficient; MD: Mean of the differences; SEM: standard error of measurement difference; SEM%: standard error of measurement expressed in percentage of rater's mean.

Table 3: Results of the intrarater reliability analysis

	Rater 1.1 mean (SD)	Rater 1.2 mean (SD)	intra ICC (95%CI)	MD intra (SD)	SEM	SEM%
SCAR	4.53 (.75)	4.48 (.81)	.822 (.585-.929)	.05 (.47)	.329	7.32
HEALTHY	3.19 (.67)	3.57 (.58)	.807 (.555-.923)	.38 (.39)	.269	7.95

SD: standard deviation; ICC: intraclass correlation coefficient; MD: Mean of the differences; SEM: standard error of measurement difference; SEM%: standard error of measurement expressed in percentage of raters' mean