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# 12-Year within-wound study of the effectiveness of custom pressure garment therapy

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ABSTRACT

Pressure garment therapy is standard of care for prevention and treatment of hypertrophic scarring after burn injury. Nevertheless there is little objective data that confirms effectiveness. The purpose of this study was to determine the effectiveness of pressure garment therapy with objective data obtained with a randomized within-wound comparison. We enrolled consecutive patients with forearm injuries over a 12-year period. The subjects wore custom garments with normal and low compression randomized to either the proximal or distal zones. Hardness, color and thickness of wounds were objectively measured using appropriate devices; clinical appearance was measured by a panel masked to the identity of the pressure treated area. Wounds treated with normal compression were significantly softer, thinner, and had improved clinical appearance. There was no interaction of any effect with patient ethnicity. However, these findings were clinically evident only with moderate to severe scarring. We conclude that pressure garment therapy is effective, but that the clinical benefit is restricted to those patients with moderate or severe scarring.

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## 1. Introduction

Pressure therapy for scars and keloids has a long history as summarized by Linares et al. [1], extending back to Ambroise Pare in the 16th century. Lawrence [2] treated a keloid with scarification and pressure (scarification refers to multiple horizontal and vertical closely spaced incisions turning the keloid into ''mince-meat''). Pressure therapy for hypertrophic burn scars was first popularized at the Shriners Galveston Burn Hospital. In 1971 Larson et al. [3] from Galveston reported that pressure therapy ''decreased'' hypertrophic scarring after thermal injury. The authors included photos of three patients demonstrating soft, flat scars under Ace bandage pressure and hypertrophic scars in areas of no pressure. Ward [4] reported that Silverstein was also involved in the early ''discovery'' of the effect of pressure therapy. Subsequently the Galveston group published many papers on the effect of pressure therapy, but none were controlled studies. In addition, the

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group reported that pressure therapy does not work on the sternum, abdomen and buttocks [5,6]. In 1976 MacMillan [7] reported on 500 patients treated at the Shriners Cincinnati Burn Hospital and concluded that pressure had a significant effect on the maturing of scar tissue and reduced the number of surgical procedures necessary for correction. In 1977 Baur et al. [8] commented that ''The effectiveness of elastic pressure-bandage therapy in the prevention of hypertrophic scars, or in the acceleration of their remodeling processes, is without question.'' Other centers also published clinical series reporting on the benefit of pressure therapy [9–17]. As a result of these reports, pressure garment therapy became the standard of care. Later, in 1993, Linares et al. [1] reviewed the history of pressure therapy and indicated that 15 mmHg pressure is necessary for effectiveness.

However, it has become apparent that few randomized clinical trials have been accomplished. In 2009 Anzarut et al. [18] attempted a meta-analysis of the effectiveness of pressure therapy. He found only two controlled trials, one by Chang et al. [19] and the other by Van den Kerckhove et al. [20].

Chang et al. [19] in 1995 published a between-subjects, randomized comparison of 64 patients treated with pressure therapy and 58 without. There was no difference in age, TBSA and length of stay and the authors reported no difference in time to maturity of the wounds. There was, however, no stratification by wound treatment, ethnicity, and body part involved. No minimum/maximum was presented for time to maturity and no data was presented to summarize the status at maturity of the various wounds.

Van den Kerckhove et al. [20] in 2005 reported a between-subjects randomized trial of 60 Caucasian patients with 76 wounds on the forearm or calf that had healed spontaneously. Patients were randomly assigned to a ''normal'' pressure class or a ''low'' pressure class and the color and thickness of the wounds measured. Patients were evaluated 1, 2 and 3 months post-injury. There was no difference in color measurements between the two groups; however the ''normal'' pressure group demonstrated thinner scars. The authors commented ''Only a minority of the scars developed thick scars.''

After reviewing these two papers, Anzarut et al. [18] concluded, ''...there is insufficient evidence to support the widespread use of pressure garment therapy.''

In 2002 an international panel of experts reviewed the literature on scar management and concluded ''Widespread burn scars should be treated with first-line therapy of silicone gel sheeting and pressure garments, although there remains limited significant evidence for the effectiveness of pressure garments [21].''

Macintyre has also extensively reviewed the literature on pressure garment therapy [22–25] and agreed that scientific evidence of effectiveness is lacking and the optimum pressure is unknown.

