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Randomized controlled trial of the immediate and long-term effect of massage on adult postburn scar

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ABSTRACT

Background: One objective of massage therapy applied to hypertrophic scar (HSc), is to improve the structural properties so skin possesses the strength and elasticity required for normal mobility. However, research supporting this effect is lacking. The objective of this study was to characterize the changes in scar elasticity, erythema, melanin, and thickness immediately after a massage therapy session and after a 12-week course of treatment compared to intra-individual matched control scars.
Methods: We conducted a prospective, randomized, single-blinded, pragmatic, controlled, clinical trial evaluating the impact of a 12-week course of massage therapy. Seventy burn survivors consented to participate and 60 completed the study. Two homogeneous, intra-individual scars were randomized to usual care control or massage therapy plus usual care. Massage, occupational or physical therapists provided massage treatment 3x/week for 12 weeks. Scar site characteristics were evaluated weekly immediately before and after massage treatment including elasticity (Cutometer), erythema and melanin (Mexameter), and thickness (high-frequency ultrasound). Analysis of covariance (ANCOVAs) were performed to test for immediate and long-term treatment effects. A mixed-model approach was used to account for the intra-individual scars.
Results: Scar evaluation immediately before and after massage therapy at each time point revealed changes for all scar characteristics, but the group differences were predominantly present during the early weeks of treatment. The within group long-term analysis revealed a significant increase in elasticity, and a reduction in thickness, during the 12-week treatment period for both the control scar (CS) and massage scar (MS). The increase in elasticity reached significance at week 8 for the MS and week 10 for the CS and the reduction in thickness at week 5 for the CS and week 7 for the MS. There was no significant within group long-term differences for either erythema or melanin. There were group differences in erythema at week 8 and 11 where the CS was less erythematous than the MS.

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Conclusions: The immediate impact of forces applied during massage therapy may lead patients and therapists to believe that there are long-term changes in elasticity, erythema, and pigmentation, however, once baseline measures, the control scar, and time were incorporated in the analysis there was no evidence of long-term benefit. Massage therapy applied with the objective of increasing scar elasticity or reducing erythema or thickness over the long-term should be reconsidered.

1. Introduction

Hypertrophic scars (HSc) occur approximately 33–91% of the time after burn injuries, depending upon the depth of the injury, location of the injury, number of surgical procedures required, type of graft used, genetic susceptibility, and time to wound closure [1–5]. Because of the magnitude of burn injuries, burn scars are larger in surface area and more serious when they reach their peak than surgical scars, therefore are more likely to be associated with significant cosmetic, functional and psychosocial morbidity and reduced quality of life [6–13]. Although there are a number of treatments recommended to ameliorate scar, there is a need for well-designed clinical trials to determine the efficacy of these treatment approaches [14].

Manual massage therapy is a treatment modality that 81% of burn therapists and 100% of pediatric burn therapists in the United Kingdom report using for burn scar [15,16]. Theoretically, the therapeutic benefit of massage therapy is that by manually applying mechanical forces to the burn scar there is a realignment of the extracellular matrix proteins and/or a reduction in edema resulting in increased pliability and reduced thickness of the tissue [17,18]. One of the major barriers to obtaining evidence for the efficacy of massage-therapy and other treatment approaches for HSc has been our inability to accurately measure scars [19]. There have been multiple reviews calling for the use of objective assessment tools where the clinimetric properties have been evaluated [20–22].Our lab has examined the intra- and inter-rater reliability, sensitivity and specificity, and concurrent validity of the Cutometer, Mexameter and high-frequency ultrasound for the evaluation of skin and scar elasticity, erythema, melanin and thickness and have found them to be reliable and valid [23,24]. Thus, these instruments can confidently be used to obtain objective, accurate quantification of skin and scar characteristics.

To date, several studies have been published where the efficacy of massage therapy to improve elasticity, erythema, melanin, and thickness was evaluated, with mixed results. One study [25] yielded no statistically significant changes in scar pliability, vascularity or wrist range of motion (ROM), but data was collected after only one treatment session and deployed insensitive instruments to measure pliability and vascularity changes. A randomized controlled trial [26] tested the efficacy of friction massage in children and found no significant difference in the vascularity, pliability or height of the scars between the treatment and control groups using the Vancouver Scar Scale (VSS) [27]. Although the VSS is clinically the most commonly used burn scar outcome measure [28], issues associated with its reliability [23,24,27] may render it too insensitive to measure change. More recently Cho et al. [29] performed a prospective, randomized, single-blind, controlled trial of 160 burn survivors where 80 participants were randomized to the massage group. The study period was for approximately 35 days during which the massage group received an average of 12, thirty-minute treatments. There was a significant reduction in pain, itch, thickness, melanin, erythema, and trans-epidermal water loss in the massage group when compared to the control group. Electronic instrumentation was deployed for the evaluation of scar thickness, melanin, erythema, and trans-epidermal water loss, however close examination of this data leaves the reader questioning whether the changes are clinically important. Unfortunately, the authors do not provide the effect size nor do they include the data in their manuscript required to perform these calculations. In addition, an expert panel of researchers from the Wound Healing Society has advocated that when conducting clinical trials designed to determine the efficacy for potential scar prevention and reduction therapies that self-controlled or intra-individual designs be employed. This design controls for the marked heterogeneity of scar morphology and the intra-individual inherent variation of their natural potential for spontaneous recovery [30]. This design was not employed by Cho et al., opening the possibility that the reported changes were due to inter-participant variability.

Thus, although massage therapy is one of the most commonly employed treatment methods to reduce the scar formation after a burn injury, there is a need for well-designed studies to determine treatment efficacy. The availability, and confirmed validity and reliability, of electronic instrumentation to accurately measure skin and scar characteristics provides the necessary evaluation tools. Thus, the purpose of this study was to characterize, in adult burn survivors, the changes in scar elasticity, erythema, melanin, thickness, pain, and itch, immediately after a massage therapy session, and after a 12-week period of massage therapy, in comparison to usual care of intra-individual, matched control scars.

