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The Scarbase Duo®: Intra-rater and inter-rater reliability and validity of a compact dual scar assessment tool.

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Conflict of Interest

There is no conflict of interest

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1.0 Abstract

Objective scar assessment tools were designed to help identify problematic scars and direct clinical management. Their use has been restricted by their measurement of a single scar property and the bulky size of equipment. The Scarbase Duo[®] was designed to assess both trans-epidermal water loss (TEWL) and colour of a burn scar whilst being compact and easy to use.

Twenty patients with a burn scar were recruited and measurements taken using the Scarbase Duo[®] by two observers. The Scarbase Duo[®] measures TEWL via an open-chamber system and undertakes colorimetry via narrow-band spectrophotometry, producing values for relative erythema and melanin pigmentation. Validity was assessed by comparing the Scarbase Duo[®] against the Dermalab[®] and the Minolta Chromameter[®] respectively for TEWL and colorimetry measurements.

The intra-class correlation coefficient (ICC) was used to assess reliability with standard error of measurement (SEM) used to assess reproducibility of measurements. The Pearson correlation coefficient (r) was used to assess the convergent validity.

The Scarbase Duo[®] TEWL mode had excellent reliability when used on scars for both intra- (ICC = 0.95) and inter-rater (ICC = 0.96) measurements with moderate SEM values. The erythema component of the colorimetry mode showed good reliability for use on scars for both intra- (ICC = 0.81) and inter-rater (ICC = 0.83) measurements with low SEM values. Pigmentation values showed excellent reliability on scar tissue for both intra- (ICC = 0.97) and inter-rater (ICC = 0.97) with moderate SEM values.

The Scarbase Duo® TEWL function had excellent correlation with the Dermalab® ($r = 0.93$) whilst the colorimetry erythema value had moderate correlation with the Minolta Chromameter ($r = 0.72$).

The Scarbase Duo® is a reliable and objective scar assessment tool, which is specifically designed for burn scars. However, for clinical use, standardised measurement conditions are recommended.

1.5 Highlights

- The Scarbase Duo® measures two scar properties: trans-epidermal water loss and colorimetry
- Intra- and inter-rater reliability was good-to-excellent for TEWL and colorimetry on scars
- The Scarbase Duo® was validated against other established tools of TEWL and colorimetry assessment
- The Scarbase Duo® was easy to use and compact, but required link-up to a laptop computer
- The Scarbase Duo® is a reliable scar assessment tool however clinical use requires standardised conditions

1.6 Keywords

Objective scar assessment, burn scar, Scarbase Duo, trans-epidermal water loss, colorimetry, clinimetrics

1.7 Abbreviations

- TEWL – trans-epidermal water loss
- ICC – intra-class correlation coefficient
- SEM – standard error of measurement
- r – Pearson correlation coefficient

2.0 Background

Survival after severe burns and trauma has dramatically improved over the last decade but this has not always been paralleled with a similar increase in quality of life. Patients have to contend with the sequelae of scarring, which can lead to an array of appearance-related, psychological and functional problems. Scars represent a significant challenge to the multidisciplinary care team and a large burden on the resources of health care systems. Research into the area of improving treatment options for scarring is relevant both on an individual and a societal level [1].

Scar assessment tools are used for monitoring the quality of scars against time, the effect of treatments and for comparing scars. The ideal scar assessment tool needs to be reliable (error of measurement), valid (measures what it is meant to measure) and feasible (easy to administer with minimal patient burden). Scar assessment can be achieved via subjective or objective methods. Subjectively, scars can be assessed by patients, clinicians/medical professionals and third party observers. However, subjective scales can be unreliable due to a great variability in interpretation [2]. Various assessment scales have been created but the

most commonly used are the Vancouver Scar Scale (VSS) and the Patient Observer Scar Assessment Scale (POSAS) [3][4][5].

Objective scar assessment has an advantage over subjective assessment because the reliability of measurements between observers tends to be greater. Objective scar assessment tools can provide a quantitative measurement of physiological or physical scar parameters. Physiological properties include trans-epidermal water loss (TEWL), hydration, perfusion and trans-cutaneous oxygen level. Physical properties include colour, elasticity, topography and planimetry [6].

