Research Report

Validation of a New Device to Measure Postsurgical Scar Adherence

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Background and Purpose. Scarring after surgery can lead to a wide range of disorders. At present, the degree of scar adhesion is assessed manually and by ordinal scales. This article describes a new device (the Adheremeter) to measure scar adhesion and assesses its validity, reliability, and sensitivity to change.

Design. This was a reliability and validity study.

Setting. The study was conducted at the Scientific Institute of Veruno.

Participants and Methods. Two independent raters, a physical therapist and a physical therapist student, used the Adheremeter to measure scar mobility and contralateral normal skin in a sample of 25 patients with adherent postsurgical scars before (T1) and after (T2) physical therapy. Two indexes of scar mobility, the adherence's surface mobility index (SM_A) and the adherence severity index (AS), were calculated. Their correlation with the Vancouver Scar Scale (VSS) and its pliability subscale (PL-VSS) was assessed for the validity analysis.

Results. Both the SM_A and the AS showed good-to-excellent intrarater reliability (intraclass correlation coefficient [ICC]=.96) and interrater reliability (SM_A: ICC=.97 and .99; AS: ICC=.87 and .87, respectively, at T1 and T2), correlated moderately with the VSS and PL-VSS only at T1 (r_s=−.58 to −.66), and were able to detect changes (physical therapist/physical therapist student): z score=−4.09/−3.88 for the SM_A and −4.32/−4.24 for the AS; effect size=0.6/0.4 for the SM_A and 1.4/1.2 for the AS; standard error of measurement=4.59/4.79 mm^2 for the SM_A and 0.05/0.06 for the AS; and minimum detectable change=12.68/13.23 mm^2 for the SM_A and 0.14/0.17 for the AS.

Limitations. The measurement is based on the rater's evaluation of force to stretch the skin and on the patient's judgment of comfort.

Discussion and Conclusions. The Adheremeter showed a good level of reliability, validity, and sensitivity to change. Further studies are needed to confirm these results in larger cohorts and to assess the device's validity for other types of scars.

Scarring after surgery can lead to a wide range of disorders such as pain, movement limitation, functional impairment, and aesthetic or psychological disturbance.[1,2] The assessment of pathological postsurgical scars is crucial for planning their treatment.[3–6] It usually includes evaluation of physical characteristics (eg, height, pliability, relief, adhesion), cosmetic appearance (color, cosmetic defects), and the patient's symptoms (pain, itching). In particular, *scar adherence* (defined as the failure of the tissues to successfully establish independent layering)[7] may produce several clinical problems, limiting range of motion and muscle strength (force-generating capacity) and altering the local proprioceptive input.[6,7]

To date, most clinicians assess adherent scars only by simple manual evaluation.[8] None of the available scar rating scales[9,10] have been proved valid for measuring scar adherence.[6] Moreover, there are many devices for measuring different aspects of scars,[11,12] but none for scar adherence.

Due to the lack of assessment tools for scar adherence and the clinical impact of this disturbance for physical therapist practice, we focused our attention on developing a simple new device for scar adhesion assessment: the Adheremeter. The aim of this study was to validate the Adheremeter in assessment of postsurgical scars by analyzing its reliability, concurrent validity with the Vancouver Scar Scale (VSS), and sensitivity to change.

Materials and Method

Examiners

After a pilot study, 2 raters—a physical therapist and a physical therapist student—were selected as representatives of 2 hypothetical categories of interest among raters: expert and inexpert, respectively. The physical therapist was an employee of the Scientific Institute of Veruno, who was experienced in treating patients with postsurgical scars. The student was in the third year of study for a physical therapy degree and had no specific experience in assessing postsurgical scars. Both raters were briefly taught how to use the device. Neither rater was involved in the patients' treatment.