2. Methods

2.1. Trial design

This was a prospective, pragmatic, intra-individual, randomized, single-blind, controlled study of adult burn survivors who were recruited from a single burn center. Eligible participants were all adult burn survivors aged 18 or over who had sustained a thermal injury then subsequently developed HSc and were being treated at Villa Medica Rehabilitation Hospital in Montreal, Canada between November 2008 and

February 2016. They needed to have two scar sites that were greater than 2.034 mm thick, but within 0.5 mm of each other [23,24]. Exclusion criteria included patients who had formed keloids, had a psychiatric illness that would prevent them from completing the treatment and follow up visits, had sustained an electrical, chemical, or cold injury, had a dermatological condition in the region of the evaluation sites that may interfere with the study results, had a suspected or known allergy to ultrasound gel, or were unable to communicate in English or French. Members of the clinical team initially approached potential participants who met the inclusion criteria outlined above. If they agreed to participate they were asked to provide written informed consent.

2.2. Sample size

Based on the results of a pilot study, a sample size of 60 was determined to be sufficient to detect a clinically significant difference of 75 points (measured on a 1000 point scale) in erythema values from baseline between the treatment and control scars, assuming a standard deviation of 81 in erythema measurements, using a 2-tailed paired t-test of the difference between means, a power of 80%, and a significance level of 5%.

2.3. Procedures

Due to the heterogeneity of scar formation, progression, and response to treatment, the treatment and control sites were located on the same individual so that the scars being compared were as homogeneous as possible [30]. Once the research assistant obtained signed informed consent, two independent scars on the same individual (approximately $\leq$16 cm^2) were selected and the thickness of the sites determined. Baseline thickness measurements of the two sites had to be within 0.5 mm of each other to ensure that they were as homogeneous as possible, and were 2.034 mm or thicker to establish that they clearly fell outside the range of normal skin thickness [23,24]. If the selected sites did not meet these criteria, alternative sites were selected until two suitable sites were found. Once the research assistant selected the sites for inclusion, they were assigned labels ‘A’ and ‘B’ and full scar evaluations were performed as described below.

As can be seen in the enrollment section of the CONSORT flow diagram [31,32] (Fig. 1) six potential participants were excluded because they did not meet the inclusion criteria due to the fact that they did not have two independent and homogenous HSc sites. An additional two participants declined to participate after signing the consent, but prior to starting treatments. Their reason for declining to participate was their inability to be available for treatment three times a week for 12 weeks plus the follow up evaluation. One participant withdrew prior to allocation because of a surgical intervention unrelated to this study.

In order to minimize the risks of both biased allocation and un-blinding of the research personnel, scar sites were randomized to massage treatment plus usual care or usual care by a notice in a sealed envelope. Envelopes were prepared prior to the trial commencing and were opened by the treating therapist. The envelopes were prepared so that the two scars were randomized independently of other patients, based on a computer-generated table of binary values (1 or 2). The value ‘1’ assigned scar ‘A’ to usual care and scar ‘B’ to massage therapy. The value ‘2’ assigned scar ‘A’ to massage therapy and scar ‘B’ to usual care. A digital photograph of the selected, labeled scar sites was provided to the treating therapist, who opened the consecutively numbered envelope immediately prior to initiating treatment, then transferred the assigned treatment allocation to the photograph. The treating therapist kept the photograph so that they could refer to it, and only once the study was complete were the photographs provided to the research assistant so that the randomization code could be revealed. The participants were instructed not to reveal the group allocation to the research assistant.

The massage treatment sessions occurred three times per week for 12 weeks. Trained massage, occupational, or physical therapists with extensive experience treating burn survivors performed all treatments.

Measurements were conducted in a standardized fashion. If pressure garments were worn, they were removed $^1/_2$ h prior to scar assessment. A flexible, transparent film (Cling Vinyl Grafix, Creative-Coldsnow Artist Materials, Overland Park, KS, USA) was applied to the measurement site, the scar traced, and a hole cut over the exact site to be measured. Photographs were obtained of the scar sites to facilitate relocation for serial measurements and treatments, but not for evaluation purposes. The research assistant measured the scar sites, ‘A’ and ‘B’, at baseline immediately before the first treatment session began, then immediately after treatment was complete using the Cutometer, Mexameter, and high-frequency ultrasound. Itch and pain were measured on a 10 mm visual analogue scale. The scar sites were re-evaluated once a week before and immediately after the treatment, for 12 weeks, and one month after treatment termination. All adverse events were recorded.

During the study period the participants may have been receiving massage therapy on scar sites that were not located adjacent to site ‘A’ or ‘B’, based upon the therapist’s judgement. Since these sites were not being evaluated they were not considered in the results or discussion. However, the expectation that the control site did not receive any massage therapy, other than what is described in the treatment description, was reinforced to the participants by the clinicians. Participants were asked to complete a weekly treatment diary so that the dosage of usual care interventionscould be monitored but the majority of participants failed to complete these, so the results could not be analyzed. Neither the participants nor the therapist were blinded to the random allocation of the sites, since it was not possible. However, the evaluator remained blind to the massage and control scars throughout the study period since the evaluations were conducted in a space separate from the treatment and were performed by a research assistant who was not involved in patient care.

2.4. Measurement tools

The clinimetric properties of the Cutometer, Mexameter, and high-frequency ultrasound for the evaluation of HSc have previously been evaluated and reported [23,24].

