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THE EFFECTS OF ELASTIC THERAPEUTIC TAPE ON HYPERTROPHIC SCARS : A COHORT STUDY

FINAL REPORT

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Introduction

Description of the investigational medicinal product and its intended purpose

Elastic therapeutic taping is an acrylic adhesive that is often used as a physiotherapeutic tool for the treatment of various musculoskeletal disorders and other clinical conditions in athletes and patients(1,2), e.g. one brand is Curetape®. Curetape® meets the highest quality standards in the field of medical taping with an anti-allergic acrylic layer. Its ventilated and skin-friendly properties mean that the tape can be kept on for longer periods than would otherwise possible. The tape is hypo-allergenic, elastic and water resistant.

Curetape® is registered as a medical device Class 1, meets the strictest quality requirements, is safe to use and does not contain any latex (TÜV quality mark).

Elastic therapeutic tape can be used for a wide range of different therapeutic applications, including treating injuries, reducing inflammation or fluid retention (oedema and hematomas), correcting posture, pain inhibition, treating complaints arising for strain. Various effects can be achieved by using different taping techniques(2).

In burn- and trauma scars hypertrophic scarring is a common complication following injury. It is generally accepted that hypertrophy and scar contraction can be minimized by reducing mechanical tension on the affected scar site. Cells such as fibroblasts sense extracellular mechanical forces originating from the environment. Therefore the purpose of this study is to investigate the effects of the reduction of tension on scars by applying the elastic therapeutic tape around the surface of the scar.

Background and justification for the design of the clinical investigation

Mechanotherapy:

In recent years there has been an increasing interest in the mechanobiology of scars. The influence of mechanical forces on skin has been examined since 1861 when Langer first reported the existence of lines of tension in cadaver skin(3). Internal tension in the dermis leads to cell – extracellular matrix and cell – cell interactions transferring external mechanical forces into biochemical signals inside the cell(4). Khan et al. reclaimed the term ‘mechanotherapy’ and presented the current scientific knowledge underpinning how mechanical load may be used therapeutically to stimulate tissue repair and remodelling(5). It has long been thought that the effectiveness and efficiency of physical therapy would improve if our understanding of the cell biology/biochemistry that participates in mechanics could be improved. Traditional physical therapy focuses primarily on rehabilitation, but recent developments in mechanobiology that illuminated the effects of physical forces on cells and tissues have led to the realization that the old therapy model should be updated. Recent studies showed how mechanotherapies target particular cells, molecules, and tissues. The role of mechanical force in various therapies, including micro-deformation of soft tissue techniques, shockwave, vacuum massage, tissue expansion, skin stretching and tension reduction (tissue targeting) therapies is the subject of numerous ongoing clinical trials(6–9).

All adherent cells including endothelial cells, fibroblasts and myofibroblasts sense tension originating from the environment. Tension is transmitted via Cell-Extra Cellular Matrix (ECM) contacts, leading to reorganization of the cytoskeleton and the elicitation of specific signals that modulate gene expression. In skin, alterations of mechanical forces are continuously recognized by cells and their functions are adapted according to the biological requirements. If mechanical tension is removed, those tissues undergo atrophy, indicating the important role of mechanical signals for maintaining proper functioning of the organism. Obviously, fibroblasts and myofibroblasts are cells implicated in scarring, which is strongly influenced by mechanical tension.

Mechanism The precise mechanisms by which different cell types transmit mechanical signals are not fully understood. They might involve stretch-activated ion channels, direct interactions between structural and signalling components, or activation of small GTPases . As outlined above, many cooperative interactions exist between integrins and growth factor signalling. In particular, fibroblast to myofibroblast conversion and α-SMA expression crucially depend on a combination of mechanical tension and TGF-β. Thus in scarring, generation of tension can induce myofibroblast formation, causing a self-perpetuating loop. A similar autocrine loop is discussed for the induction of collagen synthesis in fibroblasts by mechanical tension. In this case, TGF-β is induced by tension, which in turn activates collagen synthesis via the classic pathways. These data clearly demonstrate that mechanical tension, which is generated during wound contraction, scar formation and in fibrotic tissue, can modulate the gene expression of fibroblasts and myofibroblasts embedded into this tissue at different molecular levels. Translated into a clinical situation, this means a retractile scar with adhesions between the dermal tissue and the underlying viscera.

The mechanotransduction theories provide possible evidence for several physical non-invasive treatment options. It was suggested that many of the physical scar management methods, including compression therapy, silicone therapy, adhesive tape, and occlusive dressing therapy, are related to mechanotransduction mechanisms. Mechanical compression seems to induce apoptosis and to regulate cytokine release, so reducing hypertrophic scarring. The effects of mechanical tension on TGF-beta1 and collagen synthesis leads towards the hypothesis that brief, moderate stretch of scar tissue seems to down-regulate hypertrophy and retraction of scars and could be the best option for splinting, positioning and postural stretching(10).