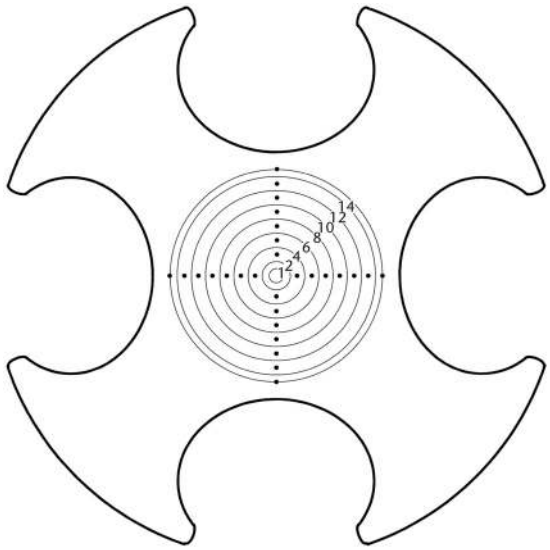

Figure 1.
The Adheremeter. The diameter of the largest concentric ring is 28 mm, and the external edge of the device is 17.5 mm from the center.

Adheremeter

The Adheremeter is a new device designed to measure *adherence* of postsurgical scar, which is defined as the restriction of scar mobility with respect to underlying tissue of the worst adherent point when stretched in 4 orthogonal directions. It is an inexpensive and easy-to-use instrument with an ergonomic shape, consisting of 9 concentric rings with radii of 1, 2, 4, 6, 8, 10, 12, 14, and 15 mm, respectively (Fig. 1), printed on flexible transparency film for copiers (product no. PP2500)* to ensure maximum adaptability to different anatomical surfaces.

* 3M, Corporate Headquarters, 3M Center, St Paul, MN 55144-1000.

Vancouver Scar Scale

The VSS is the most widely used outcome scale for scars. Four physical characteristics are rated: vascularity, pigmentation, height, and pliability. In the original version, each variable includes ordinal subscales that are summed to obtain a total score ranging from 0 to 13, with 0 representing normal skin. A different weight is given to each item (eg, the pliability subscale [PL-VSS] ranges from 0 to 5 points). Scar characteristics are defined not only by a numerical score, but also by descriptors to increase the potential for objective rating and facilitate the training process for observers.[6] Although the literature on the VSS focuses predominantly on

Table 1.
Main Characteristics of the Study Participants and of the Scars

Patient or Scar Characteristic	Data
Sex, male/female	8/17
Age (y), $\bar{X}$ (SD)	38.3 (14.3)
Scars, linear/arthroscopic	21/4
Body region, upper arm/leg	8/17
Location, over a joint/not over a joint	13/12
Linear scar length (mm), $\bar{X}$ (SD)	5 (3.3)
Suture material, needles/staples/adhesive skin closure strips	11/11/3
Time from surgical treatment (d), $\bar{X}$ (SD)	72 (49.2)

burn scars, the scale also has been validated for rating postsurgical scars.[13,14] In this study, we used the modified version proposed by Nedelec et al,[9] which takes into account the concept of scar adherence defined as firmness.[11] Global adherence in local structures surrounding the scar is assessed with the PL-VSS, in which Nedelec et al changed the term "banding" to "adherent" and eliminated the term "contracture," reducing the score for this item to a maximum of 4 points. They also slightly adjusted some other subscales, increasing the possible total score to a maximum of 14 points. This version has been proposed to increase the reliability and the validity of the scale, but, to our knowledge, its psychometrical properties have never been analyzed.

Participants

The participants in this study represented a convenience sample of patients who were recruited with a consecutive sampling method over a period of 10 months. All participants were patients referred to the Scientific Institute of Veruno, Salvatore Maugeri Foundation, for rehabilitation assessment and treatment. They were assessed by a physiatrist and recruited if they had an adherent scar on one limb as a consequence of orthopedic surgery. The exclusion criteria were: scars on the face, head, or trunk; previous surgery in the same area; other local problems reducing skin elasticity (eg, hyperkeratosis) in the affected or contralateral limb at the corresponding site of the adherence, considered a reference measure of normal skin mobility. Twenty-five patients between the ages of 21 and 79 years were enrolled in the study. Causes for surgical interventions were: fractures (n=10), ligament (n=4) and tendon (n=4) repairs, entrapment syndromes at the wrist (n=3), joint prosthesis (n=1), arthrodesis (n=1), Dupuytren disease (n=1), and traumatic injury of the hand (n=1). Table 1 shows the main characteristics of the study sample and of the scars. The mean (SD) duration of treatment was 10 (2) sessions, with a frequency of 2 to 3 sessions per week. During each session, patients underwent a physical therapy program including scar manual therapy plus stretching, joint mobilization, muscle strengthening, and functional exercises, depending on the goal of rehabilitation and their injury. The study was approved by the local institutional review board, and written informed consent was obtained from all participants in accordance with institutional review board guidelines.

