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THE EFFECTS OF DEPRESSOMASSAGE ON COLOR AND TRANSEPIDERMAL WATER LOSS RATE IN BURN SCARS: A PILOT COMPARATIVE CONTROLLED STUDY (PART 1)

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Abstract

Objective: Depressomassage is a non-invasive massage technique using a mechanical suction device that is used in the treatment of traumatic or burn scars. Since color and transepidermal water loss (TEWL) are respectively the most important physical and physiological characteristic of hypertrophic scar formation, we wanted to investigate the effects of depressomassage on the recovery of color and TEWL in burn scars compared to the traditional physiotherapy.

Methods: In this pilot comparative controlled study a total 43 burn patients were included and allocated into 2 groups. All patients received standard physical therapy, and the test group received additional depressomassage during 6 months. Color was assessed using the POSAS questionnaire (for color, vascularity and pigmentation) and the Minolta Chromameter. TEWL was measured using DermaLab.

Results: Patients of both groups were evaluated at baseline, after 1, 3 and 6 months and after 1 year. The evidence for a difference in evolution of color and TEWL between both groups in our study was minimal.

Conclusions: In practice, precise indications to begin depressomassage have to be kept in mind. Perhaps other scar abnormalities such as decreased elasticity, increased thickness, excessive pain or itching could be sufficient reasons to begin depressomassage and should be assessed.

Key words

burn scar, massage, mechanical suction, color, transepidermal water loss

1. Introduction

One of the main problems after burn injury is hypertrophic scar formation, which leads to an array of functional, aesthetical and psychological problems. It can also affect the quality of life of the patient [1]. A variety of non-invasive treatments exist, such as pressure therapy, silicone gels, hydration, massage therapy, mobilization, stretching, rehabilitation, splinting and casting [2].

Massage therapy has shown some effects in the reduction of pain [3,4] and itching in burn scars [3-5]. Improvements of patient's perspectives on scar related characteristics, such as pruritus, pigmentation, pliability, vascularity and height, were found in the study of Roh and co-authors in 2007 [5], but they could not reconfirm these findings in 2010 [6]. These results were based on subjective scar? rating scales. Cho and co-authors found promising results for thickness, melanin, erythema, TEWL and elasticity after massage therapy on scar tissue using objective scar assessment tools [4]. However these results were again not confirmed in the second study of Roh and co-authors [6]. In all these studies massage therapy was performed manually [3-6], nevertheless different treatment protocols were presented and the depth and effects of the different scar massage techniques could be dissimilar.

Depressomassage is a non-invasive massage technique using a mechanical device that lifts the skin by means of negative pressure and creates and mobilizes a skin fold [7-10]. In the past depressomassage was used to improve the aesthetic appearance of healthy skin e.g. cellulite [11]. Currently depressomassage is also used in the treatment of traumatic or burn scars [12]. However at present, there is no comparative trial investigating the effects of mechanical massage therapy after a burn injury.

One of the major features of hypertrophic scarring is the red to deep purple color [13]. The amount of erythema (or redness or vascularity) and pigmentation contribute to scar color. Erythema is caused by neovascularization and pigmentation disorders resulting from differences in melanocytes concentration and melanin production after a burn injury. Erythema usually diminishes after several months or sometimes years and is considered to be the most important feature in the assessment of scar evolution. Pigmentation disorders often remain to some extent in burn scars [14]. Due to the disruption of the skin barrier after a burn the amount of transepidermal water loss (TEWL) is considered to be the most important physiological characteristic of scars [15]. Since color and TEWL are two important characteristics of hypertrophic scar formation, to investigate the effects of massage therapy using a mechanical suction device (depressomassage) in a comparative controlled trial. The aim of this study was

to examine the added value of depressomassage on the recovery of color and TEWL in burn scars compared to usual care therapy.

2. Material and Methods

2.1. Study design

The study design was a non-randomized controlled trial. Data were collected between February 2009 and May 2014 in Oscare, organisation for burns, scar after-care & research, Antwerp, Belgium. Patients were allocated into 2 groups , a test group and a usual care group based on the possibility to come to our center (allocation criteria). The treatment of all patients consisted of standard physical therapy (manual physiotherapeutic techniques, massage therapy, pressure garments, silicone gels, hydration). The test group additionally received depressomassage (massage therapy using a mechanical suction device) during 6 months. Therapists and assessors were aware of treatment allocation.