Based on the aforementioned increased mechanical tension hypothesis, it makes sense to minimize mechanical forces after surgery or spontaneous healing of (burn)wounds. Tension on a scar in one direction will result in a stretched scar. Multi-directional or cyclical tension on scar will result in a hypertrophic scar(11,12). Clinical experience has shown us that the most reliable way to support a scar is using tape. Reiffel et al.(13) suggested longitudinal taping in the direction of the scar rather than at right angles to it. A strip of paper tape, approximately two to four inches longer than the wound, was applied to the normal skin, beyond the wound. The tape is then pulled as it is laid down, compressing it. It was usually changed daily and could develop blisters under the tape, although a number was not mentioned. Noncompliance of some patients was reported. Atkinson et al. (14)recommended multidirectional application of paper tape as scar support. Paper tape is rigid and can prevent an increase of tension but will not be able to reduce the already existing tension. They reported adverse reactions such as localised red rash (12%) and increased rate of wound infection (9%). A drop-out rate of more than 40% was noted and attributed to the possibility that the treatment demands were higher than the anticipated benefits. None of these studies investigated whether the application of paper tape did actually reduce tension at the wound/scar site.

We developed a new technique for tension reducing tape application using elastic therapeutic tape. It provides multidirectional tension relief. A longitudinal incision is made in the middle of the tape at

approximately 5mm from both ends. By means of this incision the tape can be applied around the scar tissue approximating the scarred skin from the ends towards the middle, horizontally as well as vertically. In this way tension reduction can be obtained in all directions, without touching the scarred skin, thus avoiding maceration of the wound/scar site. This technique also allows movement without increasing tension at the wound/scar site.

Method

Objective of the Clinical Investigation

Primary objective:

In this cohort study we investigated if this taping technique can decrease scar hypertrophy (primary outcome: scar thickness).

Secondary objective:

Evaluation of the effects on other scar related characteristics (secondary outcomes: scar redness, trans-epidermal water loss, elasticity, water content, subjective scar characteristics and quality of life).

Design of the Clinical Investigation

This is a cohort study, a longitudinal observational study.

Methods and timing for assessing, recording, and analysing variables

- Baseline measurements (T0):

Skin colour is measured with the Minolta Chromameter® CR-400 (Konic Minolta, Tokyo, Japan). Following dimensionless parameters are registered: l* parameter (reflection of light), a* parameter (redness of the skin).

Trans-epidermal water loss (TEWL) is measured with the Tewameter®TM300 TEWL-probe and is expressed in g/m²/h.

Skin distensibility is evaluated using the Cutometer® MPA580 (Courage & Khazaka Gmbh, Köln, Germany) and the vertical skin deformation is expressed in mm.

Thickness of the scar in mm is determined by High Frequency Ultrasound 22MHz (DUB®Cutis, Taberna pro medicum, Lueneburg, Germany).

The hydration of the scar is measured by a Corneometer® (Courage & Khazaka, Köln, Germany).

Subjective scar related characteristics are assessed using the Patient and Observer Scar Assessment Scale (POSAS).

- Application:

In all phases of the project the elastic therapeutic tape will be applied in the same manner: A longitudinal incision is made in the middle of the tape at approximately 5mm from both ends. By means of this incision the tape can be applied around the scar tissue approximating the scarred skin from the ends towards the middle, horizontally as well as vertically. The tape makes no direct contact with the scar site, thereby avoiding maceration of the scar. The tape is removed after 2 days and re-applied after at least 24h without tape. This tape application process will be repeated up to 3 months.

- Follow up:

Follow up measurements (see baseline measurements):

T1: After 1 month

T2: After 3 months

T3: After 6 months

T4: After 1 year

Inclusion criteria for subject selection

- All participants are between 18 and 70 years old
- Caucasian males and females
- Burn scars and trauma scars in the upper and lower extremities (except hands and feet) and the trunk
- Scar age between 1 and 18 months

Exclusion criteria for subject selection

- Patients with diabetes, vascular diseases or pathologies (such as use of blood thinners; see below) other than scarring are excluded
- Women who are pregnant at the time of enrolment
- Patients with extremely high sensitivity for skin irritations
- Patients who are obliged to take one of the following medications: Aspirin®, Warfarin®, Marcumar®, Methrotrexate®, Cyclosporin®
- Central neurological conditions
- Peripheral paralysis
- Cortisone therapy up to six weeks before investigation
- Patients unable to give informed consent

Results

Statistics

Statistics included descriptives and one-way repeated measures manova. For the outcomes that showed statistically significant improvement over time, the effect size was determined by the cohen's d. If the absolute value of cohen's d is higher than 0.8, the effect size is considered as high. A value of $p<.05$ was considered statistically significant.

Adverse effects

One patient showed skin irritation after 10 weeks of application. The first ten weeks no irritation was visible, after that we couldn't resolve this problem and had to stop the tape application. A possible cause can be that the patient developed an allergic reaction to the tape during those 10 weeks.

One other patient showed skin irritation after 5 weeks of application. The tape application was stopped for 2 weeks and restarted. After restart no problems occurred. A possible cause here could be that the patient applied hydrating crème within 4 hours before tape application.

One patient showed a small skin tear after 4 weeks. The tape application was stopped for 2 weeks and restarted. A possible cause here could be the location, which was high on the upper-arm close to the axilla.

No further problems occurred during the study.

Demographics

In total 20 patients have enrolled in the study. One of the patients stopped because of skin irritation, one other patient stopped after 3 months due to severe illness and 4 patients dropped out because they did not want to carry on with the study. Finally 14 patients have completed the assessment at endpoint (1 year after baseline). The descriptive characteristics of these patients are found in Table 1.

Table 1: Descriptive characteristics of the subjects.