Procedure

The Adheremeter and the VSS were administered simultaneously before (T1) and at the end (T2) of the physical therapy intervention. Only the physical therapist administered the VSS. The 2 raters performed the measurement on the same day (in the morning), one 10 minutes after the other, in random order. During testing, each examiner was alone with the patient in the room. Each rater was blinded to the other's assessment and their own previous results (at T2).

Each rater identified as landmarks the worst adherent point and the skin on

The Bottom Line

What do we already know about this topic?

Assessment of skin adherence postsurgical scaring is crucial prior to planning treatment. Clinicians need tools to reliably measure scar adhesion rather than estimating it or using less reliable methods.

What new information does this study offer?

This study reports on the Adheremeter: a new and easy-to-use device for measuring scar adhesion in clinical practice.

If you're a patient, what might these findings mean for you?

Quantification of the extent of scar adhesion with the Adheremeter makes it possible to reliably assess changes at follow-up, and, secondarily, to make better judgments of the effects of your treatment.

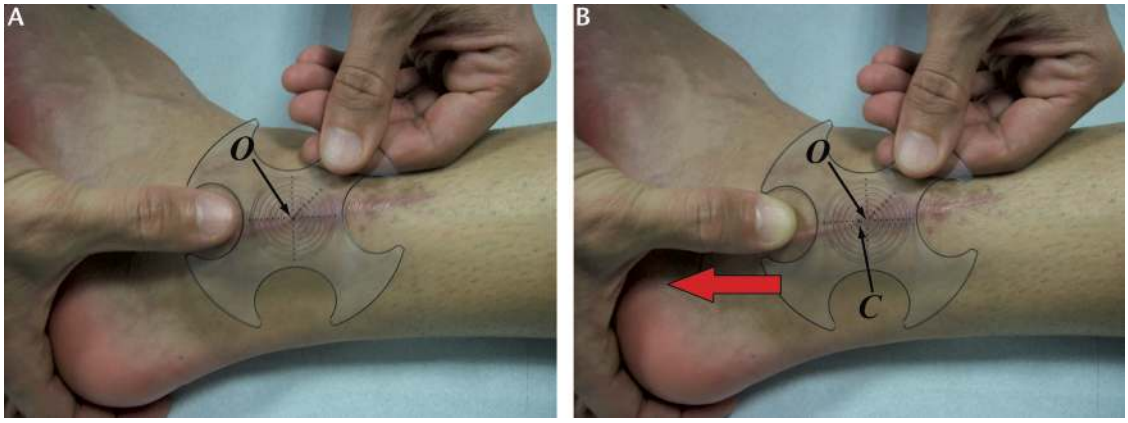

Figure 2.
Scar adherence (marked with a black fine-point pen) in original position (*O*) at rest (left) and at maximal caudal excursion (*C*) (right) when stretched with maximal force within a comfort range for the patient. Red arrow shows stretching direction. In this example, maximal caudal excursion of the adherence (from *O* to *C*) is 3 mm.

the contralateral anatomic position of the adherence and marked them with a fine-line pen. Both surfaces were cleaned. In linear scars, the rater reported on the patient record the position of the worst adherent point by measuring its distance from the 2 extremities of the scar. The Adheremeter was positioned so that the rings were centered on the landmark. Skin was relaxed, and nearby joints were in a loose-packed position. The rater held the device in the hand, supporting the hand on the patient's body in such a way that there was no contact between the Adheremeter and the patient's skin. The other thumb was positioned close to the external edge of the device (17.5 mm from the center) (Fig. 2). Before stretching the skin with the thumb with maximal force within a comfortable range for the patient, the rater said to the patient, "Now, I'm beginning to stretch the skin; if you feel any discomfort, tell me immediately." Traction was applied centrifugally in 4 directions: caudal, rostral, right side, and left side. For every traction, the rater read on the Adheremeter the position of the landmark at the maximal excursion. Once the tension was released, the rater verified that the landmark returned to the Adheremeter's center and, if not, repeated the measurement. Markers on the skin were cleaned at the end of each measurement. The whole procedure generally took a few minutes per landmark.

