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Variability of pressure at the pressure garment-scar interface in children after burn: A pilot longitudinal cohort study

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ARTICLE INFO

Article history:
Accepted 30 August 2018

Keywords:
Burns
Cicatrix
Burn scar
Paediatrics
Pressure garment therapy
Interface pressure

ABSTRACT

Background: Current consensus for the ideal pressure range at the pressure garment to scar interface is 15–25 mmHg. Interface pressure variability has been reported at new pressure garment fitting in children. Pressure reductions up to 25% have been recorded over one month in adults.

Method: A pilot longitudinal cohort study was completed with children aged less than 18 years receiving pressure garment therapy after burn. Interface pressure was measured at first pressure garment fitting, one month and three months after fitting. Analysis was conducted using Linear Mixed Models.

Results: Thirty-four children were recruited to the study, 62% were male. Participants had a median (IQR) age of 3 (6) years. At the first garment fitting, 32% of stationary and 25% of dynamic measurements were within 15–25 mmHg. Pressure variations were recorded at one and three months with scar location ($p=0.03$) and %TBSA ($p=0.006$) identified as predictors of stationary interface pressure. No statistically significant predictors of dynamic pressure were identified.

Discussion: Interface pressure variability was recorded over time during children's wear of the first pressure garment after burn. Further investigation of factors contributing to pressure changes, subsequent impact on adherence and the effect of sub-optimal pressure application on burn scar outcomes is indicated.

1. Background

The application of pressure to the burn scar via pressure garment therapy is a common burn scar management intervention in high income countries [1–3]. However, pressure garment therapy has an unknown mechanism of action, an unconfirmed ideal pressure 'dosage' at the interface of the pressure garment and burn scar and minimal high quality evidence supporting its use [4,5]. It has been postulated that an interface pressure at or above capillary pressure is required to occlude local capillaries, thus creating hypoxia in the cells leading to cellular changes including collagen breakdown [3,6,7]. Though it has also been suggested that a consistent level of pressure (unknown level) is

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https://doi.org/10.1016/j.burns.2018.08.029
0305-4179/

required to improve the rigidity of the extra-cellular matrix, thus increasing mechanoreceptor activity and consequent apoptosis of cells, and reducing production of scar fibroblasts [8]. The exact mechanism of action however is still to be confirmed and thus impacts knowledge regarding the ideal 'dosage' of pressure garment therapy.

A minimally effective interface pressure of 15 mmHg has been previously recommended [9,10]. However it has also been suggested that a pressure at or above capillary pressure (24–25 mmHg) is required. As a result, common consensus has been that pressure garment therapy must provide 15–25 mmHg for 23 h per day for improved scar outcomes [3,5–7,11]. Additionally, higher levels of interface pressure (e.g. 20–25 mmHg vs 10–15 mmHg [5]) have been reported to have greater effects on scar outcomes particularly scar thickness [4,10]. As a result it has been suggested that the 'dose' of pressure garment therapy may need to be increased to 20–25 mmHg [5]. Though it must be noted this recommendation of higher pressure may be more suited to the developed adult hypertrophic scars included in that study. Pressure above 40 mmHg is reported to result in adverse events such as skin breakdown [6,7]. The definitive level of pressure at the pressure garment-scar interface over time has not been ascertained in a paediatric population.

Previous investigations into the level of pressure at the interface of the pressure garment and burn scar over time has been completed in adult populations in stationary postures. Adult studies have reported pressure reductions of up to 25% of the original interface pressure over the first one month of pressure garment wear [7,12]. Participants receiving higher levels of compression (20 mmHg) at baseline have been reported to experience greater reductions in the interface pressure than those receiving low level pressure garment therapy (10 mmHg) [7]. Difficulty maintaining a consistent level of pressure over the study period has been identified in adults [3,5,12]. In addition, a wide variety of interface pressures at new pressure garment fitting has been reported in a paediatric investigation [13].

Multiple factors have been postulated to influence interface pressure variations related to the person, wound, or environment. Person-related factors include body composition, body location of the scar, and the size of the limb [12,14]. These factors influence the hardness or softness of the area of interest and the diameter of the area being measured. Larger diameters are expected to result in reduced pressure due to the Law of Laplace (fabric tension is inversely proportional to circumference) [14], though a smaller radius of curvature has been found to contribute to a greater pressure loss over time [12]. It has been acknowledged that mobilisation may impact interface pressure readings and continuous pressure monitoring may provide greater insight into interface pressure levels, though continuous monitoring is not yet possible with current sensor types [5]. Burn wound-related factors such as the type of wound (graft or healed wound) and the maturity of the scar when pressure garments are applied influence pressure fluctuations due to resulting changes in the rigidity of the scar [3,9]. When pressure has been measured subdermally, greater pressures have been identified over bony prominences compared to those measured over 'soft' sites such as musculature [15]. Environmental-related factors include moisturisers, silicone products, pressure garment design variables (e.g. fabric type, tension and colour) and fabric stress relaxation have also been acknowledged as potential factors influencing pressure variations due to stretch and breakdown of the pressure garment fabric [5,11,14,16,17].