Mean age	42 years ±15 years
Mean scar age	6,9 months ±2,9 months
Gender	8 male – 6 female
Type of healing	8 split thickness grafts – 4 spontaneous healing – 2 sutures or strips
Scar Location	All in between joints
Ethnicity	13 Caucasian – 1 North African

POSAS Patient

The Patient Scale contains six questions applying to pain, itching, colour, pliability, thickness and relief. Because it was too difficult for patients to make the distinction between pigmentation and vascularity, both characteristics were captured in one item: colour.

Each of the six items on both scales has a 10-point score, with 10 indicating the worst imaginable scar or sensation. The lowest score is '1', and corresponds to the situation of normal skin (normal pigmentation, no itching etc.).

The Patient Scale POSAS contains the following questions:

1. Has the scar been painful the past few weeks?

2. Has the scar been itching the past few weeks?

3. Is the scar colour different from the colour of your normal skin at present?

4. Is the stiffness of the scar different from your normal skin at present?

5. Is the thickness of the scar different from your normal skin at present?

6. Is the scar more irregular than your normal skin at present?

Besides these six questions, the patient is asked to provide an Overall Opinion regarding scar quality. At the end the "Total Sum of Scores" is calculated by adding up all six items.

Following parameters have shown to be statistically significantly improved:

- **Itch** was statistically significantly different at the different time points during the one year period ($p = .010$) . Post hoc analysis revealed statistically significant differences after six months ($p = .003$) while Itch has decreased from 4.1 at baseline to 1.8 after one year ($d = 1.41$).
- **Colour** was statistically significantly different at the different time points during the one year period ($p < .0005$). Post hoc analysis revealed statistically significant differences after one year ($p = .028$) while colour has decreased from 5.9 at baseline to 3.5 after one year ($d = 1.32$).
- **Stiffness** was statistically significantly different at the different time points during the one year period ($p = .001$). Post hoc analysis revealed statistically significant differences after one year ($p = .013$) while stiffness has decreased from 6.1 at baseline to 3.4 after one year ($d = 1.60$).
- **Texture** was statistically significantly different at the different time points during the one year period ($p = .041$). Post hoc analysis revealed statistically no significant differences while texture has decreased from 5.1 at baseline to 3.6 after one year.
- **Overall opinion** was statistically significantly different at the different time points during the one year period ($p < .0005$). Post hoc analysis revealed statistically significant differences after 3 months ($p = .016$) while Overall Opinion has decreased from 5.7 at baseline to 3.4 after one year ($d = 1.42$).
- **Total Sum of Scores** was statistically significantly different at the different time points during the one year period ($p = .002$). Post hoc analysis revealed statistically significant differences after 6 months ($p = .016$) while Overall Opinion has decreased from 28.6 at baseline to 17.6 after one year ($d = 1.32$).

Table 2: POSAS Patient scores at baseline. 1. 3. 6 and 12 months after baseline .

POSAS Patient Scores					
	Baseline (T0)	T0 + 1 month	T0 + 3 months	T0 + 6 months	T0 + one year
	Mean	Mean	Mean	Mean	Mean
	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)
					Cohen's d*
pain	2.3	1.8	1.6	1.3	1.7
	(1.1-3.5)	(1.0-2.6)	(1.1-2.0)	(1.0-1.6)	(0.8-2.7)
itch	4.1	2.6	2.4	1.8	1.8
	(3.1-5.1)	(1.6-3.6)	(1.2-3.7)	(0.9-2.6)	(0.8-2.7)
					1.41
colour	5.9	5.1	4.8	3.9	3.5
	(4.8-7.0)	(4.4-5.9)	(3.9-5.6)	(2.9-4.9)	(2.4-4.6)
					1.32
stiffness	6.1	5.2	4.4	4.1	3.4
	(5.2-6.9)	(4.2-6.2)	(3.3-5.4)	(2.7-5.6)	(2.2-4.5)
					1.60
thickness	5.1	4.7	4.6	3.9	3.7
	(4.0-6.1)	(3.8-5.7)	(3.6-5.6)	(2.8-5.0)	(2.4-5.0)
irregularity	5.1	3.8	4.1	3.9	3.6
	(3.9-6.3)	(3.0-4.6)	(3.3-4.8)	(2.6-5.2)	(2.2-4.9)
					0.74
overall opinion	5.7	4.7	4.3	4.2	3.4
	(4.9-6.5)	(4.0-5.4)	(3.2-5.3)	(3.0-5.4)	(2.2-4.5)
					1.42
SUM score	28.6	23.2	21.8	19.0	17.6
	(24.3-32.9)	(20.3-26.1)	(17.9-25.6)	(14.1-23.9)	(12.1-23.2)
					1.32

POSAS Observer

In the POSAS observers rate vascularity, pigmentation, pliability, thickness, relief and surface area. The directions for use of the different parameters of the Observer Scale POSAS are as follows (all parameters should be compared to normal skin at a comparable anatomical site whenever possible):

Vascularity: Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas.

Pigmentation: Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity.

Thickness: Average distance between the subcuticular-dermal border and the epidermal surface of the scar.

Relief or Texture: The extent to which surface irregularities are present (preferably compared with adjacent normal skin).

Pliability: Suppleness of the scar tested by wrinkling the scar between the thumb and index finger.

Surface area: Surface area of the scar in relation to the original wound area.

The **Overall Opinion** is assessed as well and the **Total Sum of Scores** is calculated by adding up all six items.

Following parameters have shown to be statistically significantly improved.