The Anzarut manuscript was submitted in January 2007; therefore we searched Medline for ''burn'' or ''thermal'' and ''pressure'' and ''2007:2009'' for more recent manuscripts with objective data on the effectiveness of pressure therapy. We found that Harte et al. [26] compared pressure to pressure with silicone but there was no group that did not receive pressure. We found no other recent studies randomly comparing pressure with no pressure. We also found three papers from 1978 [10], 1979 [27] and 1982 [13] that were not mentioned in the Anzarut report and which, although not randomized, did include control groups. The authors of these papers did conclude that the treated scars had better appearance than those not treated. We also located a doctoral thesis by Naismith [28] who studied the effect of varying pressures on remodeling and concluded that 15 mmHg is necessary to achieve benefit, that more pressure results in a greater effect, and that pressures greater than 40 mmHg result in complications. The papers by Van den Kerckhove et al. [20] and Naismith [28] are among the few with objective data.

There is a clear discrepancy between the extensive clinical experience from Galveston and Cincinnati in the 1970s and the more recent clinical comparative studies. In 1995 we began a within-wound study of the effectiveness of pressure therapy and herein report the results.

## 2. Materials and methods

### 2.1. Patients

During the 12-year period from 1995 to 2007, in accord with the Human Subjects Division of the University of Washington, 67 consecutive patients were enrolled. Inclusion criteria included ages 7–65 years and a forearm burn $\geq$4 cm in diameter that was grafted or required $\geq$3 weeks to heal. Burns that required a fascial excision of the injury were excluded, as were patients who were non-compliant with burn care or who could not return regularly to the Burn Center for follow-up. Patients were identified either when inpatient or outpatient.

Thirteen patients exited the study prior to any data collection. Eleven of these chose to remove themselves, one was lost to follow-up and the reason was not recorded for one patient. Data was then obtained on 54 patients. Six of the patients were injured on both arms; for these six, data from the arms was averaged and included as one value in the analysis. For purposes of data analysis, follow-up was divided into five blocks of 2–3 month periods, thus defining follow-up periods 1 through 5. The patients were followed for up to 1 year until the wounds were clinically stable, the person elected to leave the study, the patient did not return and was lost to further follow-up, or in one case the patient died during follow-up from unrelated medical matters.

### 2.2. Garments

Pressure garment therapy was started within 2 weeks of re-epithelialization. A custom-fit pressure garment (Fig. 1) was fabricated by Medical Z Inc. (Medical Z, San Antonio, TX) and

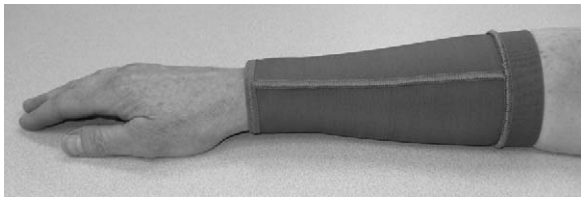

**Fig. 1 – An example of the garment.**

designed such that it applied pressure to only one-half of the wound, proximal or distal (according to coin toss by a consistent individual not involved in data collection for the study). The standard Lycra® 6-way stretch fabric was designed to apply 17–24 mmHg to the normal compression zone and <5 mmHg to the low compression zone. Subjects were instructed to wear the garments 23 h per day, removing them only for bathing. Representatives from Medical Z trained the fitter.

Self-reported wearing compliance data was collected in a daily calendar diary format. This form required the patient to document their actual wear-time for their pressure garments. Space on the form was available for comments concerning issues or concerns that may have impacted their wear-time.

### 2.3. Pressure

Several investigators [22–25,29–32] have reported that pressure under garments varies with body part and age of garment and cannot be assumed. Therefore pressure ''dose'' was measured directly. Pressure measurements were obtained at the scar/garment interface using the I-Scan™ System (Tekscan, Inc., South Boston, MA). The I-Scan™ System has demonstrated accurate and reliable pressure measurements beneath pressure garments [32,33].

The device was calibrated and the pressure determined in mmHg. Pressure measurements were obtained by a therapist not involved in the care of the patient, who was trained in the use of the device. The number of patients with pressure comparisons was 41 at follow-up 1, 43 at follow-up 2, 36 at follow-up 3, 31 at follow-up 4 and 24 at follow-up 5.