TEWL is an important physiological marker to measure the efficiency of the human skin barrier to retain water [7]. The hydration and water content of skin is important as it helps to maintain normal skin turgor and texture and is strongly related to TEWL. TEWL can be used as an indirect measurement of the barrier function of skin because when skin is damaged, as is the case during scarring, TEWL increases [8]. Open chamber devices are the most common method of measuring TEWL. They detect the water vapour gradient near the surface of the skin based on the principle of Fick's law of diffusion [9].

Scar colour is a key physical property because its comparison to uninjured, surrounding skin is correlated with relative patient satisfaction and reflects biological processes within the scar [10]. Colour assessment forms a component of subjective scar assessment scales because patients commonly are dissatisfied with a mismatch of scar colour compared to their surrounding skin. Clinically, colour assessment is useful as an indicator of the scar maturation and as an early, quantifiable index of the likelihood of the scar becoming hypertrophic [11,12]. The colour of a scar is a complex physical property that is contributed to by three main components (brown melanin pigment, red oxyhemoglobin and yellow bile).

Colorimetry tools commonly assess the colour of scars via tri-stimulus reflectance colorimetry (the level of light reflected from the scar surface) or narrow-band spectrophotometry (the absorption of light in the scar) [6].

Objective scar assessment tools have predominantly tested a single characteristic of the scar and their use has largely been restricted to the research settings due to their bulky, impractical size. Anthonissen et al. (2013) were the first authors to report about the utility of a dual scar assessment device called the Dermalab[®] (Cortex Technology, Hadsund, Denmark); this measures both elasticity and TEWL via a single central unit [7]. A new device called the Scarbase Duo[®] (Courage + Khazaka, Cologne, Germany), calculating TEWL and colorimetry, has been designed to be small, easy to use and affordable.

The aim of this study was to assess intra- and inter-rater reliability, validity and feasibility of the Scarbase Duo[®] for use in research and clinical application.

3.0 Methods

This study was designed in accordance with the Guidelines for reporting reliability and agreement studies [13].

3.1 Patients and Observers

Patients were recruited from the OSCARE Centre (Burns and Scar Aftercare Centre) in Antwerp, Belgium over a three week testing period. Patients were eligible when they were at least 16 years old with scars in the active phase of healing after complete wound closure.

Previous treatment for these scars followed a clinical protocol and was recorded in each patient. Patients who were unable to provide consent due to a language barrier or psychiatric disorder were excluded. Scars had to be situated on the upper or lower limbs with the exclusion of the hands, feet, trunk or head and neck. These chosen sites have been shown to have lower and more consistent rates of TEWL [14]. Contralateral areas of healthy skin were used for comparison and in cases where these too were scarred, adjacent healthy skin was tested. The two observers collecting the data were a clinician and physiotherapist. The study protocol was approved by the ethics committee of the Hospital Network Antwerp (ZNA), Belgium (Ethical committee 009OG031, study number EC4549).

3.2 The Scarbase Duo

The Scarbase Duo® (Courage + Khazaka, Cologne, Germany) device consists of a main unit, two probes and a sensor for room temperature and humidity. The probes, one for the Tewameter® (TEWL) and one for the Mexameter® (colorimetry), attach to the main unit via independent leads into separate channel inputs (see Figure 1).

3.2.1 TEWL mode

The Tewameter® (see Figure 2) open chamber probe consists of a hollow tube (1cm x 2cm) containing combined humidity and temperature sensors, positioned at different heights above the skin surface. The local relative humidity and temperature are recorded at both sites and a corresponding vapour pressure is calculated automatically. TEWL is expressed in grams per square meter per hour ($\text{g}/\text{m}^2/\text{h}$). At the start of each testing day, the Tewameter®

was calibrated. In order to measure TEWL correctly, the open chamber was held perpendicular to the scar or skin surface and away from a direct light source. The small size of the chamber minimised the local airflows known to distort open chamber results [15]. Patients were asked to turn their face away from the Tewameter® when testing so that the air currents of breathing did not interfere with assessments. Measurements were stopped after 30 seconds (time required for TEWL equilibrium to be reached [16]) and the mean/standard deviation of the TEWL measurements were recorded.