The Cutometer (MPA 580, Courage & Khazaka Electronic GmbH, Koln, Germany) is an electronic instrument that assesses skin elasticity based on the suction and elongation

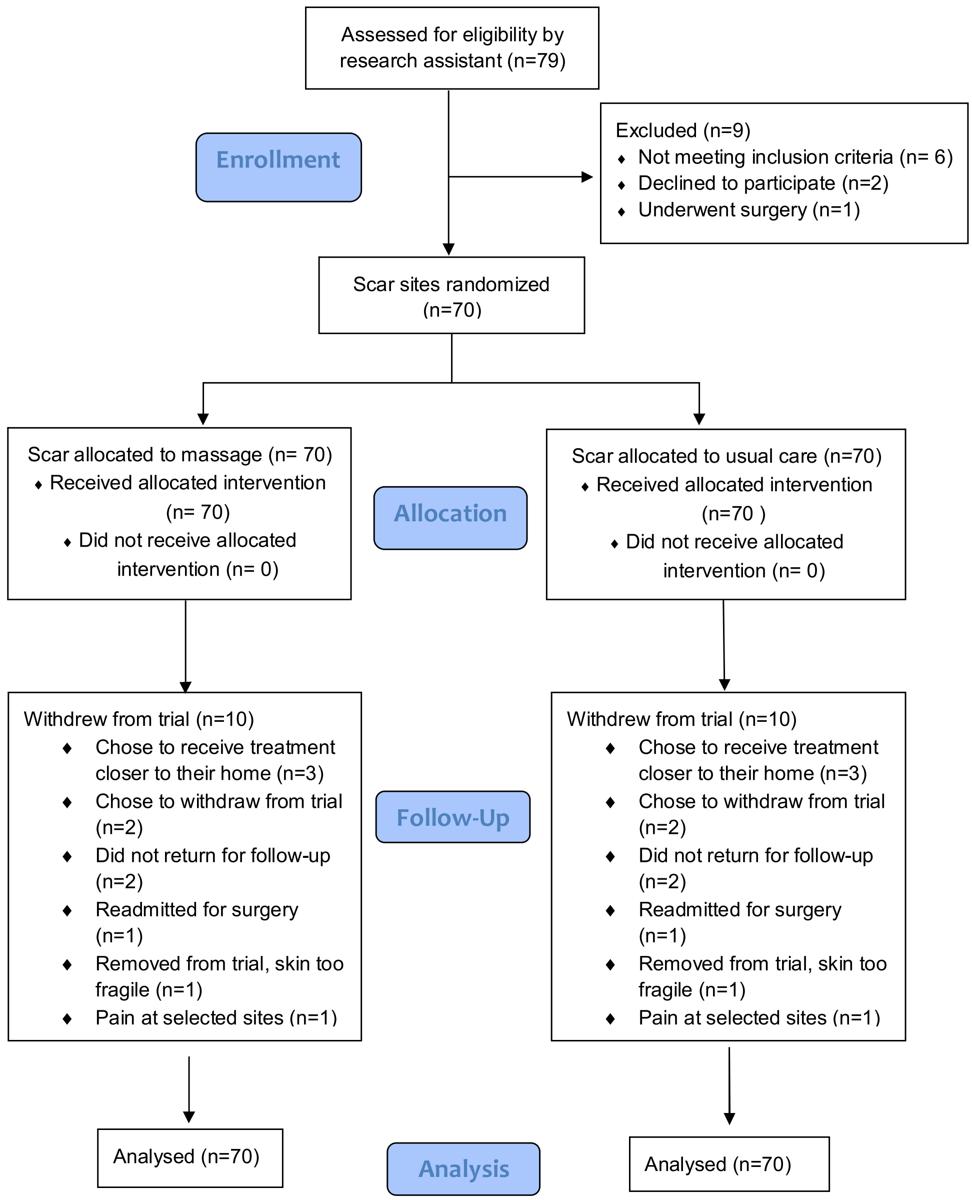

Fig. 1 – CONSORT flow diagram: of the 79 participants assessed for eligibility for participation by the research assistant, 70 were eligible and agreed to participate. Since this was an intra-individual study the scar sites were randomly assigned to massage therapy plus usual care or usual care, therefore those lost to follow up are identical in both allocation arms of the study.

measuring principle. The device generates negative pressure, which draws the skin into a hollow aperture in the centre of the probe and estimates skin penetration depth with an optical measuring system. Four different measurement modes feature pre-programmed sequences of "on/off" pressure cycles. For this study mode 1 was chosen as it delivers three cycles of negative air pressure (450 mbar) for 2 s followed by 2 s of no pressure. The results are expressed as the mean of three measurement cycles. The probe with a 6 mm hollow aperture was used for this study. Prior to the measurement cycle, the probe is applied lightly on the skin, without the outer ring contacting the skin surface, at a perpendicular axis to the skin. During the measurement cycle, it is important that neither the subject nor the probe move. Skin elasticity parameters are traditionally expressed as either absolute parameters (Ua, Ue, Uf, Ur, Uv) or relative parameters (R-parameters). However, since the R0=Uf parameter (which represents the maximum deformation or total distention of the skin) has previously been shown to provide the most reliable measurement of scar tissue when using the Cutometer [23,33], only this measurement was used for analysis in this study. The Cutometer was cleaned and calibrated biweekly as per the manufacturer's specifications.

The Mexameter (MX18, Courage & Khazaka Electronic GmbH, Koln, Germany) quantifies skin erythema and melanin based on the tissue's narrow wavelength light absorption. The probe has 16 light-emitting diodes that send three defined wavelengths of light (568, 660, and 880 nm). A receiver then measures the light reflected by the skin. Since the quantity of emitted light is known, the absorption rate of defined wavelengths can be ascertained, which are selectively absorbed by melanin (660nm) pigments or haemoglobin (568nm). For eachmeasurement, the probe was held perpendicular to the skin. It lightly touched the skin surface, without the outer ring making contact, activating the light emitter. The reflected light was measured by the receiver and the erythema and melanin index (range 1–1000) was immediately displayed on the console, thus the probe only remains in contact with the skin for several seconds. The Mexameter probe was cleaned and the accuracy checked monthly, as per the manufacturer's specifications.