### 2.4. Hardness

A single Rex Durometer Hand Model 1600, Type 00, without a foot attachment (Rex Gauge Company Inc., Glenview, IL) was used to measure scar hardness throughout the study. This device measures hardness of light foams, sponge rubber gels, and animal tissue in ''durometer units''. Durometers have demonstrated reliability in the objective assessment of skin hardness in patients with different skin diseases [34–43].

Measurements were obtained by the research assistant, who could not be blinded to which zone was receiving pressure, but used the same area for measurement each time. Measurements were obtained with the person in the sitting position with the forearm supported in a horizontal position on a desk and the shoulder adducted. The area of interest was triangulated and measurements obtained at the corners were averaged; the sides of the triangle were 3–5 cm. The number of patients with hardness observations was 51 at follow-up 1, 44 at follow-up 2, 37 at follow-up 3, 33 at follow-up 4 and 26 at follow-up 5.

### 2.5. Color

The perception of color involves three parameters, hue, saturation and brightness and can be expressed with several numeric color space systems. The $L^*a^*b^*$ color space was described by The Commission Internationale de l'Eclairage (CIE) in 1976. ''L'' refers to brightness and varies from 100 (white) to 0 (black), ''$a$'' to the red green axis that varies from 60 (red) to −60 (green), and ''$b$'' to the yellow blue axis that varies from 60 (yellow) to −60 (blue). The CIE also described the $L^*C^*h^*$ color space. This color space uses the same color diagram but uses cylindrical rather than rectangular coordinates. ''L'' is the same as in the $L^*a^*b^*$ system. ''C'' refers to chroma or saturation and ''h'' to hue or color. This system permits one to apply the descriptive terms lighter, paler, darker and deeper. We studied the outcome on the ''L'', ''a'' and ''b'' axes in the $L^*a^*b$ color space and used the descriptive terms with the $L^*C^*h^*$ color space.

A single Chromameter Minolta CR-300 (Konica Minolta, Ramsey, NJ) was used to measure skin color throughout the study. With this instrument the skin surface is illuminated by a pulsed xenon arc lamp and the light reflected perpendicular to the surface is collected for a tri-stimulus color analysis. The device has been found to be useful for measuring reflected color and color differences in a wide variety of situations [44–47].

Measurements were obtained by the research assistant, who could not be blinded to which zone was receiving pressure, but used the same points for measurement each time. The area of interest was triangulated and measurements obtained at the corners were averaged; the sides of the triangle were 3–5 cm. Measurements were then taken on the forearm in the sitting position with the forearm supported in a horizontal position on a desk and the shoulder adducted. One measurement consisted of three flashes of illumination in order to obtain a mean value. Prior to each set of measurements, the instrument was calibrated to a standard white plate. There were 52 patients with color measurements at follow-up time 1, 42 at time 2, 30 at time 3, 22 at time 4 and 19 at time 5.

### 2.6. Thickness

High-resolution ultrasonography provides an accurate assessment of skin and scar thickness [48–55]. Scar thickness in millimeters was obtained with high-frequency ultrasonography in the Department of Radiology. Several machines and probes were used over the years each with accuracy to 0.5 mm. The area of interest was triangulated and measurements obtained at the corners were averaged; the sides of the triangle were 3–5 cm. Thickness was measured at the final follow-up in 28 patients.

### 2.7. Clinical appearance

Film slides or digital images of the treatment sites were taken at the time of enrollment, each follow-up assessment (approximate every 3 months), and at the completion of the study. Usable photos were available at the final follow-up in 41 patients. The images were marked with Zone A and Zone B where one was the normal compression zone and the other the low compression zone. The images were shown to a group of 10 burn providers including three surgeons, one pediatrician, two therapists, three nurses, and one vocational rehabilitation provider. The image survey was also shown to one biostatistician. Raters were blinded as to zone of compression. Each rater was simply asked ''Which zone has the better cosmetic appearance?'' and accepted answers included A, B, or No Difference.

### 2.8. Compliance

The subjects were asked to complete a compliance form indicating how many hours the garment was worn each day.

