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Validation of the Pliance X System in measuring interface pressure generated by pressure garment

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ABSTRACT

Introduction: Pressure monitoring is crucial for effective pressure therapy. Precise and reliable interface pressure measurement system, however, remains unavailable in current practice.

Methodology: This is a validation study on the application of a recently developed device, the Pliance X System, for static interface pressure measurement. Sensor properties were evaluated through series of laboratory tests in the first phase of the study. Phase II was a clinical study using the Pliance X system to differentiate the loading generated on the patients' scars through additional inserts and pressure garment.

Results: Results showed high test–retest and inter-rater reliability (ICC $\geq$ 0.995) with good linearity (adjusted *R*-square = 0.997) by measuring standard weights. The maximum deviation between the measurement generated by the sensor and the sphygmomanometer cuff was $\pm$1.451 mmHg. Results in the clinical trial revealed its discriminant ability in distinguishing different levels of pressure loading on patients with scars ($p < 0.01$).

Conclusion: The commercially available pressure measurement system was found to be a reliable tool for measurement of low interface pressure under static condition.

1. Introduction

Persistent and adequate pressure application to the skin surface has been established for decades as one form of conservative treatment for hypertrophic scar [1–4]. It has also demonstrated some positive effects on venous ulcers, edema and deep venous thrombosis [5,6]. Nevertheless, recommendations for pressure administered are based merely on empirical observations in most clinical settings, possibly attributed to the paucity of easy-to-use, accurate and reliable measuring equipment [7]. Over the years, many attempts have been made to measure the therapeutic pressure range, nonetheless, it remains a challenge due to the unavailability of a precise and reliable instrument [8–12].

An ideal interface pressure device, usually in the form of a force sensor, should be small, thin and highly flexible and be sensitive in detecting the range of pressure as low as 0–50 mmHg [13–19]. It should be able to display a continuous output and free from error of measurement on curved surfaces and from the effects of temperature and moisture. The sensor should also be highly conformed to the body contour without distorting the actual geometry. Sensors developed over the year were, however, unable to fulfill this ascertained definition.

The earlier techniques used to measure pressure including electro-pneumatic [14,20–24] and fluid-filled pressure transducers [25,26] are refuted with low sensor accuracy and hysteresis [11,19,21,24,27] and poor conformity to body curvature [7]. Measuring pressures sub-dermally by a 19-gauge needle was suggested to monitor the actual value transmitted to skin tissue [28,29]. Due to its invasive nature, the system was not popular in both clinical and research industries. By means of piezoresistive elements such as strain gauges and force-sensing resistors, resistive pressure devices,

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for instance, Iscan [10] and FlexiForce Sensor [8,30], were reported to have higher accuracy. The piezoresistive elements, however, were found sensitive to temperature [31], and the sensor sensitivity is limited at forces less than 10 mmHg [8].

Capacitive pressure sensor was also developed to determine the pressure. It is an electrical element that stores energy in the form of an electrical field, in which their electrical characteristics change in response to external pressure. By translating signals of pressure changes into electrical capacitance variation, the capacitive transducer was found to provide not only higher sensitivity and flexibility, lower temperature dependency, but also more robust structure and lower power consumption than piezoresistive devices [18,31–34]. It was commonly used on support systems such as seating for paraplegics and geriatrics [35,36] and also on rehabilitation engineering prosthesis and orthosis [37,38] with high interface pressure. A commercially available capacitive sensor, Pliance X System (Germany-Novel Electronics, Munich, Germany), has been recently developed for low interface pressure application between skin and pressure garment or bandages [39] (Fig. 1). The whole system, including the electronic analyser, the software and the sensor, costs approximately US$ 21,250. In addition to the advantages of general capacitor transducers, the sensor is designed with a small (10 mm in diameter) and ultra-thin (less than 1-mm thick) sensing area connected to the system via an extended conductive strip which favors insertion to clothing with long sleeves. The system also allows flexibility in sensor configuration as a single sensor or in a matrix (with multiple sensors) for multiple measurements. The system appears to be a good device for measurement of interface pressure generated by pressure garment to the skin tissue. This study therefore aimed to evaluate the application of Pliance X System for measurement of interface pressure through series of laboratory tests and clinical trial.