It must be noted that different pressure measuring devices have been used in previous investigations into interface pressure levels with a burns population including the Kikuhime® (Medigroup, Melbourne, Australia) [12], Pliance X® (Novel, Munich, Germany) [9] and I-scan® (Tekscan, South Boston, United States of America) [13,18]. The 3 mm thickness of the Kikuhime sensor [19] has the potential to distort the pressure garment and/or skin/scar surface and thus may impact the accuracy of the results [18], though it has a reported acceptable reliability (ICC=0.90) in the adult after burn population [12]. The Pliance X and I-scan have low profile sensors (<1 mm [9,20], Pliance X=10 mm wide). The I-scan is reported to experience reduced accuracy when measuring low interface pressures, such as those beneath a pressure garment, and additional calibration procedures prior to use are reported to increase its accuracy [18]. The Pliance X has acceptable reliability for research use (ICC=0.87) in a paediatric burn population [21] and excellent test-retest reliability (ICC=0.998) when assessed on a hard surface and acceptable accuracy on a soft surface when compared to a sphygmomenometer cuff [9].

1.1. *Objectives*

The primary objectives of this pilot study were to determine: (1) the pressure at the pressure garment-scar interface, and (2) the percentage of participants who were receiving pressures of 15–25 mmHg at first pressure garment fitting and subsequent follow ups over the first three months of scar management for children and adolescents with, or at risk of, scarring after a burn. The secondary objective was to identify whether select factors (namely participant age, percent total body surface area burned (%TBSA), scar location, scar thickness, wound healing type, pressure garment manufacturer, and/or pressure garment colour) influenced interface pressure.

It was hypothesised that: (1) the mean interface pressure at baseline would not be outside of the recommended range of 15–25 mmHg and would reduce by 25% over the first one month of wear; and (2) the location of the scar would influence the interface pressure.

2. Methods

2.1. *Study design*

This study was a pilot longitudinal cohort study with consecutively sampled participants. Recruitment was completed from January to June 2016 as well as during the month of August 2016. Recruitment was not conducted in July as the outcome assessor was unavailable. Follow up data was collected by November 2016.

Ethical clearance was received from the Children's Health Queensland Human Research Ethics Committee, Brisbane (HREC/15/QRCH/240). This study is reported according to STROBE guidelines [22].

2.2. Setting

Data were collected in the burns outpatient unit of a large quaternary metropolitan children's hospital in Australia. Patients attending the unit with acute burn injuries were predominantly male, treated for scald and contact burn injuries and had a median age of two years [23].

2.3. Participants

2.3.1. Inclusion criteria

Inclusion criteria for this study included children and adolescents aged less than 18 years with, or at risk of, burn scarring; children and adolescents fitted with their first custom made pressure garment within the first three months after burn; children and adolescents likely to return to the participating burns outpatient centre for fitting and ongoing review of their pressure garment; and children and adolescents accompanied by a parent or guardian who was able to provide informed consent.

2.3.2. Exclusion criteria

Children and adolescents who had not been prescribed a pressure garment for burn scar management; children and adolescents with comorbidities that might influence the interface pressure such as an amputation, and children and adolescents involved with the Department of Communities (Child Safety) were excluded, which was standard practice at the study site at the time of recruitment. Children receiving pressure garment therapy for the prevention or management of burn scarring on fingers and/or toes only were also excluded if the sensor was too large to fit beneath the pressure garment at the extremities.

2.4. Sample size

A sample size of 33 participants were estimated to test the primary objective. This estimate was based on an anticipated mean pressure of 20.0 mmHg at baseline, a correlation of 0.7 between pressure measurements at baseline and one month follow-up, clustering of scar sites within participants, a standard deviation of the mean pressure over the study period of 5 mmHg, a 1% significance level, a power of 90%, and the inclusion of body location of the garment as a covariate.

Expected mean pressure losses were based on a pressure loss of 4.82 ± 2.99 mmHg (20%) over a one month period in a normal compression group for thigh and forearm garments in adults [7]. Correlations between pressure readings over time were based on the lowest correlation reported for intra-observer reliability (0.83 over a one month period using a Kikuhime pressure sensor to the forearm and calf) [12] as no values were available for the Pliance X using scar sites. A lower correlation of 0.7 was anticipated based on expected greater variability in body locations than the forearm and calf [7].

2.5. Outcomes

Participant sociodemographic and clinical characteristics: were recorded from the caregiver and/or medical records. Characteristics included gender, age, % total body surface area burned (%TBSA), caregiver education, wound healing type, scar location (torso, upper limb, lower limb), Fitzpatrick skin type and number of days after burn. Pressure garment characteristics collected from the medical record included pressure garment manufacturer, fabric and colour.

Interface pressure: was measured using the Pliance X device® (Novel, Munich, Germany) [24]. Test-retest reliability has been supported [9,21] as discussed.

Scar severity: was measured using the Patient and Observer Scar Assessment Scale (POSAS). Items of the POSAS including observer reported thickness, vascularity, pliability, pigmentation, relief and overall opinion and patient report items of itch, pain, colour, stiffness, thickness, irregularity and overall opinion were collected. Caregiver proxy report was collected for participants of all ages. The POSAS has been reported to have adequate test-retest reliability for observer reported thickness in adults [25] and children of all ages (unpublished data).