The DermaScan C (Cortex Technology, Handsund, Denmark) is a high-frequency (20MHz), ultrasound scanner that captures and reproduces high-resolution soft tissue images. Image processing software (Dermavision 2D, Dermascan C v. 3, Cortex Technology, Handsund, Denmark) allows skin thickness measurement. A medium focus transducer with a 12mm wide viewing field that was able to penetrate to 15mm below the skin surface was used for this study. Prior to each measurement, a thin layer of conducting ultrasound gel (EcoGel 100 Imaging Ultrasound Gel, Eco-med Pharmaceutical Inc., Mississauga, Ontario, Canada) was applied to the transducer to provide contact between the clear plastic diaphragm and the skin surface. The transducer was held perpendicular to the site while the echographic image was recorded. The research assistant, using the dedicated computer software, later generated the thickness measurements. The mean of three evenly spaced measures of the distance between the outer surface of the echogenic stratum corneum and the inner surface of the dermis, which is the boundary of the hypoechogenic subcutaneous fat, was recorded as the total skin thickness in millimetres. All measurements were performed with the ultrasound velocity set at 1580m/s.

2.5. *Treatment*

Massage lotion (Elta® Lite, Swiss-American Products, Dallas, TX, USA) was applied to both the control and treatment sites. The control site received very light effleurage for the time period required to work in the massage lotion and to obtain maximum hydration benefits, but minimal mechanical force was applied. This controlled for the hydration effect of the massage lotion and touch that was applied, but did not provide any of the force application associated with the massagetherapy. At the treatment site, in addition to the lotion, the scars were subjected to five minutes of friction massage techniques. Sufficient drag was applied to mobilize the tissue relative to the subcutaneous tissue, but not enough to cause damage. Tension and shear forces were used first, then bend and torque forces (petrissage) as the tissues became more pliable. When the superficial fascia could be lifted, skin rolling was introduced [17,34]. Over the 12-week time period, the force intensity was augmented based on the response of the tissue to massage. The therapists tailored their approach to the individual participants, the treatment site, their scar condition and the participants' comfort, which would be consistent with normal practice [35].

Usual care consisted of regular application of moisturizers, pressure therapy and gels if the therapists determined they were required, in addition to stretching and strengthening exercises as well as activities of daily living training. Participants and therapists kept the usual care treatment applied to the two sites consistent during the 12-week period and identical at the two sites.

2.6. *Statistical analyses*

The primary variables that were evaluated were the Mexameter (measurement of erythema and pigmentation), Cutometer (measurement of elasticity), and high-frequency ultrasound (measurement of thickness). Secondary variables included pain and itch.

Descriptive statistics for categorical variables are reported as frequency counts and percentages. For continuous variables, we report the mean and standard deviation (SD) when the distribution of values presented evidence of normality; otherwise we report the median and inter-quartile range (IQR: 25th percentile–75th percentile), or the median and range.

Analysis of covariance (ANCOVA) models were performed to investigate immediate treatment effects at each of weeks 1–12 by comparing posttreatment measures between groups after adjusting for the immediate pretreatment measure. To evaluate long-term treatment effects from baseline, we investigated changes within each treatment group with paired *t*-tests at weeks 1–12 and compared the pretreatment measures between groups at weeks 1–12, after adjusting for the first pretreatment measure with ANCOVA models. For all ANCOVAs, a mixed-model approach was used to account for the correlation between measurements on intra-individual scars. All statistical tests of hypothesis were two-sided and performed at the 5% level of significance. *p* Values were not adjusted for multiple testing in order to avoid being overly conservative and subsequently missing important treatment effects [36,37]. All analyses were performed using SAS, version 9.4 (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. *Study participants*

Seventy participants started treatment. Three chose to discontinue, at weeks 6, 6, and 8, because they transferred to therapy services closer to their home. Two participants informed the research assistant that they wanted to withdraw from the trial, at week 2 and 4, but continued with usual care. Two participants were lost to follow up at week 7 and 8. One was admitted for reconstructive surgery so was withdrawn after week 1. Two participants were removed from the trial by the treating therapist at the first treatment session; one because their skin was too fragile and the other because they experienced an increase in pain associated with the forces applied during massage therapy (Fig. 1).

For the 70 subjects who participated in the study, 41 (59%) were male. The median age was 45 years (IQR 29–55). The majority (81%) were burned by fire or flame. The median total body surface area (TBSA) burned was 21.5% (IQR 10–36). Their median length of stay was 22days (IQR 13–42) in the acute care unit and 22days (IQR 12–34) in the rehabilitation hospital. They had a median of 5days (IQR 3–8) from the time of their injury until the first grafting procedure and a median of two surgical procedures (IQR 1–4). The median burn survivor was 133.5days

(IQR 77–176) postburn when they were recruited into and started the massage therapy protocol. Participants' skin type spanned all categories of the Fitzpatrick Scale [38], with the most common (36%) being skin type III. The scar site was most commonly located on the upper extremity or torso. The demographic and clinical characteristics of the participants were similar when those who withdrew from the study are excluded (Table 1).

The baseline assessment of scar characteristics at the control and massage site were similar (Table 2).

3.2. *Pain and itch*

The pain and itch evaluation of the scar sites revealed that the participants reported minimal amounts of pain or itch at both sites at baseline (Table 2). Although there was a reduction of both pain and itch at both sites during the 12-week course of treatment, this was not evaluated statistically since the baseline measures were too low to allow for a statistically significant or clinically meaningful improvement with time or treatment. In addition, the median and interquartile range for both pain and itch were identical at week 12 to the data at baseline.

3.3. *Immediate response to massage*

There was an increase in elasticity with massage therapy with a statistically significant group difference at week 2 ($p=0.03$). There were no other significant group differences in elasticity at any other time point (Fig. 2A).