2. Methods

2.1. *Phase I—Laboratory tests*

2.1.1. *Linearity and repeatability test*

In order to assess the mechanical properties and generalizability of the system, a set of tests was adopted to testify the validity of the pressure system with the experimental design sketched in Fig. 2. A 10 mm × 10 mm × 4 mm plastic disc was placed under the pressure sensor such that all forces of the loading weight were transferred only to the sensor. The data of weight recorded was converted to force in millimeter mercury (mmHg) by the equation:

$$\text{applied pressure (mmHg)} = \frac{\text{force}}{\text{area}} = \frac{\text{weight (kg)} \times 9.81\,\text{m/s}^2}{(\text{contact surface area})\,\text{mm}^2} \times 7500.637554$$

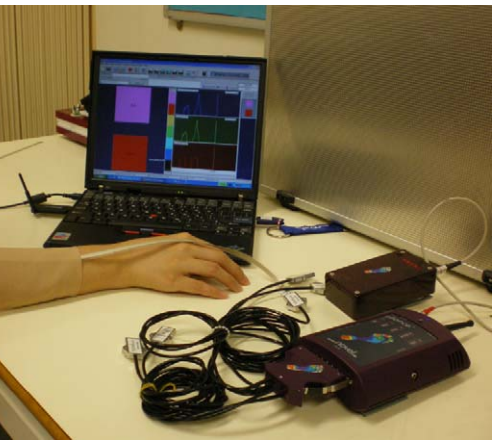

Fig. 1 – Pliance X System.

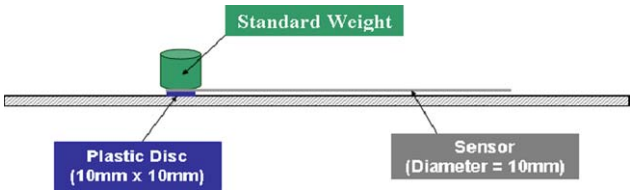

Fig. 2 – Sketched experimental design for linearity, repeatability and drift tests.

The test was to examine the accuracy of the pressure device by measuring the proportionality of the sensor response to a range of standardized loads. The device was calibrated before the experiment. Standard weights were applied to the sensor and 1000 readings per weight were recorded 1 min after loading with 10 repetitions. Pearson's Moment Correlation was used to determine the linear relation between the applied forces and sensor values. Evaluation of the test–retest reliability of Pliance X System was also conducted through analysis of intra-class correlation coefficient, ICC (3, 10). The same procedure with five trials was repeated by three independent assessors for its inter-rater reliability which was analyzed by ICC (2, 5).

2.1.2. *In vivo pressure measurement*

To testify to the effect of human skin elasticity on the sensor accuracy, the sensor was re-assessed with the measurement of the interface pressures between the human skin surface and a sphygmomanometer cuff [25,40]. The sensor was taped onto the skin underneath the cuff of the mercury manometer which was used to measure the pressure. The readings generated by the sensor would be compared with the readings taken by the mercury manometer when pressure was increased. Five healthy volunteers (three males and two females; age ranged from 23 to 50) were recruited. Eight anatomical locations, namely lateral aspect of upper arm (10 cm above elbow), forearm (10 cm below elbow), thigh (10 cm above knee) and calf (10 cm below knee) were selected to evaluate the effect of human skin elasticity [20,23]. All measurements on the upper limbs were taken at a seated position with the arm in natural resting while those on the lower limbs were taken in standing position [41]. Measurements were taken starting from 10 to 50 mmHg with increments of 10 mmHg and the procedure was repeated five times.