- **Vascularity** was statistically significantly different at the different time points during the one year period ($p < .0005$). Post hoc analysis revealed statistically significant improvement already after 3 months ($p = .020$) while vascularity has decreased from 4.8 at baseline to 2.6 after one year ($d = 2.03$).
- **Thickness** was statistically significantly different at the different time points during the one year period ($p = .001$). Post hoc analysis revealed statistically significant differences already after 3 months ($p = .026$) while thickness has decreased from 4.1 at baseline to 3.1 after one year ($d = 0.76$).
- **Pliability** was statistically significantly different at the different time points during the one year period ($p = .037$). Post hoc analysis revealed no statistically significant differences while pliability has decreased from 4.8 at baseline to 2.8 after one year ($d = 1.58$).
- **Overall opinion** was statistically significantly different at the different time points during the one year period ($p < .0005$). Post hoc analysis revealed statistically significant improvement already after 3 months ($p = .019$) while Overall Opinion has decreased from 4.6 at baseline to 2.8 after one year ($d = 1.87$)
- **Total Sum of Scores** was statistically significantly different at the different time points during the one year period ($p <.0005$). Post hoc analysis revealed statistically significant improvement after 3 months ($p = .005$) while Total Sum of Scores has decreased from 23.6 at baseline to 16.9 after one year ($d = 1.72$)

Table 3: POSAS Observer scores at baseline. 1. 3. 6 and 12 months after baseline

POSAS Observer Scores					
	Baseline (T0)	T0 + 1 month	T0 + 3 months	T0 + 6 months	T0 + one year
	Mean	Mean	Mean	Mean	Mean
	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)
					Cohen's d*
vascularity	4.8	3.7	3.4	2.9	2.6
	(4.0-5.6)	(3.1-4.3)	(3.0-3.9)	(2.3-3.5)	(2.3-3.0)
					2.03
pigmentation	3.0	2.6	2.6	2.6	2.3
	(1.9-4.1)	(1.8-3.5)	(1.8-3.3)	(1.8-3.4)	(1.7-2.9)
thickness	4.1	3.7	3.2	3.0	3.1
	(3.4-4.8)	(2.8-4.7)	(2.6-3.8)	(2.1-3.9)	(2.2-3.9)
					0.76
relief	3.2	2.9	2.8	2.7	2.4
	(2.4-4.0)	(2.4-3.5)	(2.3-3.2)	(2.4-3.1)	(2.1-2.8)
pliability	4.8	3.7	3.1	3.0	2.8
	(3.9-5.7)	(2.9-4.5)	(2.5-3.7)	(2.3-3.7)	(2.2-3.4)
					1.58
surface area	3.7	3.8	3.6	3.6	3.6
	(2.9-4.6)	(3.0-4.6)	(2.9-4.4)	(2.9-4.3)	(2.8-4.5)
overall opinion	4.6	3.9	3.5	2.9	2.8
	(4.0-5.3)	(3.5-4.4)	(3.1-3.9)	(2.5-3.4)	(2.3-3.3)
					1.87
SUM score	23.6	20.5	18.7	17.9	16.9
	(21.0-26.0)	(1801-22.9)	(16.4-21.0)	(15.3-20.4)	(14.6-19.2)
					1.72

Colorimetry

The colour is measured using a Minolta Chromameter CR-400. The Chromameter indicates three components: L* (reflection of the light), A* (level of red component) and B* (yellow-blue component), all expressed in Arbitrary Units (AU). The results of the L* and the A*-component, representing respectively the brightness and the redness of the scar, are displayed below. To minimize the external factors of influence like temperature, humidity, season, etc; the differences between healthy skin and scarred skin were taken in account

The L*-component (brightness) of the colorimetric assessment was statistically significantly different at the different time points during the one year period ($p < .0005$). Post hoc analysis revealed statistically significant improvement after 3 months compared to baseline ($p = .015$). The mean difference values of the L*-component have improved from 54.2 at baseline to 59.2 after one year ($d = 0.91$).

The A*-component (redness) of the colorimetric assessment was statistically significant different at the different time points during the one year time-period ($p < .0005$). Post hoc analysis revealed statistically significant improvement after 6 months compared to baseline ($p = .012$). The mean difference values of the A*-component have decreased from 15.0 at baseline to 12.1 after one year ($d = 1.17$).