For the first 7 weeks there was an increase in erythema of the massage scar immediately after treatment with a statistical

Table 1 – Demographic and clinical characteristics of participants. The participant demographic data and burn injury characteristics are presented for all 70 who were recruited into the study and the 60 participants who completed the 12 weeks of massage therapy. Since the treatment and control site were located on the same participant, the participant characteristics were identical for the two groups.

	n=70		n=60	
Gender (M:F), n (%)	41 (59%):29 (41%)		36 (60%):24 (40%)	
Age (years), median (IQR)	45 (29–55)		45.5 (30.5–55)	
TBSA (%), median (IQR)	21.5 (10–36)		20 (10–35)	
Etiology, n (%)				
Fire/flame	57 (81.4%)		49 (81.7%)	
Scald	6 (8.6%)		6 (10.0%)	
Electrical	3 (4.3%)		3 (5.0%)	
Chemical	2 (2.9%)		1 (1.7%)	
Other	2 (2.9%)		1 (1.7%)	
Days postburn until enrollment, median (IQR)	133.5 (77–176)		133.5 (79–165)	
(range)	(20 to 856)		(34 to 768)	
Fitzpatrick Scale, n (%)				
Type I	3 (4.3%)		3 (5.0%)	
Type II	17 (24.3%)		11 (18.3%)	
Type III	25 (35.7%)		23 (38.3%)	
Type IV	20 (28.6%)		18 (30.0%)	
Type V	3 (4.3%)		3 (5.0%)	
Type VI	2 (2.9%)		2 (3.3%)	
Location of scars, n (%)				
	CS	MS	CS	MS
Upper extremities	22 (31.4%)	25 (35.7%)	18 (30.0%)	21 (35.0%)
Hand	7 (10.0%)	5 (7.1%)	6 (10.0%)	4 (6.7%)
Torso	31 (44.3%)	30 (42.9%)	27 (45.0%)	26 (43.3%)
Lower extremeties	8 (11.4%)	8 (11.4%)	8 (13.3%)	8 (13.3%)
Foot	2 (2.9%)	2 (2.9%)	1 (1.7%)	1 (1.7%)
Inpatient length of stay (days) median (IQR)				
Acute care	22 (13–42)		21.5 (12.5–41)	
Inpatient rehabilitation	22 (12–34)		21.5 (12.5–34.5)	
Days postburn to 1st surgery median (IQR)	5 (3–8)		5 (3–8)	
(Range)	(1–32)		(1–32)	
Number of surgeries, median (IQR)	2 (1–4)		2 (1–4)	
(Range)	(1–17)		(1–17)	

CS=control scar; IQR=interquartile range (25th percentile–75th percentile); MS=massage scar; TBSA=total body surface area.

Table 2 – Baseline scar characteristics. Baseline scar characteristics were similar for the scars randomized to the control and massage group. Due to technical problems with the measurement instrumentation there was missing baseline data for several of the scar characteristics.

	CS	MS
Pain (VAS), median (range)	0 (0–8) (n=70)	0 (0–8) (n=70)
Pruritus (itch scale), median (range)	0 (0–10) (n=70)	0 (0–10) (n=70)
Elasticity (R0) (mm), mean (SD).	0.44 (0.22) (n=69)	0.51(0.24) (n=68)
Erythema index, mean (SD)	450.3 (98.0) (n=68)	441.7 (85.0) (n=68)
Melanin index, mean (SD)	160.1 (153.2) (n=68)	168.4 (172.4) (n=69)
Thickness (mm), mean (SD)	3.3 (1.0) (n=67)	3.2 (0.9) (n=67)

CS=control scar; MS=massage scar; SD=standard deviation; VAS=visual analogue scale.

significant group difference at week 2 (p=0.04), week 6 (p=0.01), and week 7 (p=0.02). There were no other significant group differences in erythema at any other time point (Fig. 2B).

Throughout the 12 weeks of treatment, there was a reduction in pigmentation or melanin immediately following massage. There was a statistically significant group difference compared to the control scar at week 1 (p=0.01), 4 (p=0.01), 6 (p=0.03), 8 (p=0.01), and 10 (p=0.01) (Fig. 2C).

There was a reduction in scar thickness immediately following massage with a statistically significant group difference at week 3 (p=0.004). There were no other significant group differences in thickness at any other time point (Fig. 2D).

3.4. *Long-term response to massage*

Paired t-tests within each treatment group revealed that there was a statistically significant increase in elasticity of the control and massage scar between baseline and week 12 (control p=0.03; massage p=0.04) (Fig. 3A). This cumulative within group effect revealed a statistically significant difference relative to