Data Analysis

The 4 measurements (ie, caudal, rostral, and the 2 side maximal landmark excursions from the rest position), taken both for the scar and for the normal contralateral skin, were used to obtain a couple of indexes of surface mobility: the adherence's surface mobility index for the scar (SM_A) and the surface mobility index for the normal contralateral skin (SM_N). The score of each index of surface mobility was obtained by calculating the area of the quadrilateral whose diagonals, which are orthogonal to each other, are the side-to-side and rostro-caudal landmark maximal excursions (Fig. 3). Then, the SM_A was compared with the SM_N, thus giving an index of adherence severity (AS). The AS estimates the ratio between the SM_A and the SM_N: $AS=SM_A/SM_N$ (Fig. 4). Its values thus calculated range from 0 to 1, where 0 represents scar immobility in at least one diagonal (side-to-side or rostro-caudal) and 1 represents completely normal scar mobility. In both indexes, an increase of values means a better scar condition (ie, a higher surface mobility for the SM_A and a scar surface mobility approaching that of normal skin for the AS).

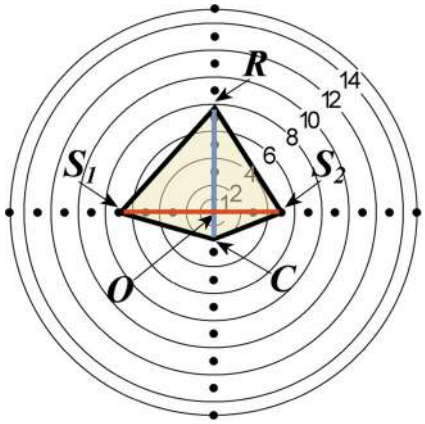

Figure 3.
Graphic representation of the surface mobility index. *O* is the original position of the evaluation point, S_1 and S_2 represent the 2 maximal lateral excursions, and *C* and *R* represent the maximal caudal and rostral excursions. Because the diagonals, S_1S_2 (side-to-side, red) and *RC* (rostro-caudal, blue), intersect at right angles, the area of the quadrilateral (yellow) is computed as: $(S_1S_2 \times RC)/2$. In this example, $S_1S_2=7+5=12$ mm, $RC=8+2=10$ mm, and, consequently, the surface mobility index is scored as $12 \times 10/2=60$ mm^2.

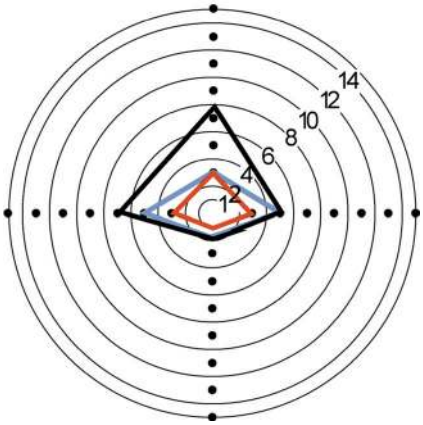

Figure 4.
Graphic representation of the surface mobility index (patient 7) showing differences between the adherence's surface mobility index for the scar (SM_A) (pathological condition, red quadrilateral) and the surface mobility index for the normal contralateral skin (SM_N) (normal skin condition, black quadrilateral) at the initial examination (T1) and the SM_A at the end of treatment (T2) (outcome, blue quadrilateral). The figure clearly shows, in this patient, an improvement in scar mobility after the treatment (the blue quadrilateral is larger than the red quadrilateral), but also that maximal rostral excursion did not change. In this example: at T1, SM_A=10 mm^2, SM_N=60 mm^2, and, consequently, AS is scored as 10/60=0.17; at T2, SM_A=12 mm^2, SM_N=60 mm^2, and, consequently, AS is scored as 12/60=0.20.

Intrarater and interrater reliability were calculated by computing the intraclass correlation coefficient (ICC [2,1]) at T1 and T2. Intraclass correlation coefficient values higher than .75 were considered good, and those above .90 were considered excellent.[15] The sample size of 25 patients assessed by 2 raters was determined on the basis of the pilot study expecting to obtain ICC values of about .90, with a 95% confidence interval (CI) close to .2.[16] The intrarater reliability of the SM_N (T_1 versus T_2) was calculated for both raters. Interrater reliability was analyzed by comparing the SM_A, SM_N, and AS at both T1 and T2 for both raters.