3.2.2 Colorimetry mode

The Mexameter® (see Figure 3) utilises narrow-band spectrophotometry to measure the vascularity and pigmentation (called erythema and melanin respectively) of the skin based on differences in absorption of red and green light. The haemoglobin component of skin reflects red light and absorbs green whilst the brown of the melanin component absorbs light of all wavelengths. The distal end of the probe is equipped with a spring mechanism which calculates the colour characteristics when a defined pressure is reached on the skin surface. A separate measurement was created for erythema and melanin. Measurements range from 1-1000 for both the erythema and melanin index with higher readings representing more erythematous and darker pigmentation respectively. Three measurements were taken in succession and mean values were calculated.

3.3 Instruments to test for validity

3.3.1 Dermalab®

TEWL was assessed by the Dermalab[®] (Cortex Technology, Hadsund, Denmark) which is an open chamber system, similar in design to the Tewamater[®]. The TEWL component of the Dermalab[®] is regarded as a typical open chamber TEWL device and has been used experimentally before as a baseline for validity due to its accurate and concise measuring mechanism [16,17]. The Dermalab[®] has not previously been validated for testing TEWL in scars [7].

3.3.2 The Chromameter[®]

The Minolta Chromameter[®] (Minolta Camera Co., Osaka, Japan) utilises tri-stimulus reflectance colorimetry according to the Commission International de L'Éclairage system producing a three dimensional measurement (L^* represents the relative brightness (with a scale of 0 to 100), a^* represents the range of green (-60) to red (60) reflected light, and b^* represents the range of blue (-60) to yellow (60) reflected light). Higher values for a^* correspond with increasing redness of the scar [18]. The Chromameter[®] has shown excellent intra- and inter-rater reliability along with moderate correlation to the colour and vascularity component of the POSAS scale [19]. Three separate measurements were taken by the Chromameter[®] and mean values for the L^* , a^* and b^* were calculated.

3.3 Measurement Procedure

Informed written consent was obtained from all patients. Thirty minutes before measurements were taken, patients acclimatised to the testing environment by waiting in the testing room, in the position in which they were to be tested and with the scars and

corresponding healthy skin uncovered. The patients were in a sitting position for scars on the upper limb and a lying position for scars on the lower limb. Testing was performed in the same room with room temperature and humidity recorded immediately prior to the start of measurements being taken. Care was taken to place the temperature and humidity sensor away from any heat source (e.g. patient or computer). The boundaries of the test sites were marked with circular adhesive markers.

Two consecutive measurements were taken by the first rater for TEWL and colorimetry using the Scarbase Duo® on the scar and healthy skin. The first rater then measured the same areas with the Chromamater® and the Dermalab®. The second rater conducted a single measurement for TEWL and colorimetry using the Scarbase Duo® on the identical scar and healthy skin sites. A period of four minutes was observed between any TEWL measurement or any colorimetry measurement. This allowed both equilibrium time for condensation in the TEWL probe (= zero-drift) and the skin capillary refill time recovery after pressure from the colorimetry device [7].

3.4 Statistical Analysis

Statistical analysis was performed using the statistical program SPSS v20.0 (Armonk, NY: IBM Corp.)

3.4.1 Reliability

Reliability refers to the consistency of the assessment tool measurements (i.e. whether measurement is the same when no real change has occurred). The intra-class correlation coefficient (ICC) with its 95% confidence interval was used to measure the intra- and inter-

rater reliability on scars and normal skin [20]. A two-way random-effect model and absolute agreement was selected and calculated for all of the scores. The Fleiss and Shrout classification for reliability coefficients (ICC_{2,1}) was used to describe the degree of reliability [20]. The single measure ICC was used to interpret the results. Reliability was judged to be good if the ICC was >0.75, moderate 0.4-0.75 or poor <0.4 [21]. The reproducibility of the Scarbase measurements was deduced via the standard error of measurement (SEM), calculated by dividing the standard deviation of the difference between mean scores at baseline and follow-up (SDd) 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 [22]. Bland-Altman plots and limits of agreement were used to analyse the repeatability of a single measurement method and to compare measurements between two raters [23].

3.4.2 Validity

Validity refers to the truth of the assessment tool measurements (i.e. whether the tool is measuring what it is meant to). Tests of validity are indirect and rely on comparison against a method believed to be correct. Pearson's correlation coefficients were calculated to assess the convergent validity of the Scarbase Duo[®] compared to other assessment tools. Validity was judged to be good if the Pearson's correlation or the ICC was >0.6, moderate 0.3-0.6 or poor <0.3 [21]. Where necessary, data was transformed using linear regression scales. Bland-Altman plots and limits of agreement were used to analyse the agreement of the two measurement methods [23].