A limited number of predictor variables were selected due to the pilot design of the study. Variables were selected due to their clinical relevance and potential impact on interface pressure based on previous research [3,12,14,15]. Predictor variables included participant age, %TBSA, scar location, scar thickness, wound healing type, pressure garment manufacturer, and pressure garment colour.

2.6. Procedures

Potential participants were recruited by the lead author when they attended the outpatient department of the participating burns centre for scar management. Verbal and written information regarding the study process was provided. Data collection was commenced at the scar management appointment once written consent was received.

2.6.1. Intervention

Participants in this study received pressure garment therapy as part of a multi-modal approach to burn scar management. All therapists had received training in measurement practices for custom made pressure garments as part of their orientation to clinical service provision. Standard clinical practice at the participating burns centre was to fit pressure garments that extend 5 cm beyond the scar border where able, to avoid the lower pressure that is known to exist around the pressure garment opening [26,27].

Participants were provided with two custom made pressure garments fabricated by the pressure garment manufacturer of the therapist's choice approximately every three months until scar maturation, as per standard practice at the participating burns centre. Participants (and their families) were instructed in how to don the pressure garment and ensure it is worn for 23 out of 24 h every day; follow washing instructions as per the manufacturer's directions; moisturise up to five times per day and use sunscreen when out in the sun for longer than 15 min. Pressure garment design, use of zips and inserts in pressure garments as well as silicone products were chosen at the treating occupational therapist's discretion. Exercises and splints were also prescribed by the treating occupational therapist or physiotherapist where deemed appropriate.

Occupational therapists were blinded to the results of the interface pressure at each review point.

Families were requested to attend appointments at the participating burns centre at one and three months after pressure garment fitting. Ongoing scar management appointments were then scheduled approximately every three months (after the study period) until pressure garment cessation/scar maturation or as requested by the family. These timeframes were considered feasible for families and the health service to enable assessment of the scar and pressure garment fit.

2.7. *Interface pressure measurement procedure*

One long, thin sensor of the Pliance X was used for all interface pressure measurements to maintain consistency. The Pliance X was set up as illustrated in Figs. 1 and 2, or if working with a young child, the device was set up and worn by the user in the *Novel* belt to prevent dropping/moving of the device by the child. Prior to measurement, the sensor was positioned on a flat surface and 'zeroed' to ensure there was no load on the sensor surface as per the device's instructions. The sensor was then positioned beneath the pressure garment and over the scar, at the pressure garment-scar interface. To do this, the pressure garment was donned over anchor points, the sensor was placed over the scar and held in place by the researcher whilst the remainder of the pressure garment was donned. Alternatively, the edge of the pressure garment nearest the selected scar site was raised, allowing the sensor to slide over the skin, beneath the pressure garment and rest over the scar. The sensor was not taped in place during the study.

One 10s stationary measurement, followed by one 10s dynamic measurement was completed. A 10s period was used for stationary and dynamic measurements as this provided 500 interface pressure data points which was anticipated to be sufficient for pressure analysis as well as being tolerable for young participants. Age appropriate distractions were used for stationary measurements as indicated. Activities performed during dynamic measurements included walking during lower limb measurements and ring stacking during upper limb measurements. On completion of the dynamic measurement, the sensor was removed and the pressure garment re-donned. A second stationary measurement was then completed for test-retest reliability testing of the Pliance X [21]. Calibration of the device was completed as per manufacturers' guidelines throughout the study period (every three to six months) by the Australian agent of Novel using the *tru blu*® (Novel, Munich, Germany) calibration device. Relocation of the selected scar site at the one and three month follow up time points was conducted using body measurements and photographs.

2.8. *Data analysis*

Descriptive statistics were calculated for all outcomes including means and standard deviations for normally distributed continuous variables and median and inter-quartile range (IQR) for non-normally distributed data. Categorical variables were reported using frequencies and percentages. Normality of the data was assessed using the Shapiro-Wilk test. Correlations between continuous variables and interface pressure were assessed using Pearson Product-Moment Correlation or Spearman's rank correlation (when normality was not demonstrated). Due to sparse distribution of age, %TBSA and colour these variables were categorised. The Wilcoxon Signed Rank Test for