2.2. *Phase II—Discriminant validity by clinical pressure measurement on hypertrophic scar tissues*

To test the clinical application of the Pliance X System in measurement interface pressure on human subjects, eight subjects, including five males and three females aged from 18 to 40 (27.88 ± 8.31 years of age), with multiple hypertrophic scars were recruited for investigation. In total, 24 hypertrophic scars with onset ranging from 3 to 8 months (5.48 ± 1.58 months of scar age) were selected. They were further subdivided into younger ($\leq$6 months, $n = 16$) and older (>6 months, $n = 8$) scar groups for analysis. Eleven hypertrophic scars over upper limbs and 13 over lower limbs were recorded. The exact location on the opposite limb of each scar was also measured to compare the interface pressure between scar tissue and normal skin.

Each subject was prescribed with a tailor-made PG with 5% tensile strength by a registered occupational therapist. Pressure paddings with a 3 mm thickness per layer were moulded according to the body curvature and inserted underneath the PG to increase the pressure onto the skin tissue. As localized pressure is believed to increase with additional inserts, the same measuring sites were subjected to three levels of pressure loading for five trials: PG; PG with a layer of padding (PG + 3 mm); and PG with two layers of padding (PG + 6 mm). PG alone was expected to generate the minimal pressure to the skin tissue while the highest pressure was assumed in PG with two-layered padding. With the same protocol as mentioned above, measurements over the upper and lower limbs were taken in sitting position with the arm in the natural position.

3. Results

3.1. *Phase I—Laboratory tests*

3.1.1. *Linearity and repeatability test*

The results of linearity and repeatability on rigid surface are shown in Table 1. The correlation between the applied pressure and the sensor output is illustrated in Fig. 3. The coefficient of variation ranges from 1.097% to 8.450%, with the higher variations in the lower range forces. The difference between the applied pressure and sensor output were less than 1 mmHg (0.175 ± 0.264 mmHg). Correlation between the applied pressure and sensor output was revealed with

Table 1 – Results of linearity test.

Standard weight (g)	*Applied pressure (mmHg)	Sensor value mean (mmHg)	S.D.	Coefficient of variation (%)
5	4.215	4.059	0.343	8.450
10	9.393	9.717	0.648	6.669
20	18.276	18.512	0.641	3.463
30	28.139	28.646	0.643	2.245
40	37.513	38.114	0.418	1.097
50	46.396	46.662	0.748	1.603

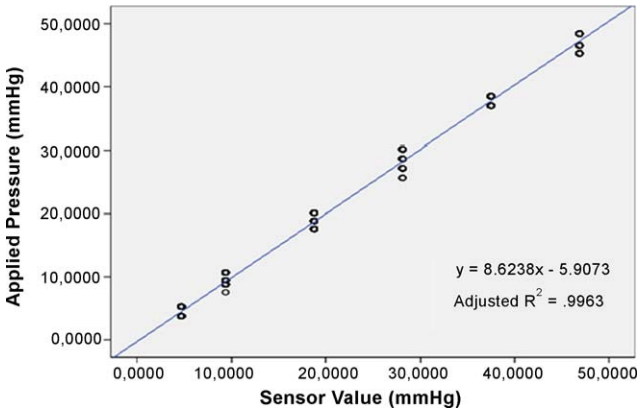

Fig. 3 – Association between sensor output and applied pressure.

Pearson's Moment Correlation $r = 0.998$ and adjusted $r^2 = 0.997$. Test–retest reliability was revealed with an ICC (3, 10) of 0.998. The inter-rater reliability ICC (2, 5) among the three independent assessors was 95% with CI from 0.995 to 1.00. Results demonstrated high correlation on linearity and repeatability of the system.

3.1.2. *In vivo pressure measurement*

The sensor accuracy was evaluated by placing the sensor between the human limbs and a sphygmomanometer cuff on five healthy volunteers. Table 2 summarizes the mean pressure in each body location. No significant discrepancies between the readings of sphygmomanometer and the Pliance X system were obtained. The maximum mean percentage difference was 6.42%.