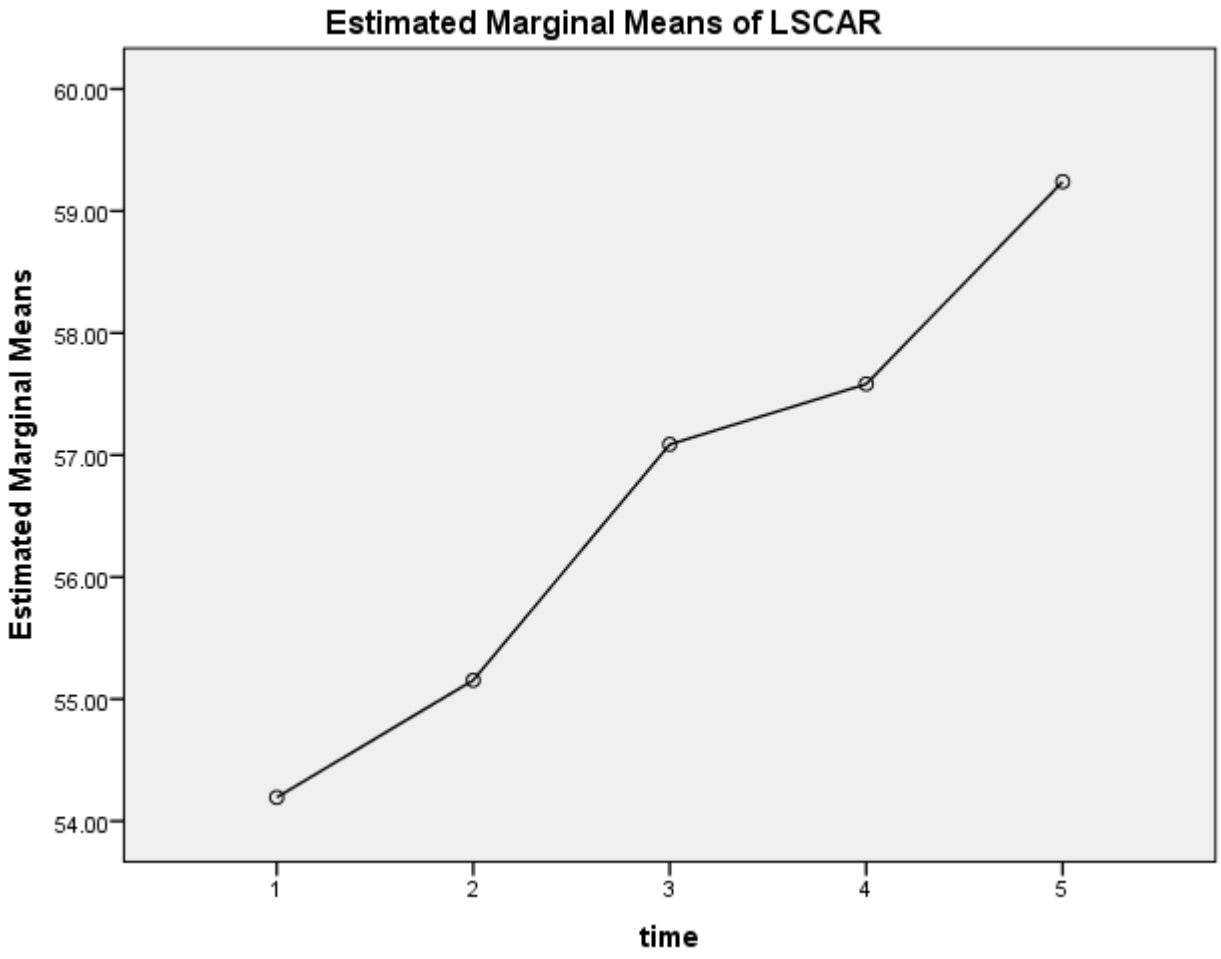

Fig 1: Graphical representation of the results of the L*-component of the colorimetric assessment