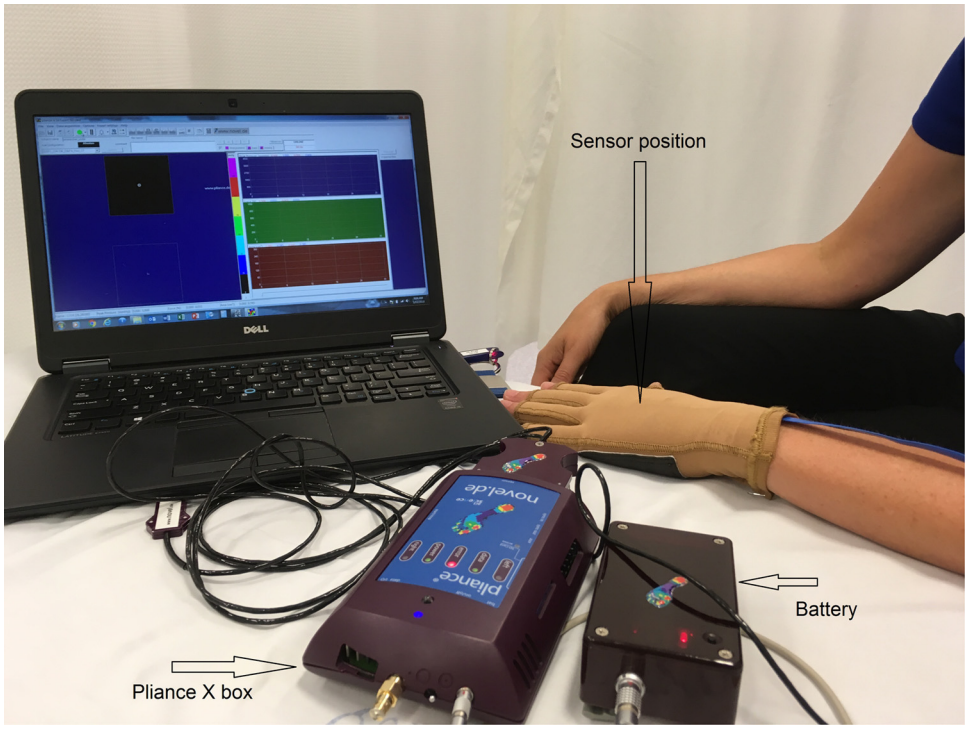

Fig. 1 – Pliance X set up for upper limb stationary measurements.

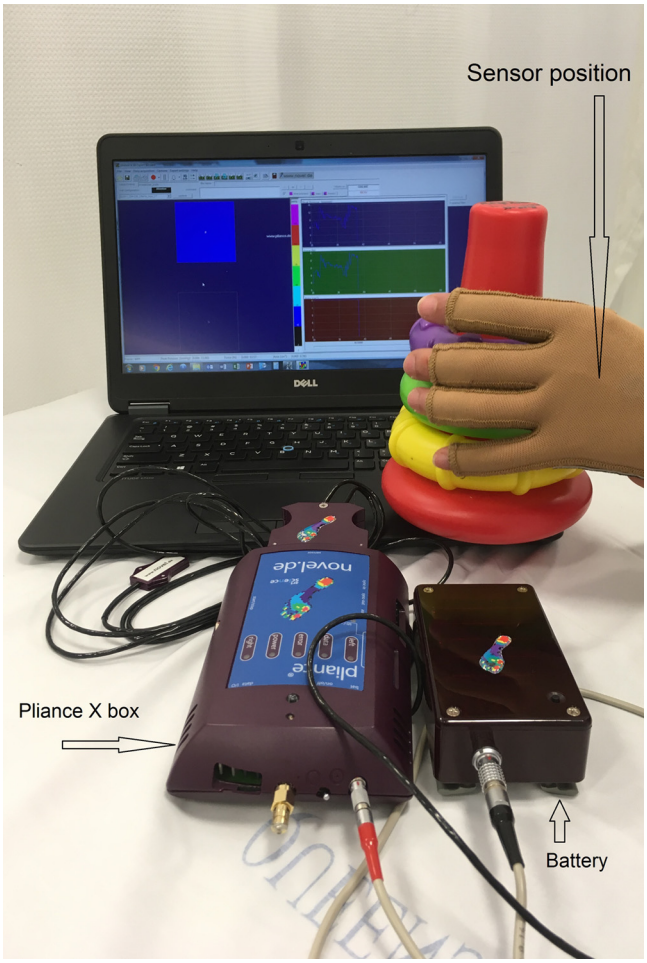

Fig. 2 – Pliance X set up for upper limb dynamic measurements.

ordinal data and McNemar Test for nominal data for related-sample data were used to examine differences in sociodemographic and clinical variables of participants.

Univariate Linear Mixed Model (LMM) analyses with patient as random intercept were performed to assess the influence of time, age (less than or equal to 5 years vs. greater than 5 years), percent Total Body Surface Area burned (%TBSA less than 10% vs. greater than or equal to 10%), scar location (upper limb vs. other), scar thickness (POSAS observer thickness score), wound healing type (grafted vs. spontaneous), pressure garment manufacturer (Jobskin® (Smith and Nephew, Nunawading, Victoria, Australia), Therapeutic Support Laboratory® (Abbortsford, Victoria, Australia) and Second Skin® (Osborne Park, Western Australia, Australia)), and pressure garment colour (black, dark colours (e.g. blue, purple), light colours (e.g. green, pink)) on stationary and dynamic interface pressure. Statistical analyses were completed using SPSS24 software (SPSS Inc., Chicago, IL, USA) and significance was set at $p < 0.05$.