3.2. *Phase II—Discriminant validity by clinical pressure measurement in hypertrophic scars tissues*

The mean pressures under the three pressure ranges are presented in Table 3. Based on the assumption, greater interface pressure would be exerted by increasing the number of padding inserts. The discriminant ability of the device was proven with its positive findings in differentiating pressure with different paddings as illustrated in Table 4 (H-value = 82.545, $p < 0.01$, Kruskal Wallis ANOVA). A multiple post hoc analysis Dunnett T3 test demonstrated a significant increase in pressure with 3 and 6 mm padding inserted underneath the garment with p-value < 0.01. An extra layer of padding induced approximately two times of interface pressure to the underlying skin.

Different variables, including skin tissue viability, location of measurements and age of scar, were also identified influential to the interface pressure under pressure garment. The results revealed that under the same level of pressure loading, hypertrophic scar was subjected to higher interface pressure than normal skin with t-value = 4.563 at $p < 0.01$. The two-folded pressure shown in hypertrophic scar than normal skin for both upper and lower limbs might be explained by increased skin tissue rigidity in hypertrophic scars, thus resulting increase in interface pressure between the garment and the skin tissues.

Table 2 – Sensor accuracy measured on human limbs.

Measurement site	Applied pressure (mmHg)	Output value range (mmHg)	Output value mean (mmHg)	S.D.	Mean percentage difference
Upper arm	10	9.81–11.22	10.179	0.609	1.79
	20	21.13–21.58	21.285	0.206	6.42
	30	31.02–31.70	31.451	0.279	4.84
	40	39.68–41.43	40.511	0.644	1.28
	50	48.92–51.53	49.815	1.011	0.37
Forearm	10	9.93–11.34	10.492	0.642	4.92
	20	19.72–21.13	20.757	0.590	3.78
	30	28.90–30.19	29.752	0.511	0.83
	40	39.77–40.76	40.416	0.463	1.04
	50	49.37–49.96	49.692	0.213	0.62
Thigh	10	9.81–11.32	10.314	0.696	3.14
	20	19.62–20.69	19.840	0.476	0.80
	30	30.17–30.25	30.212	0.0312	0.71
	40	39.99–40.79	40.486	0.398	1.22
	50	49.62–52.58	50.734	1.138	1.47
Calf	10	9.80–9.94	9.835	0.059	1.65
	20	19.64–21.05	20.487	0.726	2.43
	30	29.38–30.31	29.865	0.337	0.45
	40	39.24–40.71	39.978	0.705	0.05
	50	49.83–51.21	50.230	0.570	0.46

Significant variations were also observed in the upper (13.66 ± 5.91 mmHg) and lower limbs (9.44 ± 3.74 mmHg) with Kolmogorov–Smirnov Z-value = 2.205 at $p < 0.01$. All testing sites on upper limbs were found to have higher interface pressures than those on the lower limbs. It might be due to a smaller radius of curvature of the upper limbs than the lower limbs.

Significant difference ($p < 0.01$) is shown in Table 5 when there was no insertion of padding. The younger scars ($\leq$6 months) were subjected to higher pressure under all testing conditions when compared to the older ones (>6 months) as shown in Fig. 4.

4. Discussion

Though with much progression in the pressure measurement systems, researchers still encounter challenges in reflecting satisfactory parameters in clinical circumstances [12]. Great variation of pressure values from 5 to 40 mmHg has been reported. Persistent discrepancies with unreliable and inaccurate sensor equipment, possibly explain the augmentative pressure dosage [8–12]. In order to maximize the therapeutic effect of pressure therapy, there is a burning need to have an objective measurement of interface pressure.

The current study investigated the suitability of a newly available device—Pliance X system for the measurement of interface pressure between pressure garment and human skin tissue. The system is characterized by its general capacitive transducers with higher sensitivity and flexibility and minimal influence caused by temperature [18]. It also has a small and ultra-thin sensor with the capability of continuous data acquisition. The sensor properties were tested with pressure limited to 50 mmHg since adverse effects, namely maceration and parasthesia, were reported with higher pressures [18]. The overall performance of the system was considered satisfac-

Table 3 – Interface pressure measured under different conditions.