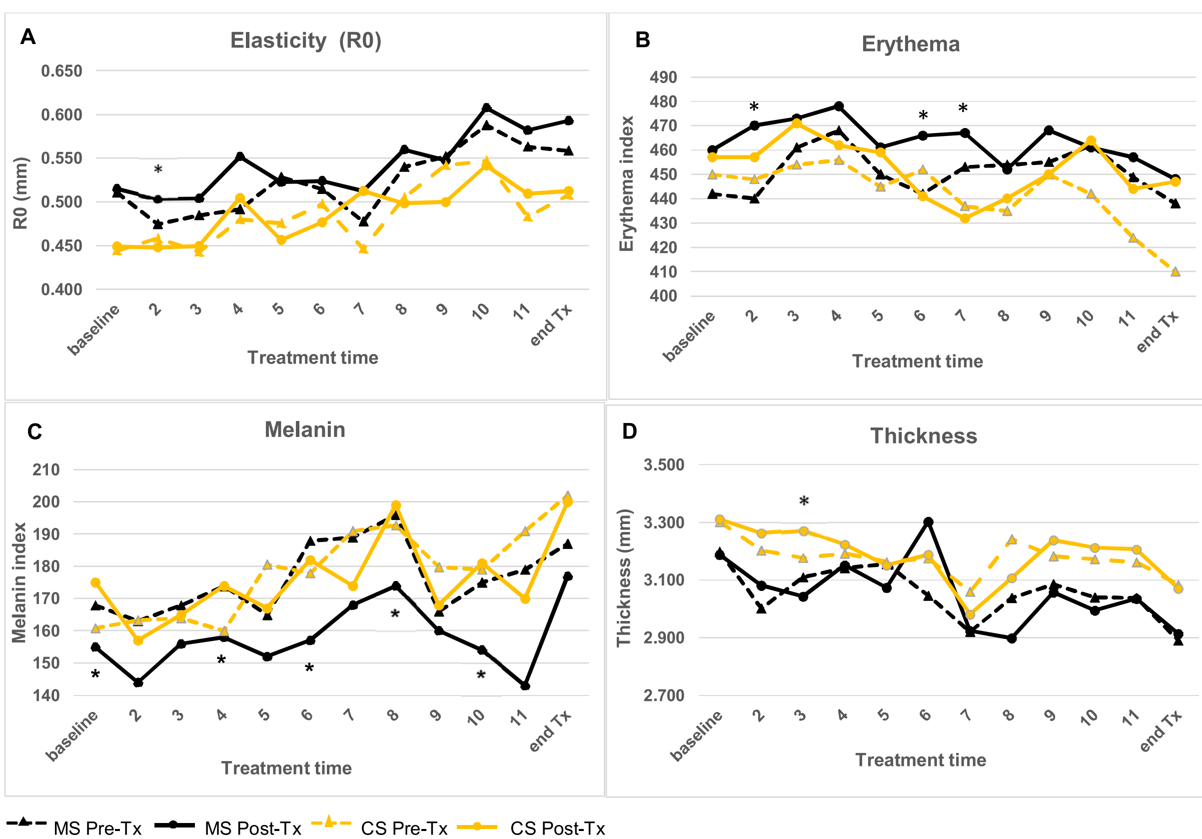

Fig. 2 – Immediate impact of massage therapy or usual care. The characteristics of the control (yellow lines) and massage (black lines) scars were measured immediately before (Pre) (dashed line) and after (Post) (solid line) treatment (Tx). The raw means were used for this figure rather than the adjusted means used in the ANCOVA analysis. Elasticity was evaluated using the Cutometer R0 parameter or total skin distention (A). Erythema (B) and melanin (C) were evaluated using the Mexameter. Thickness was evaluated with a high-frequency ultrasound scanner (D). (* denotes a significant group difference between the control and massage scar sites at posttreatment, after adjusting for immediate pretreatment measures, p<0.05). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

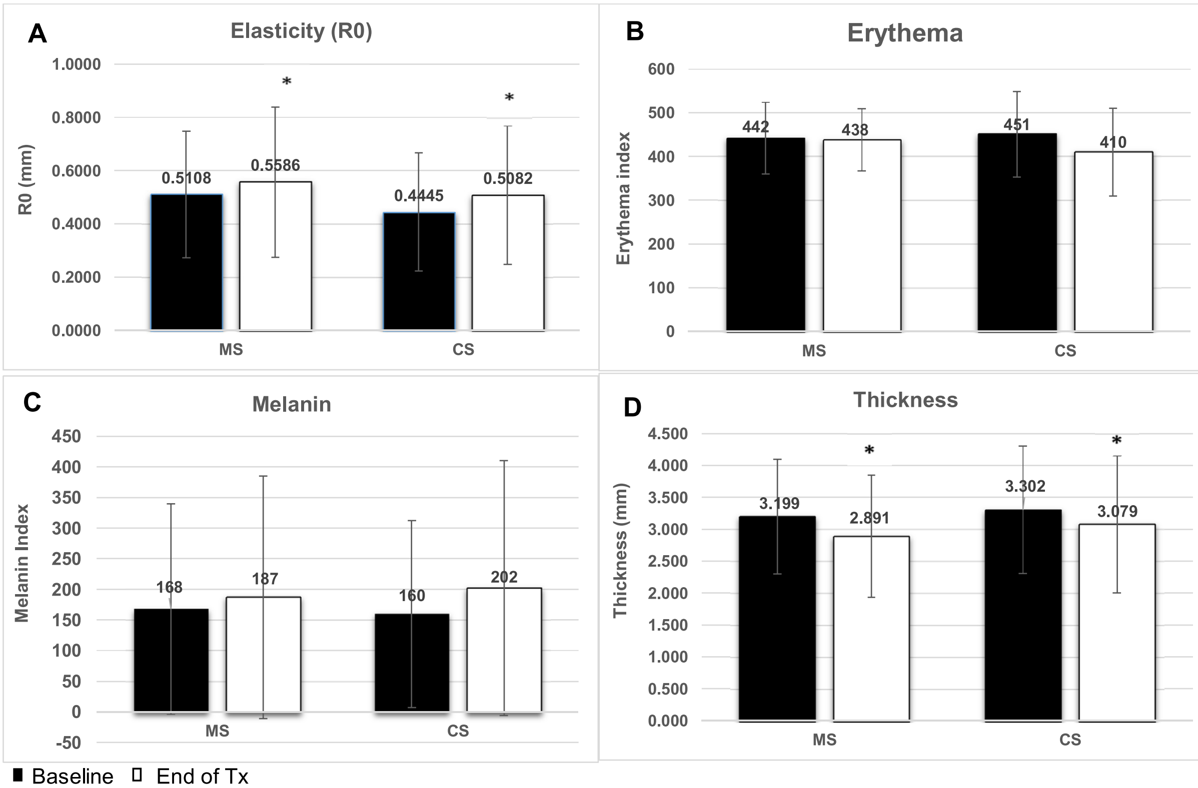

Fig. 3 – Overall long-term effect of massage therapy and usual care. The raw mean and standard deviations for the baseline measures (black) and the final measures at week 12 (white) for elasticity (A), erythema (B), melanin (C), and thickness (D) are presented. There was a significant change (denoted by *) in elasticity and thickness for both the massage scar (MS) and control scar (CS) with treatment (Tx) and usual care.

baseline as of week 8 (massage $p=0.02$), 10 (control $p=0.02$) and 11 (control $p=0.01$; massage $p=0.05$), revealing that there is a significant improvement in scarelasticity with time. The ANCOVA, however, showed that after adjusting for baseline measures, there was no statistically significant difference in posttreatment elasticity between the groups at any time point (Fig. 4A). Thus, the within group changes in elasticity were apparent between weeks 8 to 10 and were maintained until the end of the study, but cannot be attributed to treatment. Gross elasticity (R2) was also evaluated but there were no significant group differences (data not shown).