### 2.9. Financial incentive to complete the study

Since wearing a garment for up to 1 year, knowing that there may be no benefit, is a significant request, we provided a financial incentive to complete the study. In accord with the Human Subjects Division of the University of Washington, patients received $1000 if they continued to wound maturity in 7–12 months, $600 if followed to wound maturity in 4–6 months, and $300 if followed to wound maturity in ≤3 months.

### 2.10. Statistical analysis

Statistical analyses were carried out with STATA 11 (STATA Corporation L.P., College Station, TX). Multiple tests were used including mixed linear regression (xtmixed), number needed to treat (bcii), *t*-test (*t*-test), linear regression (qfit), intraclass correlation (loneway) and logistic regression (logit). Race/origin was dichotomized as White or non-White, pressure garment zone as normal compression or low compression, follow-up period as 1 = 2–3 months, 2 = 3–5 months, 3 = 5–7 months, 4 = 7–9 months, and 5 = more than 9 months. Over the years 1995–2007 there were differences in staff, garment manufacture and I-Scan hardware and software. These study periods were classified as 1 = 1995–2000, 2 = 2000–2000, 3 = 2000–2004, and 4 = 2004–2007 based on changes in these factors. Twenty-three patients were studied in period 1, 6 in period 2, 13 in period 3 and 12 in period 4. This study period was treated as a random effect in regression models.

**Table 1 – Demographic characteristics of the study patients.**

| Mean age ± sd | 36 ± 14 years |
|---|---|
| Age (years) | |
| 6–14 | 3 |
| 15–30 | 17 |
| 31–59 | 34 |
| Gender | |
| Male | 46 (85%) |
| Female | 8 (15%) |
| Race | |
| White | 37 (69%) |
| Non-White | 15 (28%) |
| Not recorded | 2 (3%) |
| Wound treatment | |
| Healed without grafting | 34 (63%) |
| Grafted | 20 (37%) |
| Days to heal or graft | |
| Mean (sd) | 21.9 (12.4) |
| Range | 5–77 |
| ≤14 days | 12 |
| 15–21 days | 12 |
| >21 days | 20 |
| Missing | 10 |
| Length of follow-up (months) | |
| Mean (sd) | 9.5 (6.2) |
| Range | 0.8–43 |
| <6 months | 16 (30%) |
| 6–12 months | 32 (59%) |
| >12 months | 6 (11%) |
| Reason for exiting the study | |
| Clinically stable | 43 |
| Died | 1 |
| Lost to follow-up | 10 |

## 3. Results

The demographic characteristics of the study patients are included in Table 1. The mean age was 36 years, 85% were male, 63% of the wounds healed spontaneously, 28% of the patients were non-White, mean time to wound closure was 22 days, mean length of follow-up was 9.5 months and the main reason for exiting the study was clinically stable wounds. Since the study was within-wounds, the demographics of the normal compression and low compression groups are the same.

### 3.1. Pressure measured under the garments

Data is available for 50 patients; for four patients interface pressure data was missing. We performed 350 pressure measurements making 175 comparisons of the pressure recorded under the low-pressure and normal-pressure zones of the garments. The mean pressure in the normal compression zone was 25.0 mm (sd = 6.3) compared to 6.4 (sd = 6.2) in the low compression zone. In the low compression zone 115/175 (66%) were ≤10 mmHg. In the normal compression zone 169/175 (91%) were >15 mmHg. The distribution is shown in Fig. 2.

To determine if the pressure delivered was confounded by other factors, the measured pressure was regressed, using a fixed effects model, on normal/low compression zone, race, grafted or healed, and study period; and on study period using a random effects model since the effects varied over the 12-year period. The regression results demonstrated that pressure in the normal compression zone was statistically higher than in the low compression zone, 18.6 mm (95% CI 17.3, 19.8). There was no difference by White vs. non-White ($p = 0.70$) or graft vs. spontaneous healing ($p = 0.06$). There was a small difference for follow-up period, −0.5 mm (95% CI −1.0, −0.1). The random effect of study period was also significant, 0.7 mm (95% CI 0.3, 1.8).