3. Results

Thirty-four children consented to participate in the study. Baseline data was obtained from 31 participants, one-month follow-up data was obtained from 19 participants and three-month follow-up data was obtained from 17 participants with reasons for non-participation shown in Fig. 3. Participants who did not attend the follow up appointment with the original pressure garment that had undergone interface pressure measurement were considered lost to follow up as interface pressure could not be measured on the same pressure garment. There was no significant differences between baseline and one month and baseline and three months for sociodemographic and clinical variables ($p > 0.05$, as per Table 1), except for scar thickness (baseline to three months, $p = 0.05$). However, it was expected that scar thickness would increase at the three month follow up due to the peak in burn scarring that occurs at this time [28]. Stationary pressure was normally distributed at baseline but not at one month after pressure garment fitting (Shapiro Wilk $p = 0.07$ and 0.005 respectively). Spearman's rank order correlation of stationary interface pressure at first pressure garment fitting and one month after pressure garment fitting demonstrated a strong, positive correlation ($r_s = 0.70$, $p = 0.002$) fitting with the assumptions for sample size.

3.1. *Participants*

At baseline, participants had a median age of three years (IQR: 6), were predominantly male (61%), had a median %TBSA of 3% (IQR:

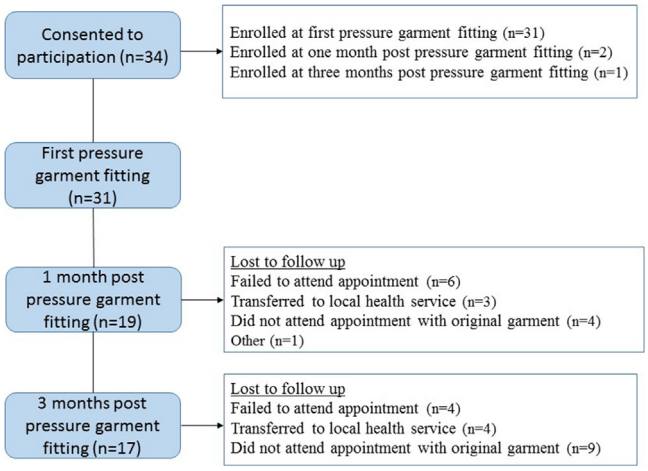

Fig. 3 – Flowchart of study participants.

5), median POSAS observer thickness score of 2 (IQR: 2) and a median of 42 days after burn (IQR: 25). Additional details of the sociodemographic and clinical characteristics of the sample are reported in Table 1.

3.2. *Interface pressure*

The mean stationary and dynamic interface pressure for each time point is illustrated in Table 2. Univariate linear mixed model analyses of stationary and dynamic interface pressure changes were not statistically significant over time ($p=0.23$ and $p=0.06$ respectively). At baseline, the mean (SD) stationary interface pressure was 15.54 mmHg (11.33) and approximately one third (32%) of participants recorded pressures within the 15–25 mmHg range. At one month after pressure garment fitting, the mean (SD) stationary interface pressure was 11.50 mmHg (9.9) and 11% of participants had pressures within 15–25 mmHg. At three months after pressure garment fitting approximately 24% of participants had an interface pressure within the 15–25 mmHg range with a mean (SD) stationary interface pressure of 12.92 mmHg (9.36).

In comparison, mean (SD) dynamic interface pressures were 20.04 mmHg (15.85) at baseline, 22.53 mmHg (30.21) at one month and 12.41 mmHg (8.27) at three months after pressure garment fitting. One quarter (25%) of participants were within 15–25 mmHg at baseline, reducing to 11% at one month and increasing to 29% of participants within the 15–25 mmHg range at three months after pressure garment fitting. Fig. 4 and Supplementary Table 1 illustrates the percentage of participants within 15–25 mmHg in further detail.

In contrast to the hypothesis, both increases and decreases of the mean interface pressure were observed during stationary and dynamic measurements when comparing baseline to one and three months after pressure garment fitting (Table 3).

3.3. *Factors influencing changes in stationary interface pressure*

Univariate Linear Mixed Model analyses with patient as random intercept (Table 4) identified scar location and %TBSA as significant predictors of stationary interface pressure. Upper limb scar sites recorded significantly lower stationary interface pressures than other body locations ($p=0.03$) and participants with greater than or equal to 10% TBSA recorded significantly lower stationary interface pressures than participants with less than 10% TBSA ($p=0.006$). Pressure garment manufacturer, pressure garment colour, scar thickness, wound healing type, and participant age were found to be non-significant predictors.

3.4. *Factors influencing changes in dynamic interface pressure*

Univariate Linear Mixed Model analyses did not identify any statistically significant predictors of dynamic pressure (Table 5).

4. Discussion

To the knowledge of the authors, this is the first study to investigate the level of pressure (mmHg) at the pressure garment-burn scar interface over time in a burn paediatric only cohort. Previous stationary interface pressure measurements have provided a snapshot of interface pressure. It has been discussed that continuous pressure monitoring may provide a more cohesive understanding of interface pressure over time [5]. Given that accurate, reliable continuous pressure measuring technology is not currently available this study assessed interface pressure during 10 s movement periods that simulate children's normal play activities.