There was no statistically significant difference for erythema between baseline and week 12 measures within groups (control $p=0.72$; massage $p=0.45$) (Fig. 3B). After adjusting for baseline measures, there were cumulative long-term group differences at week 8 ($p=0.04$) and week 11 ($p=0.05$) (Fig. 4B).

There was no statistically significant within group difference for melanin between measures at baseline and 12 weeks (control $p=0.08$; massage $p=0.45$) (Fig. 3C). After adjusting for baseline measures, there were no between group differences in melanin (Fig. 4C).

There was a statistically significant decrease in thickness within the control and massage scar groups between baseline and week 12 (control $p=0.01$; massage $p=0.05$) (Fig. 3D). The within group difference from baseline was statistically significant also at week 5 (control $p=0.05$), 7 (control $p=0.001$; massage $p=0.004$), 8 (control $p=0.02$; massage $p=0.04$), 10 (massage $p=0.01$) and 11 (control $p=0.02$; massage $p=0.02$). The ANCOVA, however, showed that after adjusting for baseline measures, there were no significant between group differences in thickness (Fig. 4D). Thus, the changes in thickness associated with time were apparent between weeks 5 to 7, but cannot be attributed to treatment.

4. Discussion

The results of this study conclude that there is no significant long-term changes of the elasticity, erythema, melanin, or thickness of postburn HSc following 12 weeks of massage therapy compared to an intra-individual control site. These results are consistent with the findings reported by Silverberg et al. [25] and Patino et al. [26], but contrary to the findings of Cho et al. [29].

There are a number of reasons that may explain the difference in the results of this study compared to this latter study. First, the control group in this study were intra-individual scars, whereas Cho et al. [29] compared scars between different individuals. Expert consensus published by members of the Wound Healing Society [30], advocates for the use of intra-individual control scars when designing studies to determine the efficacy of treatments for scar tissue, to control for the heterogeneity between individuals with respect to scar formation and response to treatment. Second, the treatment time per session in the study by Cho et al. [29] was 30 min

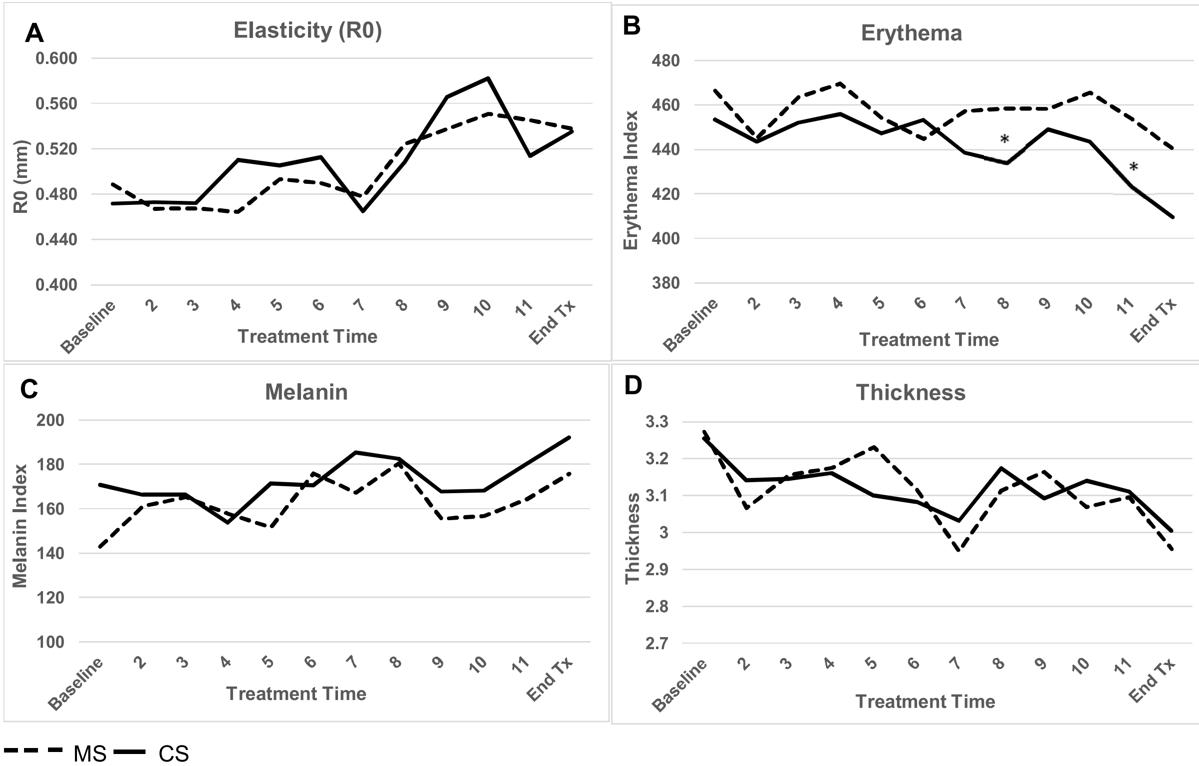

Fig. 4 – Cumulative long-term group comparison between massage therapy and usual care. The group comparison of the change in elasticity (A), erythema (B), melanin (C), and thickness (D) are presented using the adjusted means for the pretreatment evaluation massage scar (MS) (dashed line) and control scar (CS) (solid line) at each evaluation time point. The pretreatment evaluation quantifies the long-term cumulative effect without the immediate effect of treatment. (* denotes a significant group difference, $p < 0.05$).