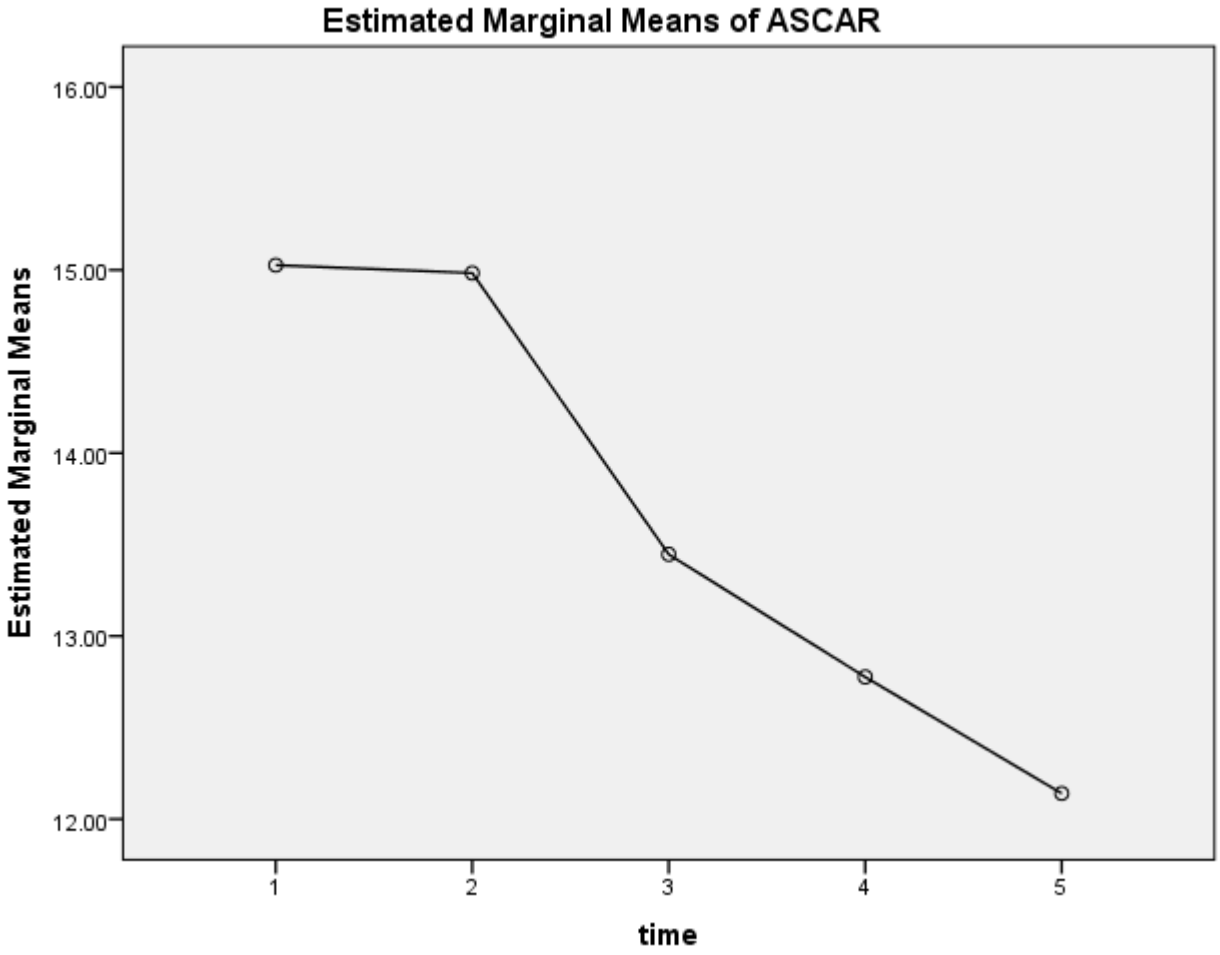

Fig 2: Graphical representation of the results of the A*-component of the colorimetric assessment

Cutometry or skin distensibility

Skin distensibility is evaluated using the Cutometer® MPA580 (Courage & Khazaka Gmbh, Köln, Germany) and the vertical skin deformation is expressed in mm. The Cutometer® measures the vertical deformation of the skin in millimetres when the skin is pulled by means of a controlled vacuum into the circular aperture of the probe. To minimize the external factors of influence like temperature, humidity, positioning, exact relocation etc; the differences between healthy skin and scarred skin were taken in account

The maximal distensibility of the skin was statistically significant different at the different time points during the one year time-period ($p = .002$). Post hoc analysis revealed statistically significant improvement after one year compared to baseline ($p = .046$). The mean values of the A*-component have improved from 0.53mm at baseline to 0.81mm after one year ($d = 1.01$).

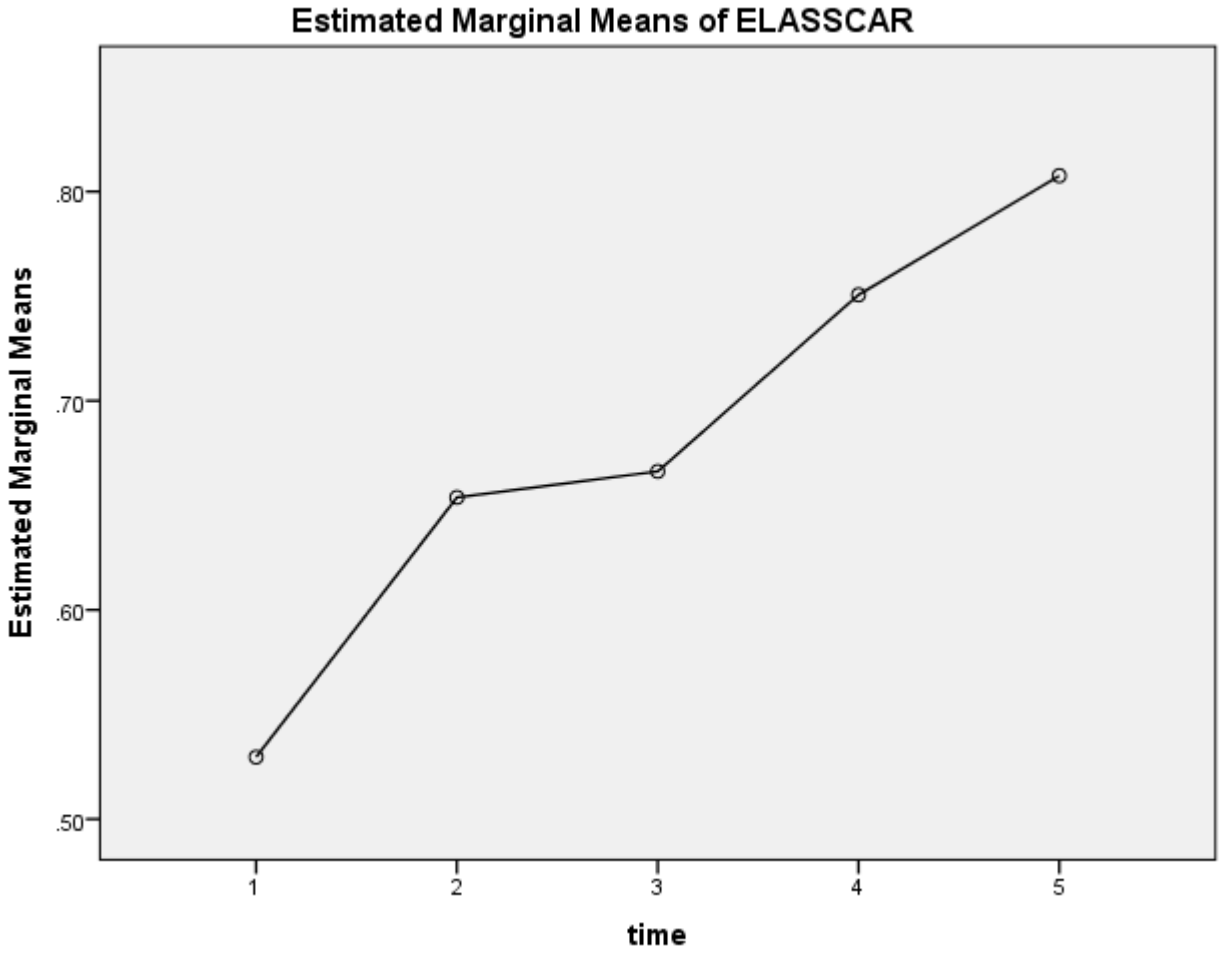

Fig 3: Graphical representation of the results from the maximal distensibility of the skin.