Given the sample size of 25 patients[15] and the link between scar adherence, pliability, and general scar healing,[5] to provide evidence of concurrent validity, we tested our *a priori* hypothesis, which was to find at least a moderate correlation ($r > .50$) between the SM_A and the AS and both VSS and PL-VSS. Correlation coefficients (r_s) were calculated using the Spearman rank method, corrected for ties. Data were analyzed using SPSS statistical software.[†]

The sensitivity to change (ie, the ability to detect change in general, regardless of whether the change was clinically relevant) of the SM_A and the AS was determined by:

1. Wilcoxon signed rank tests;
2. The effect size, defined as mean change score (T2−T1) divided by the standard deviation of the T1 (admission) scores (values around 0.2, 0.5, and 0.8 are considered, respectively, small, moderate, and good)[17];
3. The standard error of measurement (SEM) at T1, reflecting the extent of expected errors in different raters' scores, computed as follows: $SEM = SD \times \sqrt{1 - R}$, where *SD* is the standard deviation of test scores and *R* is the test-retest reliability coefficient, which in this study was the ICC[18]; and
4. The minimum detectable change in single subjects (MDC), computed from the SEM, to indicate the amount of change required to be adequately confident that the change that has occurred is not attributable to measurement error or chance variation. The MDC was estimated using a previously described method ($1.96 \times SEM \times \sqrt{2}$, where 1.96 is the 2-sided tabled *z* value for a 95% CI).[18]

[†] SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

Results

The mean duration of the rehabilitation intervention was 17 days (interquartile range=12–30 days). No patient reported discomfort during measurement with the Adheremeter. Table 2 shows the mean values for the SM_A and the AS at T1 and T2. Both scores increased significantly during the testing period (for all, $P < .001$). Figure 5 shows the correlation between the AS values at T1 and changes that occurred after the treatment period, calculated for each patient with the following formula: [(AS score at T2)−(AS score at T1)]. Table 3 shows the mean values for the VSS and the PL-VSS at T1 and T2.

Table 2.
Mean (SD) Values for the Adherence's Surface Mobility Index for the Scar (SM_A) and the Index of Adherence Severity (AS) at the Initial Examination (T1) and at the End of Treatment (T2)

	Physical Therapist		Physical Therapist Student	
Index	T1	T2	T1	T2
SM_A	20.82 (26.51)	37.96 (47.96)	22.64 (32.31)	37.18 (47.96)
AS	0.22 (0.15)	0.44 (0.25)	0.25 (0.18)	0.44 (0.25)

[a] SM_A=the adherence's surface mobility index for the scar, AS=index of adherence severity.

In normal skin, measurement of intrarater reliability showed excellent and reliable values in both raters (ICC=.96; 95% CI=.91, .98). Interrater reliability values for the SM_N, SM_A, and AS are shown in Table 4.

Correlations between both the Adheremeter's indexes (SM_A and AS) and the VSS and PL-VSS are shown in Table 5. The z values were −4.09 and −3.88 for the SM_A and −4.32 and −4.24 for the AS, for the physical therapist and the physical therapist student, respectively ($P<.001$). The effect size was 0.6 and 0.4 for the SM_A index and 1.4 and 1.2 for the AS. The SEM was 4.59 and 4.79 mm^2 for the SM_A and .05 and .06 for the AS. The MDC was 12.68 and 13.23 mm^2 for the SM_A and 0.14 and 0.17 for the AS. The MDC for the AS was met or exceeded by more than 50% (13/25) of this cohort.