compared to 5 min in this study. It is not clearly stated whether the treatment session in the study by Cho et al. involved the participants' entire scar surface, or only the scar surface that was being measured, which was the case in this study. This study was explicitly designed to provide the upper limits of massage treatment time that would normally be provided to burn survivors at any single 16 cm^2 site. The rationale for this time period is partially based on the logistical limitation of how much treatment time can be provided, but more importantly, the time that the therapists believed the scar site could tolerate without putting it at risk of breaking down. Third, the participants in the Cho et al. study reported substantially more pain and itch at the scar site than our population. Sinceour unit has been involved in multiple studies examining scar itch and pain [39–44] the prevalence of these issues has diminished, therefore these differences may be related to other treatment interventions. However, it is possible that these differences may have had an impact on the outcome. When comparing the baseline elasticity (total skin distention = R0), erythema, melanin and thickness to the scar characteristics reported in Cho et al.'s study, both their massage and control scars were thicker, had less elasticity, were more erythematous, but had similar melanin measures relative to the scar measures reported here. Thus, since elasticity, erythema, and thickness are considered the hallmarks of hypertrophic scar, the scars in the Cho et al. study appear to have been more severe. However, the number of days postburn were virtually identical between the two studies. Thus, it is possible that more severe scars demonstrate a more positive response to massage therapy. The most likely explanation for why the scars in the Cho's et al. study were more severe than the scars in this study is the fact that in this study two sites were selected using specific criteria in order to ensure that they were as homogeneous as possible at baseline. Thus, although the most severe scar site was initially selected, if an appropriately matched site was not available it was necessary to select a less severe scar site.

The other issue that should be considered is what constitutes clinically meaningful differences. Engrav et al. [45] suggested that a minimum reduction in scar height of one millimeter would be required to be considered clinically important. Although Cho et al. [29] do not report the mean reduction in scar thickness after massage therapy, it appears from their graphs that the mean reduction in thickness was substantially less than 1 mm, which is also the case for our results.

Survey data reports that the vast majority of burn therapists employ massage therapy [15,16], which makes one wonder why there is such a strong clinical impression that massage therapy is beneficial. There are two important issues that must be considered. First, when we examined the immediate effect of massage therapy, we found a reduction in melanin and an increase in elasticity and erythema during the early weeks of massage therapy. These immediate changes may lead the therapist and patient to believe that the massage therapy has a benefit, however, these changes are transient and did not result in any long-term group differences. The other issue to consider is although the survey results confirm that the majority of burn therapists employ massage therapy, we do not know from the survey results what the therapists' objectives were when employing massage therapy. There are reports in the literature that massage therapy reduces anxiety, distress, itch, and pain in burn survivors [18,46,47]. The immediate, though transient melanin reduction observed in this study suggests that massage therapy has an exfoliatin-geffect that may help to reduce itch and support scar desensitization, which may ultimately reduce pain. However, the time and intensity of massage therapy to produce these results may not require the five minutes of massage provided in this study. As well, the recommended massage techniques, when the objective is to reduce anxiety and distress, would be substantially different from the techniques used in this study. The immediate increase in pliability reported here is likely connected with the mobilization of the water away from the over abundant proteoglycans and glycosaminoglycans in HSc [48]. However, due to the hydrophilic properties of their sugar chains, the mobilized water will quickly be attracted back to these structures once the force associated with massage therapy has ended.

The significant increase in elasticity and decrease in thickness for both the control and treatment scar during the 12-week period, yet the lack of difference between groups, clearly demonstrates the value of controls when examining the potential benefits of scar treatments. Due to the spontaneous resolution of scar, and/or the benefits associated with usual care, the scars in both groups showed improvement. The change seen during this time can easily lead to the conclusion that massage therapy contributed to these improvements were it not for the ability to compare to the control scar.

The significant group difference in erythema at weeks 8 and 11 is difficult to interpret since it was not maintained at 12 weeks. It would have been ideal to have been able to follow the participants for a longer period of time to determine if the trend of less erythema in the control scar was maintained. A 16 week follow up was included in the original study design, but too many participants were lost to follow up, therefore the data could not be analyzed.

It is also important to note that two of the participants could not tolerate massage therapy. Even though massage therapy is considered a conservative treatment, the forces applied can be problematic for some burn survivors. It is therefore essential that well-trained professionals apply massage therapy with this population.

4.1. *Study limitations*

As with any study, there are limitations associated with this study that should be considered. All participants were recruited from a single center; therefore, the results may not be generalizable to different burn survivor populations. The massage therapy was administered by the OT, PT or the massage therapist involved in the burn survivor's overall care and not by one single therapist. This may have introduced variability in the massage techniques applied, however, all therapists had extensive experience working with burn survivors, therefore, this is consistent with a pragmatic study design that reflects every day practice. Although one of the proposed benefits of massage therapy is a reduction of pain and itch, this could not be evaluated in this study, therefore requires further investigation. Participants were asked to complete a diary to monitor adherence with usual care, but unfortunately, these were not adequately maintained to allow them to be summarized or analyzed. The treating therapists and their documentation support that usual care was kept consistent at the two sites, but this does not confirm that the participants adhered to the prescribed treatment recommendations. However, since this was an intra-individual study it is likely that the level of adherence was equal for the two sites.

4.2. *Future studies*

It is possible that a change in massage therapy dosage or the timing postburn when massage therapy was initiated may result in a different outcome, therefore studies with an increased number of sessions per day or week and started sooner postburn should be performed to examine these variables further. The baseline measures of itch and pain were too low in our participants to determine if massage therapy would reduce itch or pain. This potential benefit requires further exploration with a population that has high reported baseline itch and pain levels. The lack of standardization of the massage therapy may have had an impact on our study outcomes. Further investigation where the force and technique can be more precisely controlled, such as a vacuum massage device, would reduce this variability. Further investigation is required to evaluate if a critical level of scar severity determines whether the scar responds to massage therapy and longer follow up evaluations would be advantageous, which from our experience will likely require participant incentives to reduce attrition.

5. Conclusions

The immediate impact of forces applied during massage therapy may mobilize the interstitial fluid associated with the increased concentration of glycosaminoglycans and proteoglycans in HSc and may exfoliate the skin thereby reducing melanin. However, once baseline measures, the intra-individual control site, and time were incorporated in the analysis there was no long-term benefit of the 12-week massage therapy with respect to scar elasticity, erythema, melanin, or thickness. Thus, in spite of the fact that the vast majority of burn therapists currently uses massage therapy, re-examination of this treatment approach is recommended if clinically meaningful changes of these scar characteristics is the objective of this intervention.

Conflicts of interest

None

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