2.2. Study population

Burn patients eligible for this study had to meet the following inclusion criteria: (1) at least 18 years of age; (2) scars with a 40% difference of erythema and/or TEWL between the scar site and the contralateral or adjacent healthy skin (based on retrospective data). This study was approved by the Ethics Committee of ZNA campus, Antwerp (4130). Informed consent was obtained from all patients.

In total 43 Caucasian burn patients with 56 scar sites were recruited from Oscare. All patients agreed to participate in this comparative clinical trial and completed the intervention (no drop out or missed sessions). Thirty scar sites were allocated to the test group and 26 scar sites formed the usual care group.

2.3. Scar sites

In total 56 scar sites were measured. The boundaries of the test sites were carefully measured, written down in the patient chart, captured on a digital picture and referred to during each visit for defining exact (re)location for assessment.

In accordance to the inclusion criteria of 40% difference between scarred skin and healthy skin, scar sites were exclusively included in the subgroup of erythema, or exclusively included in the subgroup of TEWL or included in both subgroups. Forty-seven scar sites were included in the evaluation of erythema, with 26 scar sites in the test group and with 21 scar sites in the usual care group. In the evaluation of TEWL, 37 scar sites were included, with 20 scar sites and with 17 scar sites in respectively the test group and usual care group.

2.4. Intervention

Patients of the test group were treated during a period of 6 months with the PRUS® depressomassage device manufactured by F Care Systems in Belgium (presented in Figure 1). The principle of depressomassage or vacuum therapy is to create a skinfold in a treatment head with negative pressure. The created skinfold can be manipulated in accordance with established defibrosis techniques [16]. The treatment frequency during the first 3 months was 2 to 3 times a week (10 treatments per month), the following 3 to 6 months only once a week. The applied negative pressure can vary between 250 and 900 mbar depending on location and scar thickness. The duration of a treatment was approximately 5 minutes per 10 cm^2. The treatment protocol is presented in Table 1. All patients continued the usual physical therapy and scar care which included pressure garments, silicone gels, manual physiotherapeutic techniques, massage therapy according to the techniques of D. Jaudoin [17], hydration as prescribed by the referring medical specialist as long as necessary.

2.5. Measurement procedure, outcome measures and measurement tools

To stabilize cutaneous blood flow, all patients were asked to remove pressure garments at least 30 minutes before measurements were started. Measurements were performed before the treatment was executed. Patients of both groups were measured at baseline (pre), after 1 (1m), 3 (3m) and 6 months (6m) each time before the treatment and at follow-up after 1 year (1y).

First, color was assessed subjectively by means of the three items of the POSAS questionnaire [18] (patient scale/color with a score from 1 (as normal skin) to 10 (very different); observer scale/pigmentation; observer scale/vascularity with a score from 1 (normal skin) to 10 (worst scar imaginable). Secondly, color was registered objectively using the Minolta Chromameter CR-400[13] (expressed in L*, a* and b*) and finally, TEWL was measured to evaluate the recovery of the skin barrier function using DermaLab® [19] (expressed in $g/m^2/h$).

2.6. Statistical analyses

Means and 95% confidence intervals were obtained from a general linear model for longitudinal measurements with a covariance matrix taking into account the presence of multiple scar sites within a patient and the repeated measures over time. A random patient effect was used to model the correlation between scar sites from the same patient. For the repeated measures over time an unstructured covariance matrix was used. If the distribution of the model residuals was right-skewed, the outcome was log-transformed (natural logarithm), but figures were created after back-transforming to the original scale (in which case they refer to geometric means and their 95% CI).

Two different models were used. In the first model the evolution over time was evaluated on all repeated measures. In a second model the post-baseline values were compared between the two groups. The analysis was restricted to post-baseline values and the baseline value and the age of the scar were added as covariates in the model, their effects being allowed to vary over time (by including interactions with time). Hence, the plot depicts the mean value of scar sites of mean age and mean baseline value. The scar age (time in months (mo) between wound closure and baseline assessment) was log-transformed (natural logarithm) to downplay the potential influence of extreme observations.

All analyses were performed using SAS software, version 9.2 of the SAS System for Windows.

3. Results

Patient and scar related characteristics of the subgroup erythema are reported in Table 2. Table 3 shows the characteristics of the subgroup TEWL. In both subgroups (erythema and TEWL) mean? scar age of the test group was higher compared to the usual care group. In the subgroup erythema, this was due to three outliers (≥ 58 months) in the test group versus no outliers (≤ 36 months) in the usual care group. In the subgroup TEWL two outliers (≥ 85 months) were found in the test group and only one outlier (93 months) in the usual care group.