4.0 Results

4.1 Patient and Scar Characteristics

Twenty burn scars were included from twenty patients, 16 of whom were male with a mean age of 45 years (SD 18.22). Eleven of the scars were located on the arm (four upper arm and seven forearm) and nine were located on the leg (five upper and four lower leg) with an overall mean scar age of 5.65 months (SD 5.76). Eight of the scars had healed spontaneously with the remaining twelve having received a split skin graft.

The values for Tewameter® TEWL in healthy skin and scars ranged from 3.7 – 12.4g/m²/h (mean 6.3, SD 2.5) and 4.9 – 26.0 g/m²/h (mean 9.9, SD 5.2) respectively. The values for the Mexameter® erythema in healthy skin and scars ranged from 115.7 – 343.3 (mean 215.0, SD 66.3) and 297- 648 (mean 449.6, SD 86.76) respectively. The values for the Mexameter® pigmentation in healthy skin and scars ranged from 56.3 – 317.67 (mean 162.1, SD 76.6) and 6.7 – 374.0 (mean 161.7, SD 85.2) respectively.

4.2 Reliability

4.2.1 Tewameter® TEWL values

The ICC values ranged from 0.87-0.95 for the intra-rater and 0.9-0.96 for inter-rater reproducibility. This showed good to excellent correlation for repeated TEWL measurements and was combined with moderate SEM values (see Table 1). The Bland-Altman plots for the intra- and inter-rater agreement of two measurements on scars show that the bias of the mean is low, suggesting that no systematic error could be detected. The limits of agreement are far apart, suggesting that the high correlation between the repeated measures and the two raters is not supported by a high agreement (see Figure 4).

4.2.2 Mexameter® erythema values

The ICC values ranged from 0.81-0.94 for the intra-rater and 0.83-0.96 for the inter-rater reproducibility. This showed good to excellent correlation for repeated erythema measurements, which was combined with relatively low SEM values (see Table 2). The Bland-Altman plots of the intra- and inter-rater agreement of two measurements in scars show the bias of mean to be low, suggesting that no systematic error could be detected. The limits of agreement are far apart, but this could be due to a few outliers. 85% of the mean differences are within the acceptable limits of agreement (see Figure 5).

4.2.3 Mexameter® pigmentation values

The ICC values ranged from 0.96-0.97 for intra-rater and 0.97-0.99 for intra-rater reproducibility. This showed excellent correlation for repeated pigmentation measurements and was combined with moderate SEM values on scarred skins and relatively low SEM values on healthy skin (see Table 3). The Bland-Altman plots for the intra- and inter-rater agreement of two measurements on scars show the bias of the mean to be low, suggesting that no systematic error could be detected. The limits of agreement are far apart, suggesting that the high correlation between the repeated measures and the two raters is not supported by a high agreement (see Figure 6).

4.3 Validity

4.3.1 Validating TEWL values from the Tewameter® function of the Scarbase Duo® against the Dermalab®

The ICC value and the Pearson correlation coefficient (ICC 0.81, r 0.93) show good to excellent correlation for scars between the Tewameter® and the Dermalab®. Moderate

correlation (ICC 0.52, r 0.72) is shown between the two tools on healthy skin (see Table 4). The Bland-Altman plots for agreement between the two tools on scars show us that the bias of the mean is high, suggesting that a systematic error could be detected. The Dermalab® TEWL probe systematically measures approximately 2.5g/m² higher than the Tewameter® TEWL probe. The limits of agreement are far apart, suggesting that the high correlation between the two measurement methods is not supported by high agreement (see Figure 7).

4.3.2 Validating erythema values from the Mexameter® function of the Scarbase Duo® against the Chromameter® a* values

The ICC values and the Pearson correlation coefficient (ICC 0.47, r 0.72) show moderate to good correlation for scars between the Mexameter® erythema values and the Chromameter® a* values. Excellent correlation (ICC 0.93, r 0.93) is seen between the two measurement methods on healthy skin (see Table 5). The Bland-Altman plots for the intra- and inter-rater agreement of two measurements on scars shows us that the bias of the mean is low, suggesting that no systematic error could be detected. The limits of agreement are far apart, suggesting that the high correlation between the two measurement methods is not supported by a high agreement (see Figure 8).