We also examined interactions of the delivery of pressure by the garment with other factors that might affect scarring. There was no interaction between compression and race and compression and follow-up period ($p > 0.05$ for both). There

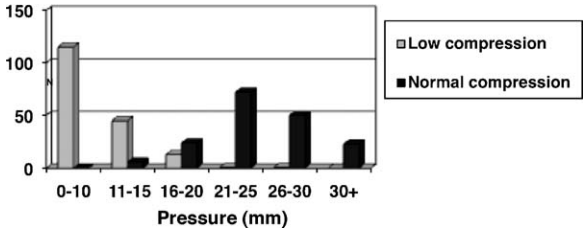


**Fig. 2 – Pressure measurements in the low and normal compression zones.**

**Table 2 – Pressure measurements by study period.**

| Pressure in low compression zone | | |
|---|---|---|
| Study period | Mean ± sd (mm) | ≥15 (mm) |
| 1 | 3.5 ± 5.0 | 4 |
| 2 | 9.9 ± 3.7 | 0 |
| 3 | 10.3 ± 7.1 | 4 |
| 4 | 12.3 ± 4.1 | 7 |
| **Pressure in normal compression zone** | | |
| Study period | Mean ± sd (mm) | <15 (mm) |
| 1 | 26.3 ± 6.4 | 0 |
| 2 | 24.5 ± 4.1 | 0 |
| 3 | 24.2 ± 5.8 | 1 |
| 4 | 20.6 ± 6.0 | 5 |

was significant interaction between compression and graft vs. healed. The interaction coefficient, −8.3 mm (95% CI −10.6, −6.0), for compression and graft vs. healed indicates that compression over scar produced higher pressures than over graft.

Since there did appear to be a random effect of the interaction of study period with pressure measurements ($p < .01$) we further investigated this effect modification. The results are shown in Table 2. Pressures increased with study period in the low compression zone and decreased in the normal compression zone. 15/175 measurements (9%) in the low compression zone exceeded 15 mm and 6/175 measurements (3%) in the normal compression zone were <15 mm.

In summary: (1) pressure was considerably higher in the normal compression zone, (2) pressure was greater when compression was applied over scar, and (3) applying a known pressure over time was very difficult given the random effects of staff, garment manufacture and software/hardware changes.

### 3.2. *Durometer (hardness)*

We made 378 observations of hardness in 54 patients, 189 comparisons of normal compression vs. low compression. The data is shown in Table 3.

**Table 3 – Hardness measurements by follow-up period.**

| Follow-up period | Mean ± sd (mm) |
|---|---|
| Hardness in low compression zone | |
| 1 | 46 ± 6 |
| 2 | 49 ± 7 |
| 3 | 48 ± 8 |
| 4 | 48 ± 7 |
| 5 | 49 ± 7 |
| Hardness in normal compression zone | |
| 1 | 47 ± 7 |
| 2 | 46 ± 8 |
| 3 | 47 ± 7 |
| 4 | 45 ± 7 |
| 5 | 45 ± 7 |
| Hardness uninjured forearm skin for comparison | 39 ± 4 |
| Hardness skin over kneecap for comparison | 72 ± 9 |

The hardness in the normal compression zone declined over time and was less at final follow-up than in the low compression zone ($p = .011$). On the contrary, hardness in the low compression zone increased over time. Hardness of uninjured forearm skin and over a bony prominence are provided for comparison.

Measured hardness was regressed using fixed effects on normal/low compression zone, White vs. non-White, graft/healed, follow-up period and using random effects on study period. Hardness in the normal compression zone was statistically lower than in the low compression zone, −1.7 durometer units (95% CI −2.8, −0.6). There was no difference for graft/healed or follow-up period. There was a statistical difference for race/origin, 2.5 (95% CI 0.1, 4.9), the scars being harder in non-White persons than White. The random effects of study period were not significant. There was no interaction between compression and race/origin ($p = 0.39$) and graft vs. healed ($p = 0.29$); there was interaction between hardness and follow-up period ($p < .05$).

According to the manufacturer (Rex Gauge) [56], a hardness difference of 10 durometer units is readily evident to palpation and a difference of 5 units is the absolute minimum clinically detectable. In 10/19 patients fully studied to completion the hardness difference exceeded 5 durometer units, in 3/19 the difference exceeded 10 durometer units. Only 3 of 19 patients thus sustained a readily apparent clinical benefit with compression in hardness of the scar.

### 3.3. *Color*

The colorimeter results from 23 patients treated in the 1990s were lost, leaving 31 for study all of whom healed spontaneously. We made 162 observations, and 81 comparisons of normal-pressure and low-pressure. The mean results of "L*", "a*" and "b*" are shown in Table 4.