In line with the primary objective of the study, results suggest that the majority of children receiving pressure garment therapy after a burn at the participating centre were not receiving the recommended pressure to the burn scar from the first wear of the pressure garment. Less than 35% of participants demonstrated an interface pressure between 15 and 25 mmHg at any time point during stationary or dynamic measurements, though the change in interface pressure over time was not statistically significant. Unexpectedly, interface pressure increases were recorded as well as the expected decreases over the course of the three month follow-

Table 1 – Sociodemographic and clinical characteristics of participants.

Participant characteristics	Number of participants (% of sample)[a,b]		
	Baseline	1 month follow-up[c]	3 month follow-up[c]
Number of participants	31	19	17
Male gender	19 (61%)	11 (58%)[c]	8 (47%)[c]
Age in years	3 (6), 1–14	4 (7.4), 1–13[c]	3 (5.5), 1–13[c]
Median (IQR), range			
%TBSA burned	3 (5), 0.5–36	4 (5.5), 0.5–36[c]	3 (5.75), 0.5–17 (p=0.32)[c]
Median (IQR), range			
Caregiver education		[c]	[c]
Completed after school qualification	18 (58%)	14 (74%)	14 (82%)
Completed senior high school	11 (36%)	4 (21%)	3 (18%)
Missing	2 (6%)	1 (5%)	
Grafted	14 (45%)	10 (53%)[c]	9 (53%)[c]
Scar location		[c]	[c]
Upper limb	9 (29%)	8 (42%)	8 (47%)
Other	22 (71%)	11 (58%)	9 (53%)
Fitzpatrick skin type		[c]	[c]
Type I — always burn	3 (10%)	3 (16%)	4 (23%)
Type II — tan with difficulty	2 (6%)	1 (5%)	1 (6%)
Type III — tan about average	11 (35%)	11 (58%)	8 (47%)
Type IV — tan more than average	5 (16%)	0 (0%)	1 (6%)
Type V — brown skin	7 (23%)	3 (16%)	3 (18%)
Type VI — black skin	0 (0%)	0 (0%)	0 (0%)
Missing	3 (10%)	1 (5%)	0 (0%)
No. of days after burn	42 (25), 20–103	71 (28), 53–103	126 (35), 96–163
Median (IQR), range			
Scar thickness — POSAS observer numeric rating scale	2 (2), 1–4	2 (1), 1–4 (p=0.16)	3 (3), 1–6 (p=0.05)
Median (IQR), range			
Missing			1
Pressure garment manufacturer		[c]	[c]
Jobstskin	13 (42%)	8 (42%)	8 (47%)
Therapeutic Support Laboratory	16 (52%)	9 (47%)	8 (47%)
Second Skin	2 (6%)	2 (11%)	1 (6%)
Pressure garment fabric		[c]	[c]
Powernet	27 (87%)	16 (84%)	15 (88%)
Primatech	3 (10%)	3 (16%)	2 (12%)
Missing	1 (3%)		

Note: IQR=interquartile range.
[a] Number (percentage) except where indicated.
[b] Missing data where stated, otherwise there was no missing data.
[c] p values for participants at 1 or 3 month follow up compared to baseline, p=1.00 except where specified.

up period. This is in contrast to the findings in adult studies where only pressure reductions were reported [3,7,12].

Pressure increases may be unique to children in that their rate of growth and changes to body composition may be faster than pressure garment fabric stress and/or breakdown, particularly given the median age of participants of three years. Whilst an observer assessment of scar thickness was not a significant predictor of interface pressure, an objective assessment of scar parameters such as thickness and pliability may shed more light on the increases in pressure observed in future studies due to changes in scar thickness and hardness. Substantial pressure increases, particularly when moving, have the potential to reduce the comfort of the pressure garment and therefore reduce adherence to the intervention. In addition, pressures were recorded at or above 40 mmHg, the level reported to result in adverse events such as skin breakdown and paraesthesia [6,7,29]. Therefore, paediatric pressure garments may need to be reviewed with increased frequency compared to current clinical practice (every three months at the participating burns centre) to monitor interface pressures both above and below the currently believed therapeutic range of 15–25 mmHg.

The hypothesis that scar location would influence the interface pressure was confirmed during this study, though only for stationary interface pressure measurements. This is in line with previous work identifying scar location as a factor influencing interface pressure [12]. It has previously been hypothesised that a smaller radius of curvature would result in larger pressure losses [12]. The current study identified lower stationary interface pressures in the upper limb when compared to the torso and lower limb, potentially due to the smaller radius of curvature. In addition, this study identified %TBSA burn as a factor influencing stationary interface pressure with children with greater than or equal to 10% TBSA burns experiencing significantly lower interface pressures than participants with burns less than 10% TBSA. This may be due

Table 2 – Mean (SD) interface pressure over time.

Time	n	Mean pressure mmHg	SD	Minimum pressure mmHg	Maximum pressure mmHg	Coefficient	Significance	Overall significance
Stationary								0.27
Baseline	31	15.54	11.33	0.00	49.32	0.62	0.78	
1 month	19	11.50	9.90	0.00	39.12	−2.35	0.26	
3 months	17	12.92	9.36	0.35	30.92	Reference		
Dynamic								0.06
Baseline	28	20.04	15.85	3.43	63.52	7.15	0.07	
1 month	19	22.53	30.21	1.95	119.13	10.66	0.03	
3 months	17	12.41	8.27	0.00	25.26	Reference		

*Coefficient, significance and overall significance from linear mixed model using time as fixed effect and patient as random intercept.