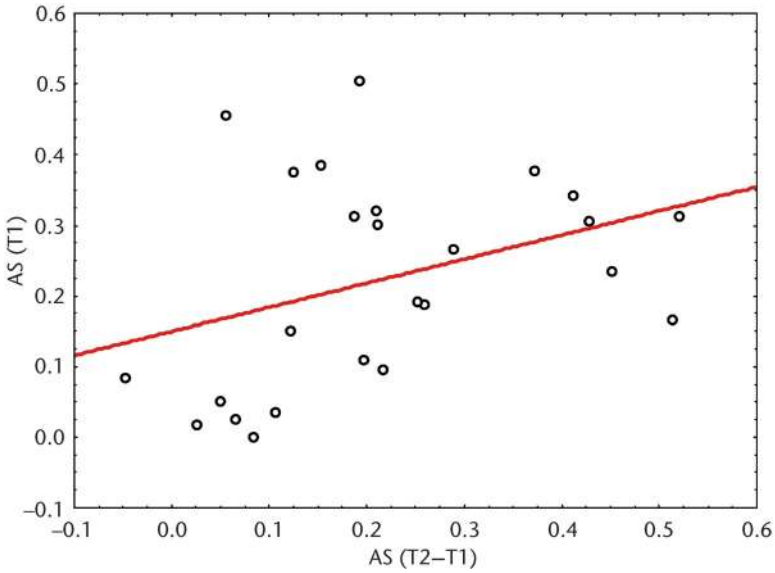

Figure 5.
Correlation between the index of adherence severity (AS) at the initial examination (T1) and the AS change after treatment (T2−T1), based on the physical therapist's measurements.

Discussion

Assessment of skin adherence is crucial to obtain outcome measurements regarding treatment of pathological scars and to quantify compensation in medico-legal settings. To our knowledge, the only scale developed for adherent scars is the Skin Glide Grade scale, a nonvalidated 5-point Likert scale for grading the amount of scar restriction.[10] In addition, a complex technological device has been proposed, but its validity has not been demonstrated.[19]

The Adheremeter showed excellent intrarater reliability, both with the expert and the inexpert examiner, and good-to-excellent interrater reliability for both normal skin and postsurgical scar. Confidence intervals for the AS were larger than for the SM_A because the AS is the ratio of 2 random variables and thus has more variability. In fact, the greater the variability, the larger the CI.

To verify the validity of the Adheremeter, we compared it with the VSS. We chose the version proposed by Nedelec et al[9] because this is the only one that considers scar adherence. The 2 Adheremeter indexes (SM_A and AS) showed a better correlation with the VSS and the PL-VSS at the initial examination than after rehabilitation. These results could be explained by the fact that scar mobility is more closely related to contraction and pliability when scar condition is worse, and they suggest a possible use of the Adheremeter to measure not only adherent scars but also scar pliability in general. Unfortunately, the PL-VSS assesses general scar adhesion and is not focused on the worst adherent point.

Table 3.
Mean (SD) Values of the Vancouver Scar Scale (VSS, Range=0–14) and Its Pliability Subscale (PL-VSS, Range=0–4) at the Initial Examination (T1) and at the End of Treatment (T2)

Index	T1	T2
VSS	5.04 (1.77)	4.44 (1.58)
PL-VSS	2.08 (.81)	1.52 (.77)

Table 4.
Interrater Reliability[a] for the Surface Mobility Index for the Normal Contralateral Skin (SM_N), the Adherence's Surface Mobility Index for the Scar (SM_A), and the Index of Adherence Severity (AS) at the Initial Examination (T1) and at the End of Treatment (T2)

Index	ICC (95% CI) at T1	ICC (95% CI) at T2
SM_N	.98 (.96, .99)	.98 (.95, .99)
SM_A	.97 (.93, .99)	.99 (.98, .99)
AS	.88 (.75, .94)	.87 (.72, .94)

[a] ICC=intraclass correlation coefficient, 95% CI=95% confidence interval.

Table 5.
Correlations Among Variables[a] at the Initial Examination (T1) and at the End of Treatment (T2)

Index	SM_A		AS	
	T1	T2	T1	T2
VSS	**−.58**[b]	−.50[b]	**−.59**[b]	−.41[c]
PL-VSS	**−.58**[b]	−.39	**−.66**[b]	−.32

[a] SM_A=the adherence's surface mobility index for the scar, AS=index of adherence severity, VSS=Vancouver Scar Scale, PL-VSS=Pliability Subscale of the Vancouver Scar Scale. Bold values indicate moderate correlation.
[b] $P<.01$.
[c] $P<.05$.