The regression results for the "L" or lightness component indicated that scars were lighter at follow-up period 5 compared with period 1, 2.08 (95% CI .20, 3.96) but there was no interaction with compression. In the regression for the "a" or red green parameter, only race/origin was significant 5.4 (95% CI 0.2, 10.7) with non-Whites being "more red". There was no interaction with compression, the results confirming that non-White skin has a greater "red" measurement. Finally, regression of "b", the yellow blue parameter, with categorical follow-up periods suggests that the wounds were undergoing a shift toward yellow with time, 2.00 (95% CI .80, 1.60).

In summary, the data suggest wounds become lighter and more "yellow" over time but that this is not influenced by compression.

### 3.4. *Thickness*

We made 28-paired comparisons of thickness by normal compression vs. low compression. The summary data is shown in Table 5.

Ultrasound thickness was regressed on fixed effects normal/low compression zone, race/origin, graft/healed, and random effects. The scars were significantly thinner in the normal compression zone, −0.65 mm (95% CI −1.2, −0.13).

**Table 4 – Mean $L^*a^*b^*$ color parameters in the low and normal compression zones.**

| Parameter | Observations | Mean ± sd | Min | Max |
|---|---|---|---|---|
| Low compression zone | | | | |
| $L$ | 81 | 55.2 ± 17.6 | 8.8 | 100 |
| $a$ | 81 | 9.5 ± 9.2 | −12.2 | 23.5 |
| $b$ | 81 | 8.5 ± 4.5 | −3.6 | 28.6 |
| Normal compression zone | | | | |
| $L$ | 81 | 56.3 ± 18.6 | 5.9 | 100 |
| $a$ | 81 | 9.0 ± 9.7 | −10.1 | 27.8 |
| $b$ | 81 | 8.2 ± 3.2 | −1.3 | 15.4 |

Race/origin and graft or healed had no significant effect ($p = 0.33$, $p = 0.67$, respectively). There was no interaction between compression and race origin ($p = 0.81$). Five of the 28 patients revealed thickness differences of ≥1 mm, which would likely be clinically detectable.

### 3.5. *Clinical appearance*

We have final photographs on 41 patients permitting the comparison of the final cosmetic result of the normal compression zone to that of low compression zone. For 3 of the 41 patients, all 11 experts agreed on which zone had the better cosmetic appearance and chose the zone of normal compression (Table 6). For these three, intraclass correlation was extremely high. However, the overall intraclass correlation was low 0.16 (95% CI 0.02, 0.29).

We used the data in Table 6 to calculate the number needed to treat. The result was 13.7 (95% CI 5.147, 39.977), indicating that we would need to treat ~14 patients for one benefit.

We next evaluated the probability of the evaluators choosing the ''correct'' zone, i.e., the zone of normal compression. The probability of evaluators choosing the zone of normal compression was low, 0.36 (OR 0.23, 0.57). We repeated this for persons of White race and non-White race. The odds ratios were low for both (.17 95% CI .06, .44 and .42 95% CI .25, .71, respectively).

### 3.6. *Compliance*

Twenty-seven of 54 patients (50%) returned complete compliance data forms. Mean hours worn per day were 20.4 ± 3.9 with maximum 23.5 and minimum 10.

### 3.7. *Summary*

The pressure differential between normal and low compression zones was significant and scars/grafts under compression were softer and thinner. All scars/grafts became lighter and more yellow over time, with or without compression. However, this translates into clinical improvement as judged by expert opinion only for moderate to severe scars.

**Table 5 – Ultrasound thickness measurements.**

| Compression zone | Observations | Mean ± sd | Min | Max |
|---|---|---|---|---|
| Normal compression (mm) | 28 | 2.8 ± 3.2 | 1 | 9 |
| Low compression (mm) | 28 | 3.4 ± 3.0 | 1 | 16 |

**Table 6 – Data table for calculation of number needed to treat.**

| | Normal compression | Low compression |
|---|---|---|
| All experts agree on zone of better appearance | 3 | 0 |
| Experts do not agree | 38 | 41 |

## 4. Discussion

Pittler and White have discussed efficacy and effectiveness [57]. Efficacy refers to ''does the treatment work under ideal conditions''? Effectiveness refers to ''does the treatment work in every day life''? This is clearly a study of effectiveness.