Table 2 represents baseline measurements for color in the test and usual care group. Baseline data for TEWL in both groups is presented in Table 3.

The *color score of POSAS patient scale* was significantly improving over time in both groups ($p < .0001$) (Figure 2), which meant a decrease in POSAS score over time. However there was

no evidence for a difference in evolution between groups (p = 0.62). After correction for baseline value and scar age, there was evidence for lower mean values in the test group, significantly after 6 months and after 1 year (p = .006 and p = .028, respectively). Note however that the difference between both groups did not significantly depend on time (p = 0.62).

The evolution of the *vascularity score of POSAS observer scale* was significantly improving over time in both groups (p < .0001) (Figure 3), meaning a decrease in POSAS score over time. The difference in evolution between test and usual care groups was significant (p = .03) with a faster decline in the test group after 1 month and 3 months but this was compensated at a later stage. However, after correction for baseline value and scar age, there was no evidence for any difference in post-baseline values.

The *pigmentation of POSAS observer scale* did not show evidence for differences over time and between both groups (results not shown).

The evolution of the *luminance parameter (L*) of Minolta Chromameter* increased over time in both groups, which meant brighter scars over time, but only significantly in the test group (p < .0001) (Figure 4). The difference in evolution between both groups was nonetheless not significant (p = 0.18). After correction for baseline value and scar age, there was evidence for higher values in the test group after 6 months (p = .011) and after 1 year (p = .016). Note however that the difference between both groups did not significantly depend on time (p = 0.35).

The *redness parameter (a*) of Minolta Chromameter* significantly decreased over time in the test group (p < .0001) and usual care group (p = .0003) (Figure 5), in other words, scars became less red over time. However, the evolutions were not significantly different (p = 0.32). Further, no significant differences between groups were present after correction for baseline value and scar age (results not shown).

The *b* parameter of Minolta Chromameter* significantly increased in the test group and usual care group (p = .02 and p = .002, respectively) (Figure 6), meaning more yellow scars. But there was no evidence of a difference in evolution (p = 0.11) Furthermore, no significant differences between groups were present after correction for baseline value and scar age (results not shown).

A significant decrease of *TEWL* over time in the test group (p = .004) and the usual care group (p = .017) was found and indicated a recovery of TEWL (Figure 7). There was no evidence for a difference in evolution (p = 0.30). After correction for baseline and age of scar, there was

evidence for lower mean values in the test group, significant only after 3 months (p = .006). Note however that the difference between both groups did not significantly depend on time (p = 0.64).

4. Discussion

The patient related characteristics pre-intervention were almost comparable in both groups. However scar related characteristics at baseline and scar age of both groups differed. Therefore the focus in the between-group analysis was on the post-baseline values in which the groups were compared after correction for the baseline value and scar age.

In examining the objective scar related parameters, we did not take into account the contralateral healthy control sites (except for inclusion) due to the seasonal variations in skin color. Therefore we only presented the measurements of the scar sites. We defined a difference of 40% between erythema and/or TEWL of scar sites and healthy skin to be the minimum to be included based on retrospective data.

Color of scars is the major feature in hypertrophic scar formation and a predictor of scar maturation [13,20]. In our study in the patient's perspectives the color of scar sites was diminishing over time in both groups due to the natural recovery and continuation of the usual care therapy. There were significant lower values in the test group after 6 months and 1 year after correction for baseline value and scar age. Since the mean difference score exceeds one point in the POSAS scale (i.e. a difference of 1.2 point after 6 months and a difference of 1.1 point after 1 year), based on an expert opinion these differences were considered clinically relevant. Results of the observer's vascularity score were somewhat in line with these findings, however there was a significant difference in evolution between both groups with a faster decline of vascularity in the test group after 1 month and 3 months but compensated afterwards. This study was not blinded, it might have affected the patient's and observer's opinion after 1 month and 3 months about the score of the scar color and scar vascularity in favor of the test group. There was a significant mean difference score after 1 month between both groups in favor of the test group, although this difference did not exceed the clinically relevant difference of 1 point in the POSAS scale. The objectively measured redness (a*) parameter confirmed the gradual decline over time but without a significant difference in evolution between both groups.

Pigmentation of scar sites was evaluated based on the observer part of POSAS, the L* and b* parameters of Minolta Chromameter. In the observer part of POSAS no evolution was shown

in either group. The values of L* and b* parameters of Chromameter increased over time in both groups with a significant evolution within groups, with the exception of the L* parameter in the usual care group. All scars became more pale and less yellowish over time, but the underlying cause was unclear. Less exposure to UV could be an explanation but this was not registered. After correction for baseline value and scar age, higher values of L* were registered in the test group after 6 months and after 1 year. However in clinical practice, the L* and b* parameters are of less importance than the a* parameter.