Trans-epidermal water loss & Hydration

Trans-epidermal water loss (TEWL) is measured with the Tewameter®TM300 TEWL-probe and is expressed in g/m²/h, while the hydration of the scar is measured by a Corneometer® (Courage & Khazaka, Köln, Germany). To minimize the external factors of influence like temperature, humidity, sweating, exact relocation etc; the differences between healthy skin and scarred skin were taken in account.

Neither the water vapor permeability, neither the water content of the skin didn't show any statistically significant differences at the different time points during the one year time-period. Eight of the participants showed an improvement while 6 participants showed no improvement. The mean difference values of the Tewameter® have decreased from 1,64 at baseline to -1,96 after one year and those of the water content have decreased from -3.42 at baseline to -3.89 after one year. The non-significant results indicate that TEWL and water content are not suitable parameters to be investigated in studying the effects of elastic therapeutic tape application on scars.

Dermal Thickness

Thickness of the scar in mm is determined by High Frequency Ultrasound 22MHz (DUB®Cutis, Taberna pro medicum, Lueneburg, Germany). The DUB®Cutis skinscanner is a 22-MHz frequency ultrasound scanning system with 57 µm resolution, a measuring depth of 10 mm and a 12,8 mm scan width. The result of ultrasonic imaging is usually presented in the form of A-scan (measurement at one point, showing the thickness of different layers of the skin).

The dermal thickness was statistically significantly different at the different time points during the one year period ($p < .0005$). Post hoc analysis revealed statistically significant differences after 6 months compared to baseline ($p = .030$). The mean values of the dermal thickness have decreased from 3811 at baseline to 3011 after one year ($d = 0.88$).