5.0 Discussion

The Scarbase Duo® has been designed to assess two objective qualities within the scar (TEWL via the Tewameter® and colorimetry via the Mexameter®), to be compact and easy to use. The Scarbase Duo® was shown to be reliable with good to excellent correlation for repeated measurements and between two observers (ICC ≥ 0.81) with low to moderate SEM

values. These results correspond with earlier findings concerning the Mexameter® [24]. The Tewameter® has been shown to be able to differentiate normal skin from mildly disrupted skin surface but has never before been tested on scars [25]. The results found in this report for the Tewameter® are slightly favourable to the findings of Anthonissen and co-workers for the Dermalab® [7].

Bland-Altman plots and the limits of agreement only show high agreement for the Mexameter® erythema values. This is not surprising since objective assessment of scar colour and trans-epidermal loss are dependent upon several endogenous, exogenous and environmental factors [26].

The ICC values and the Pearson correlation coefficient showed good to excellent correlation for scars between the Tewameter® and the Dermalab®. Moderate correlation was found for measurements taken on healthy skin. The Bland-Altman plots for the intra- and inter-rater agreement of two measurements on scars show that the bias of the mean is high, suggesting that a systematic error could be detected. The Dermalab® TEWL probe systematically measured 2.5 g/m²/h higher than the Scarbase Duo® TEWL probe. A linear regression analysis established a statistically significant correlation between both measurement methods. The regression equation was:

$$\text{Tewameter}^{\circledR} \text{ value} = 0.76 \times \text{Dermalab}^{\circledR} \text{ value}$$

The difference between the two could be due to different calibration methods. One should also take into account that the absolute value of one TEWL measurement ranges between 5 and 20 micrograms. To convert this value into g/m²/h increases the risk of systematic error. Therefore, we suggest to use arbitrary units to report TEWL values in the future.

The ICC values and the Pearson correlation coefficient showed moderate to good correlation for scars between the Mexameter® erythema values and the Chromameter® a* values. In healthy skin the two tools had excellent correlation. The Bland-Altman plots for the intra- and inter-rater agreement of two measurements on scars show us that the bias of the mean is low, suggesting that no systematic error could be detected. The limits of agreement are far apart, suggesting that the high correlation between the two measurements is not supported by a high agreement. A linear regression analysis established a statistically significant correlation between both measurement methods. The regression equation was:

$$\text{Mexameter}^{\circledR} \text{ erythema value} = 27.02 \times \text{Chromameter}^{\circledR} \text{ a* value}$$

The most influencing factors for this moderate correlation between the two measurement methods are likely to be the differences in maintaining even pressure to avoid blanching of the scar and the difference in skin measuring area, which permits the influence of differing scar texture. The two devices also make use of different colour assessment methods as the Mexameter® is a narrow band spectrophotometry device whereas the Chromameter® utilises a tri-stimulus reflectance colorimeter. This makes comparison between the two tools even more difficult.

We comment on the feasibility of the Scarbase Duo through our experience of using the tool during the testing process. The Scarbase Duo® consists of a small, light body with two small probes and immediate data logging on to the computer. A computer is always needed, which makes bedside testing difficult, but adds to uniform data storage and the software is easy to use. The Tewameter® probe is an open-chamber system, and in our experience we recommend the use of an air shield to avoid turbulence at the measurement site. The possibility of on-site calibration of the Tewameter® probe is advantageous. More details

regarding the accurate usage of an open-chamber TEWL device can be found in previous literature [9]. Design advantages of the Mexameter® probe include the spring-mounted central portion which maintains even pressure per measurement [24], whereas the Chromameter® can cause blanching of the skin when too much pressure is applied. The meaning of the Mexameter® erythema value is more comprehensible than the meaning of the Chromameter® a* value.

6.0 Conclusion

The Scarbase Duo® is a reliable and valid objective scar assessment tool which has been specifically designed for use in burn scars. Scar erythema and trans-epidermal water loss are two valuable predictors of burn scar maturation, and as such the Scarbase Duo® can help to evaluate the effects of different treatment protocols and develop practice guidelines for burn scar management. For the detection of individual clinical differences, standardised measurement conditions are recommended.

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