TEWL indicates the efficiency of the skin barrier function [19]. Our results showed a recovery of skin barrier and decrease of TEWL after 1 year in both groups. These findings were in agreement with the report of Suetake et al. [21] and Anthonissen et al. [19]. In our study we included both spontaneously healed scars and split thickness grafts, which could have an effect on the TEWL. However in the statistical analysis we did not incorporate this variable since we only had 20 scar sites (8 spontaneously healed scars and 12 split thickness grafts) and 17 scar sites (4 spontaneously healed scars and 13 split thickness grafts) in respectively the test group and the usual care group and because Anthonissen et al. reported no evidence for a significant different relation between TEWL and time after burn [19]. After correction for baseline value and scar age, lower values of TEWL after 3 months were found in the test group. However, the mean difference between both groups did not exceed the SEM * 2.77 reported in the reliability analysis of Anthonissen and co-workers and could not be seen as a real difference.

In previously published studies in burn scars, Roh and co-authors reported improvements of patient's opinion of his scars [5]. Cho and co-workers found positive results on scar melanin, erythema and TEWL [4]. Our results did not fully confirm these findings. There were some major differences in the studies. In previously published work various manual massage techniques were applied and described as follows: light stroking of palm and acupressure [5]; or effleurage, friction massage and petrissage [4]. Secondly the treatment group in the study of Roh et al. and that of Cho et al. were compared with a control group without treatment [5] or with standard therapy (without massage) [4]. In our study all patients continued the standard care after burn injury, i.e. pressure and silicone therapy, hydration, manual physiotherapeutic techniques and massage therapy. The present study is the first to use a mechanical device in the massage therapy of burn scars. An important advantage of a mechanical suction device is the consistency in therapeutic technique, however variable settings of the apparatus are possible and different treatment heads are available. Moreover several devices from various companies are on the market, making clinical comparisons and overall conclusions troublesome.

5. Limitations

There are some important limitations to our study:

1) Recruitment of burn patients was not straightforward, but we managed to include 43 patients nevertheless this took 6 years. This sample size however was not based on a priori power analysis.

2) It was a non-randomized clinical trial. Patients were allocated into one of the two groups based on the practicality for patients. To participate in the test group, patients had to be able to visit Oscare regularly for treatments and assessments. On the other hand, patients of the usual care group could be treated in a private practice closer to home and visit Oscare only for the evaluation sessions.

3) We did not include a control group without any kind of massage therapy. The test group and usual care therapy received respectively depressomassage and manual massage therapy or manual massage therapy alone. Changes in both groups were maybe due to massage therapy in general.

4) In this study, we included patients with different types of scars, grafted as well as spontaneously healed scars. In the analysis, we did not differentiate between both types, due to the small sample size. However, we have to keep in mind that grafted scars could react differently to depressomassage than spontaneously healed scars.

5) Three observers were involved in this study; potentially creating some bias. Nonetheless the inter-observer reliability of the Minolta Chromameter, DermaLab® and POSAS questionnaire are reported to be good to excellent [18, 19, 22].

6) The results of the analysis of the evolution within each group should be interpreted with caution, since improvements can be partially due to regression to the mean (since the inclusion of the scar sites is based on the baseline value).

7) Inherent to a pilot study, many outcomes were verified without applying a correction for multiple testing. Strict claims are therefore not possible for any of the outcomes.

6. Conclusion

The evidence for a difference in evolution between both groups is limited. The difference in evolution was found significant in favor of the test group for the vascularity score of POSAS

observer scale only, however this significant effect would not survive the correction for multiple testing. After correction for baseline values and scar age, better results for color in the POSAS patient scale, vascularity in the POSAS observer scale, the L* parameter of Minolta Chromameter and TEWL were found. Understandably some unmeasured variables which were not controlled in the analysis could explain these differences, for example sun exposure, type of moisturizer, scar site location, etc. Thus the difference between both groups should be interpreted with caution.

In clinical practice, it is important to carefully judge the indications to begin depressomassage. In this study we only found minimal effects for color and TEWL due to depressomassage, therefore abnormalities in these two parameters would not be sufficient reasons to start depressomassage. On the other hand scar features such as decreased elasticity, increased thickness, a lot of pain or itching could be good reasons to commence depressomassage [23]. Further research in this topic is needed to describe the effects of this type of treatment.

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