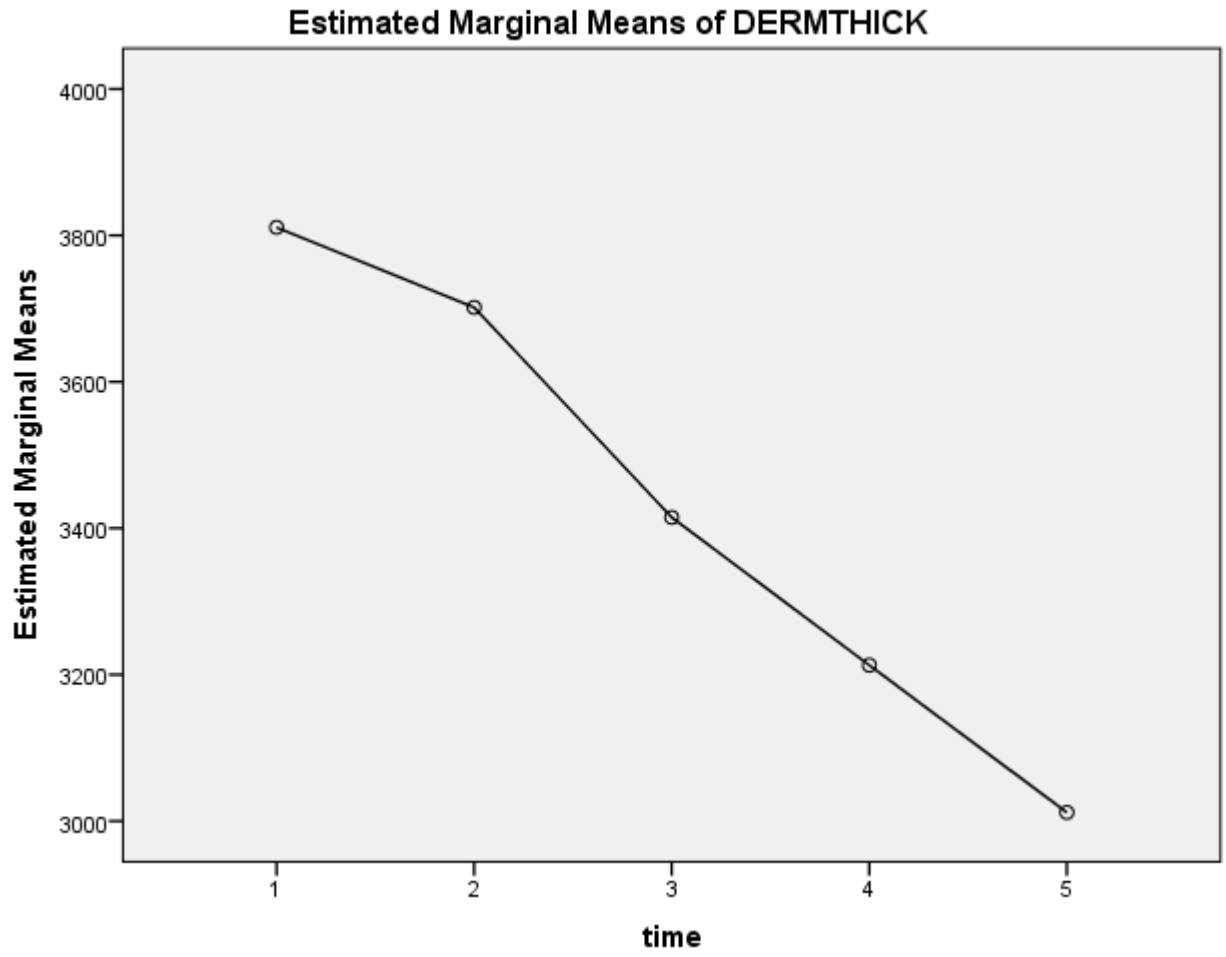

Fig 4: Graphic representation of the results for dermal thickness of scar tissue.

Discussion

We observed a statistically significant improvement with a large effect size for itch, POSAS global and SUM score, dermal thickness, colour and elasticity. The parameters colour, elasticity and thickness can be evaluated objectively and subjectively. For colour and elasticity, the improvement was observed both objectively and subjectively. In contrast, the improvement for thickness was only detected objectively.

For the improvement of elasticity over time, the effect sizes of the objective and subjective measurements differ somehow (subjective cohen's d: ±1.6 – objective cohen's d: 1.0), the p-values however are completely in line (p=.001 - .002). This is consistent with the finding that there is a moderate correlation between the Cutometer® parameters (pliability, elasticity and extension) and the pliability score of the POSAS (15)

For the parameter colour, the effects sizes of the POSAS P colour and the POSAS O vascularity are high to very high (cohen's d=1.32 - 2.03) while the effect size of the a-value is 1.17. This could indicate some form of response bias for the patients' opinion (he/she wants to please the researcher) or confirmation bias on the observers' side (he/she wants to see the hypothesis confirmed). The POSAS O pigmentation did not differ significantly, in contrast to the L-value. This corresponds to the low correlation value (r = 0.23-0.51) between pigmentation an L-value.

In contrast of elasticity and colour, the significant improvement for thickness (with high effect size) was only detected objectively. A possible explanation is that the DUB®Cutis measures the dermal thickness from the epidermis-dermis border to the dermis-hypodermis border, which is invisible. While the thickness observed by patient and observer is based on the visible and thus more superficial aspect of the scar. This could be observed as less thick in comparison with the objective dermal thickness. So possibly the POSAS measures a different aspect of scar thickness than the DUB®Cutis.

The significant improvement of the overall opinion of the scar by observer and patient, indicated by POSAS P and O global, corresponds to the improvement of visible scar parameters such as elasticity and colour, assessed by POSAS and objective instruments. At 12 months, the POSAS P global is comparable to the values of Longaker et al. (16), a randomized controlled trial that investigated the effects of a mechanical offloading device which has the same working mechanism as this taping technique. The POSAS O global values are higher compared to Longaker et al., indicating the observers in this study their overall opinion was less positive compared to the observers that assessed the surgical scars in the study of Longaker. A possible explanation is that the cause of the scars of this study is not only surgical but also included burn scars which have more tendency to hypertrophy (17). This was also confirmed when we found quite similar scores for the overall opinion of the observers in our study when compared to a subgroup of patients who healed with scars that were rated worse by the investigator (surgeon) in the study of Longaker et al.

At one year, the results of the treated scars in the study of Longaker et al. for POSAS-P thickness and elasticity are lower compared to this study. For elasticity, this is confirmed by POSAS-O, but not for thickness. The observer in this study scored higher ($\Delta > 0,5$) on elasticity, pigmentation, vascularity compared to Longaker. The scar age in this study is higher, but possibly the scars are more hypertrophic and therefor show higher scores on certain POSAS aspects. The difference in POSAS-O

vascularity can be linked to hypertrophy or scar activity but also to the skin types. In the study of Longaker, the skin types are more diverse and the ratio of Caucasian skin type is lower. The type of healing is uniform in contrast to our study. There was no objective scar assessment in the study of Longaker thus a comparison between studies is difficult.

The limitations of this study are the small sample size, the heterogeneity of the scars (e.g. type of healing, location,..) and the large drop-out. The enrolment of patients remains troublesome due to inclusion-, exclusion-criteria and drop-out. Future studies should aim for less strict in- and exclusion criteria combined with more co-variables.

Conclusions

In conclusion, the results of this longitudinal observational study support that both subjective (POSAS Patient, POSAS Observer) and objective scar outcomes (colour, elasticity and dermal thickness) are useful to include in studies that evaluate the effect of tension reducing therapy on scars.

The scar characteristics that met the criterion of statistically significant improvement over time with a large effect size (cohen's d > 0.8 or < -0.8) are **itch (POSAS P)**, **global score (POSAS P, POSAS O)**, **SUM score (POSAS P, POSAS O)**, **colour (POSAS P, POSAS O and Chromameter®)**, **elasticity (POSAS P, POSAS O and Cutometer®)** and **dermal thickness (Dubcutis®)**.

Curetape® seems to have a beneficial effect on the evolution of scars, when applied with this specific technique. A randomized controlled trial needs to be carried out to confirm these findings.

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