Figure 5 shows that AS scores changed during the testing period and that there was a greater improvement in scar mobility in participants with the highest initial scores. Both of the Adheremeter's indexes were able to detect these changes after rehabilitation. The SEM and the MDC were calculated to enhance the measure's interpretation. The results of this study demonstrate that a clinician should be confident (95%) that an AS change score greater than 0.17 in individuals is not likely to be attributable to measurement error or chance variation, whereas for a large sample, a change greater than 0.06 could be sufficient. Considering that the MDC values obtained from each rater were different, we suggest taking into account a prudent value for MDC equal to 0.20 as a change value not likely to be attributable to measurement error or chance variation. In our sample, more than 50% of the patients had an AS score increase greater than 0.20 (the MDC value suggested). Moreover, most of these individuals had at admission the highest AS scores of the overall sample. These results might suggest that the AS score could represent a possible prognostic indicator of the final outcome after rehabilitation aimed also at treating scar adhesions. In fact, patients affected by a less severe adherent postsurgical scar had a better improvement in scar mobility than the others.

The results showed that both indexes have adequate psychometric characteristics, but the AS seems the more interesting index due to the fact that differences between scar and normal skin, or different anatomical sites, are normalized.

In this study, we assessed the reliability, validity, and sensitivity to change of the Adheremeter in a sample of patients affected by orthopedic postsurgical pathological scars. Further studies are needed to assess its validity for other types of scars, such as traumatic and burn scars, or after surgery in specific clinical fields, such as plastic and reconstructive surgery.

Limitations

Intrarater reliability was assessed only on normal skin (SM_N) because different measuring sessions of scar adherence on different days might have been less valid due to a possible maturation effect, and 2 or more measuring sessions of scar adherence, conducted on the same day, could have been biased by the fact that the rater could have been influenced by the memory of the first scores (rater bias).

Nevertheless, there is a chance that such a systematic error could have been present in the intrarater reliability of the SM_A and AS scores, even if nearly 3 weeks, on average, passed between the original examination and the end of treatment. The Adheremeter showed an adequate sensitivity to change, but in future studies it would be interesting to evaluate the Adheremeter's ability to detect minimal clinical important changes using anchor-based methods (eg, patients' or clinicians' judgments about the changes that occurred). In this study, we did not calculate the measure of a minimal clinically important difference because it is said to be sample specific[20] and a larger sample would have been necessary to obtain a universal cut-point measure useful for clinical decision making.

Finally, the measurement is based on the rater's evaluation of force to stretch the skin and on the patient's judgment of comfort. The experimental protocol required a brief training of the raters in the assessment method, allowing landmark determination and end-range stretching force to vary among raters.[21] The results of this study demonstrate that the method is valid, so that minimal differences in the intensity of force (not measured in the study and thus a potential source of error) probably are not relevant. Complex and expensive electronic equipment that would be necessary for a more precise measurement of the intensity of stretching strength is not required with this method, making the Adheremeter feasible for use in any rehabilitation setting or consulting room. Finally, examiners were not completely masked, in that they were aware of the Adheremeter reading during the stretching (as is the case with other common clinical measures, such as a universal goniometer). These limitations are due to the nature of the study and to the partially standardized approach used, chosen precisely to reflect the realities of the clinic.

The Adheremeter might not be reliable for measuring scars situated in highly concave or convex anatomical zones. In the absence of a contralateral landmark (eg, amputation or scar on the midsagittal axis), we suggest comparing the adherence with the nearest healthy skin.

Conclusions

In our sample, this new method to measure adherent scars showed an adequate level of reliability, validity, and sensitivity to change. The Adheremeter could be considered a useful device for clinicians working with patients with scars. Caution should be applied in generalizing the results of this study because further studies are needed to confirm our results in larger cohorts and for other types of scars.

Dr Ferriero and Dr Vercelli provided concept/idea/project design. All authors provided writing. Dr Vercelli, Dr Stissi, and Dr Sartorio provided data collection. Dr Ferriero, Dr Vercelli, and Dr Salgovic provided data analysis. Dr Ferriero provided project management and institutional liaisons. Dr Salgovic provided consultation (including review of manuscript before submission). The authors thank Dr Franco Franchignoni for his continuing guidance and advice.

The research reported in this article was undertaken in compliance with the Helsinki Declaration and the international principles governing research on animals.

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