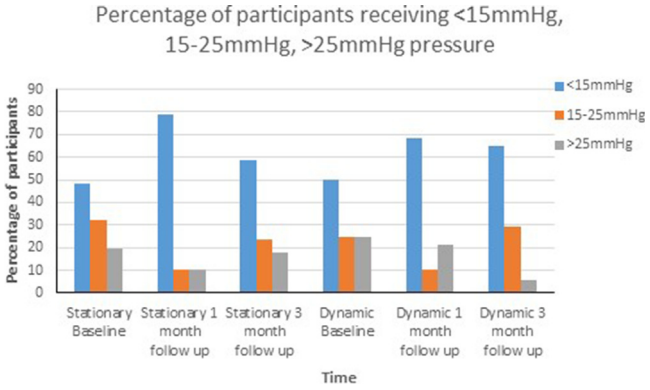

Fig. 4 – Percentage of participants receiving <15 mmHg, 15-25 mmHg, >25 mmHg pressure.

Table 3 – Mean (SE) interface pressure changes over time.

	Time	n	Mean pressure change, mmHg	SE	n	Mean increase and decrease, mmHg
Stationary	Baseline to 1 month	17	2.65	1.80	9	↑ 3.49
					8	↓ 9.45
	1 month to 3 months	12	−3.13	2.45	10	↑ 6.27
					2	↓ 9.69
	Baseline to 3 months	14	−0.38	2.67	6	↑8.65
					8	↓ 5.82
Dynamic	Baseline to 1 month	17	−5.59	4.57	8	↑17.47
					9	↓ 4.96
	1 month to 3 months	12	7.08	6.86	6	↑ 5.23
					6	↓19.38
	Baseline to 3 months	13	8.29	3.78	4	↑ 4.19
					9	↓13.84

↑ indicates pressure increases.
↓ indicates pressure decreases.

to children with larger % TBSA burns with a pressure garment that covers a larger surface area, requiring more stretch from the child when donning the pressure garment and/or slower weight gain during the immediate post-burn period.

4.1. *Limitations*

This pilot study is limited by a small sample size and higher than expected numbers lost to follow up at one and three month follow up time points (as per Fig. 3). However, there were no significant differences between the participants and non-participants at one and three months compared to baseline suggesting that the drop out did not influence the results. A lack of power for some analyses may have resulted in non-significant findings for changes in interface pressure and additional predictors. Interface pressure results are not applicable to children's fingers or toes that were too small to fit the sensor and are not representative of the pressure garment's circumferential interface pressure due to the single 10 mm sensor used in this study. In addition there are potential

Table 4 – Univariate linear mixed model analysis of select factors on stationary pressure (mmHg).

Variable	Parameter	Coefficient	SE	Significance	95% CI	Overall significance
Pressure location						0.03
	Intercept	8.77	2.90	0.005	2.85, 14.68	
	Lower limb and torso	8.06	3.47	0.03	0.99, 15.13	
	Upper limb	Reference				
%TBSA						0.006
	Intercept	3.89	3.88	0.323	−4.02, 11.81	
	<10%	12.46	4.22	0.006	3.85, 21.06	
	≥10%	Reference				
POSAS Observer thickness score	Intercept	14.46	6.64	0.034	1.14, 27.78	0.76
	POSAS score	0.80	2.98	0.790	−5.08, 6.78	
Manufacturer						0.92
	Intercept	12.90	6.04		0.6, 25.20	
	Jobskin	2.33	6.62		−11.17, 15.83	
	TSL	1.15	6.57		−12.24, 14.53	
	Second skin	reference				
Wound healing						0.61
	Intercept	15.36	2.47		10.32, 20.41	
	Spontaneous	−1.76	3.42		−8.72, 5.20	
	Grafted	reference				
Pressure garment colour						0.48
	Intercept	11.39	3.27		4.70, 18.08	
	Black	2.82	4.60		−6.54, 12.18	
	Dark	5.02	4.13		−3.42, 13.46	
	Light	reference				
Age						0.76
	Intercept	15.19	3.04		9.01, 21.37	
	≤5 years	−1.11	3.68		−8.60, 6.37	
	>5 years	Reference				

inconsistencies in relocating the exact position of the scar beneath the pressure garment, and in ensuring young children remain stationary and/or complete standardised dynamic measures in the manner required. Photographs and body measurements to assist with relocation and age appropriate distractions were used to reduce the impact of these limitations.

Detailed information regarding pressure garment properties such as elasticity, shrinkage, and yield points were not available for assessment during this pilot study. Pressure garment washing techniques and skin products used beneath the pressure garments (i.e. moisturisers, silicones) were also not assessed during this pilot study. Additionally, objective assessment of scar parameters such as thickness was not completed in this pilot study. As these factors have the potential to influence changes in pressure they should be included in future investigations.