The ''dose'' of pressure necessary to achieve an effect is unclear. Linares et al. [1] indicated that the Galveston group established that 15 mmHg pressure was required to achieve an effect but no data were provided. Naismith [28] in a doctoral dissertation reported that 15 mmHg is necessary for an effect, that more pressure increases the effect, and that pressures greater than 40 mmHg result in complications. Giele et al. [58] also suggested that pressures be above 15 mm. Van den Kerckhove et al. [20] reported that pressures of mean 15 mm yielded thinner scars than pressures of mean 10 mm at 3 months post-injury. The authors did not see a reduction in erythema between groups. Robertson et al. [12] presented pressure data but did not recommend a minimum. We considered 15 mmHg to be the minimum effective ''dose''.

Many things change and cannot be controlled in an experiment that lasts 12 years. Staff change, and in spite of training, it is known that one research assistant does not do things quite like another. The procedures and materials used in garment manufacture change and, in spite of ''standards'', the garments change. The software and hardware comprising the I-Scan System changed. And finally, it is known that localization of the study site is variable between staff and over time [55,59]. Mixed linear regression permits the inclusion of ''random effects'', effects that would not be same if the experiment were repeated. These were included in each regression model.

Based upon the clinical experience at Galveston, Cincinnati and elsewhere, the report of Van den Kerckhove et al. [20] and this experimental data, we conclude that pressure garment therapy does improve scars. If this is true, why then are there so few randomized clinical trials confirming effectiveness? We believe there are two reasons.

Applying a known compression to moving, three-dimensional body parts over a long period of time is very difficult. Larson himself reported that pressure therapy does not work on the sternum, abdomen and buttocks [5]. Others, and in particular Macintyre [23] have reported on the many problems of pressure garment therapy including garment fitting,

garment degradation, and patient compliance. And these problems are over and above those generated by between-patient and between-wound studies.

Furthermore, pressure garment therapy was developed in the 1970s when treatment likely consisted of the application of topical agents for several weeks until the wounds had healed or granulated, and then grafted with thin grafts. This therapy is precisely the therapy that results in a great scar load (i.e., large sheets of scar 1–1.5 cm in thickness). In this case, an improvement of 50% might be quite visible. Early or semi-early excision and grafting has greatly reduced the scar load; large sheets 1–1.5 cm in thickness are quite unusual. If the scar is thinner, a 50% improvement may not be very visible. As a consequence, the value of *N* to achieve sufficient power to detect differences after excision and grafting may be very large. In fact, Harte et al. [26], when comparing pressure garment therapy to pressure garment therapy with silicone with the Vancouver Scar Scale [60] indicated that each group would need 192 subjects, a number quite beyond what can be achieved in most burn centers. Even if the investigators use ''objective'' outcomes such as the durometer, the colorimeter and ultrasound, if the majority of the persons are treated by early or semi-early excision and grafting, it will require large numbers to find the difference and the improvement may not be evident to clinical inspection.

Our finding of thinner scars under normal compression confirms the findings of Van den Kerckhove et al. [20]. Therefore using pressure garment therapy to reduce the thickness of scars is an evidence-based practice.

## 5. Conclusions

Our conclusions are:

1. Compression garment therapy is effective.
2. However, the clinical benefit is constrained to those with moderate to severe scarring.
3. It is extremely difficult to apply a standard, known pressure over time. Garments must be changed as often as patients and payers will allow.
4. The pressure applied over grafts is less than over scars; garments worn over grafts may need greater compression.
5. The effect of all measurements is less on wounds excised and grafted than on wounds that heal spontaneously over weeks.

Based upon this data, our recommendations for clinical use of pressure garments are similar to those of Deitch et al. [61], i.e., to continue to use compression garment therapy but reserve it for:

1. deep dermal wounds that have healed spontaneously over weeks,
2. grafted wounds surrounded by a deep dermal wound that was permitted to heal spontaneously over weeks,
3. children and young adults,
4. persons of color,
5. body locations where compression can be applied (perhaps with inserts), and
6. instances where vascular support or protection is needed.

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## Conflicts of interest

None of the authors have a conflict of interest to declare.

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