4.2. *Future directions*

Further investigation is indicated to determine the clinical outcomes of paediatric burn scars consistently treated with pressure garment therapy that applies less than 15 mmHg, 15–25 mmHg and greater than or equal to 25 mmHg of pressure. This work has commenced in an adult population [3,5,7] though the results need to be confirmed. In addition, the best method for incorporating pressure monitoring, and the cost-benefits/consequences of pressure monitoring in clinical practice needs to be established. The use of multiple sensors within the Pliance X matrix or trialling additional sensor styles may allow for the assessment of circumferential interface pressure in future research investigations and assessment of the reliability of the Pliance X during movement and on hard vs soft surfaces needs to be completed. Exploring the use of inserts to adjust interface pressure and the impact of interface pressure on children's adherence to pressure garment therapy would also provide important information for clinical decision making. For example, pressure alterations could be made that enable pressure garment therapy that is considered effective for scar management, as well as maintaining user comfort. Investigation of all potential predictors of stationary interface pressure is also indicated. Stratifying results in future intervention studies by the predictors of pressure change identified in this study would assist in better understanding changes in pressure. Application of a consistent level of interface pressure and a pressure garment that is worn for the recommended 23 h per day would standardise the clinical use and future research into the effectiveness of pressure garment therapy in preventing and managing scarring after burn.

Table 5 – Univariate linear mixed model analysis of select factors on dynamic pressure (mmHg).

Variable	Parameter	Coefficient	SE	95% CI	Overall significance
Pressure location					0.99
	Intercept	18.95	5.29	8.41, 29.50	
	Lower limb and torso	−0.06	6.42	−12.86, 12.73	
	Upper limb	(Reference)			
%TBSA					0.11
	Intercept	7.36	7.88	−8.74, 23.46	
	<10%	14.11	8.61	−3.47, 31.69	
	≥10%	(Reference)			
POSAS Observer thickness score	Intercept	17.32	12.79	−8.41, 43.06	0.24
	POSAS score	−2.51	5.69	−13.97, 8.95	
Manufacturer					0.38
	Intercept	13.27	12.71	−12.84, 39.38	
	Jobskin	10.95	13.64	−17.07, 38.96	
	TSL	1.68	13.59	−26.24, 29.59	
	Second skin	(Reference)			
Wound healing					0.19
	Intercept	14.52	4.74	4.82, 24.22	
	Spontaneous	8.62	6.42	−4.50, 21.74	
	Grafted	(Reference)			
Pressure garment colour					0.17
	Intercept	12.47	5.47	1.55, 23.40	
	Black	2.38	8.10	−13.78, 18.54	
	Dark	11.89	6.83	−1.73, 25.52	
	Light	(Reference)			
Age					0.54
	Intercept	16.37	5.65	4.86, 27.89	
	≤5 years	4.28	6.94	−9.87, 18.42	
	>5 years	(Reference)			

5. Conclusion

This pilot study identified deviations from the recommended 15-25 mmHg interface pressure range during first fitting of a pressure garment in a small sample of children burn. Fluctuations in the interface pressure were observed over the three month period during stationary and dynamic measurements. Percentage total body surface area burned and scar location were identified as predictive factors of stationary interface pressure. Further evidence regarding the most effective interface pressures as well as routine monitoring of interface pressure is desirable to enable accurate decision-making regarding if/when pressure garment alterations or re-supply is indicated. This may need to occur more frequently than is currently completed in clinical practice, which is approximately every three months at the participating burns centre. Measurement of interface pressure during studies of pressure garment effectiveness would determine the dose of pressure that results pertain to and enable replication of effective interface pressure for research and clinical applications.

Author contributions

All authors made substantial contributions to the design of this trial. ZT contributed to the statistical design of this study. All authors contributed to drafting or critical revision of the article. All authors approved the final manuscript.

Ethics approval and consent to participate

This study has received ethics approval from Children's Health Queensland Human Research Ethics Committee: HREC/15/QRCH/240 (Lady Cilento Children's Hospital: SSA/16/QRCH/004) and the University of Queensland's Human Research Ethics Committee: 2015001939. Study investigators provided potential participants with verbal and written information prior to inclusion in the study. Consent was provided by parents/caregivers for participation in the study. Child assent was obtained for children over four years of age.

Funding

This work was supported by an Australian Government Research Training Scholarship and Children's Health Foundation Top-Up Scholarship to the PhD student (JW) as well as a research grant provided to The University of Queensland by Stratpharma. The funding bodies did not have input into the study design. The study authors report no conflicts of interest based on funding.

Acknowledgements

The author's would like to acknowledge all the children, families and health professionals at the Pegg Leditschke Children's Burns Centre at the Lady Cilento Children's Hospital, Brisbane, Australia for their participation, support and assistance of this research. The authors would also like to acknowledge Anne Bernard of QFAB Bioinformatics, Brisbane for her statistical input. This study is funded by an Australian Government Research Training Scholarship, Children's Health Foundation Top-Up Scholarship and a grant given to The University of Queensland by Stratpharma.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.burns.2018.08.029.

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