Location	Type of skin	Level of pressure loading	Interface pressure (mmHg) mean ± S.D.
Upper limb	Hypertrophic scar ($n = 11$)	PG	8.00 ± 0.92
		PG with a layer of padding (3 mm)	12.64 ± 1.94
		PG with two layers of padding (6 mm)	23.32 ± 0.78
	Normal skin ($n = 11$)	PG	3.28 ± 0.92
		PG with a layer of padding (3 mm)	8.33 ± 0.56
		PG with two layers of padding (6 mm)	17.68 ± 0.74
Lower limb	Hypertrophic scar ($n = 13$)	PG	5.41 ± 1.23
		PG with a layer of padding (3 mm)	8.85 ± 0.77
		PG with two layers of padding (6 mm)	14.07 ± 0.94
	Normal skin ($n = 13$)	PG	1.77 ± 0.58
		PG with a layer of padding (3 mm)	4.83 ± 0.87
		PG with two layers of padding (6 mm)	10.88 ± 1.37

Table 4 – Test statistics under different conditions.

	Test value		*p*-Value
Level of pressure loading	Kruskal Wallis ANOVA	82.545[a]	<0.01[c]
Type of Skin (*N* vs. HS)	Independent *t*-test	4.563[b]	<0.01[c]
Location (UL vs. LL)	Kolmogorov–Smirnov Z	2.205[a]	<0.01[c]

Dependent variable: interface pressure (mmHg).
[a] Unequal variance formula.
[b] Equal variance formula.
[c] The mean difference is significant at the 0.01 level.

Table 5 – One-way ANOVA statistics between younger and older scars.

	Upper limb			Lower limb		
	F-Value	df	*p*-Value	*F*-Value	df	*p*-Value
PG[a]	13.8155[a]	10	0.005[c]	6.1342[a]	12	0.0327[d]
PG + 3 mm[b]	4.2426[b]	10	0.070	0.8142[a]	12	0.3881
PG + 6 mm[a]	4.8938[a]	10	0.054	4.7764[a]	12	0.0537

[a] Unequal variances assumed.
[b] Equal variances assumed.
[c] The mean difference is significant at the 0.01 level.
[d] The mean difference is significant at the 0.05 level.

tory. The values obtained by the sensor were linearly correlated with the applied pressures and good test–retest and inter-rater reliability was also demonstrated. Less than 1 mmHg pressure error was found in the sensor output with standard weights of 5–50 g. Higher coefficients of variation at lower forces (8.5% at 5 g; 6.7% at 10 g), however, were obtained when compared with higher forces (2.2% at 50 g). Therefore, special attention should be consideration when measuring pressure at lower range (under 10 mmHg). Results also indicated a reasonable accuracy of the sensor placed between human limbs and a sphygmomanometer cuff with a maximum mean difference of 6.42%.

Measurements taken on clinical cases demonstrated the feasibility of using the Pliance X system for monitoring the dosage of pressure therapy. By adding layers of padding underneath the pressure garment, a pressure gradient was generated which demonstrated the discriminant ability of the system. The sensor was found to discriminate interface pressure generated under the three levels of pressure loadings ($p < 0.01$). It also showed that an additional level of padding could induce significant pressure to both hypertrophic scar and normal skin at $p < 0.01$. It was worth noting that the influence of scar location and scar maturation might be considered when applying pressure therapy. Statistical significance was also found when comparing the interface pressure between hypertrophic scar and normal skin. This might be due to the difference in skin tissue pliability between normal skin and hypertrophic scar. The scar tissues are generally stiffer than normal skin. The differences of pressure generated on the upper and lower limbs echoes with the Laplace Law that pressure is inversely proportional to the radius of body curvature and that the radius of curvature on upper limb is lower than that of lower limbs. Even though garment fabrication with same tensile strength, additional padding could be added to body surface with larger radius of curvature to attain the desired pressure. Pressure values measured on more mature scar also tended to be lower than those on the younger ones. During the course of scar maturation, hypertrophic scars tend to gradually become thinner and softer. The change of the tissue pliability might explain the pressure disparities recorded between younger and older scars, though no statistical significance was observed.

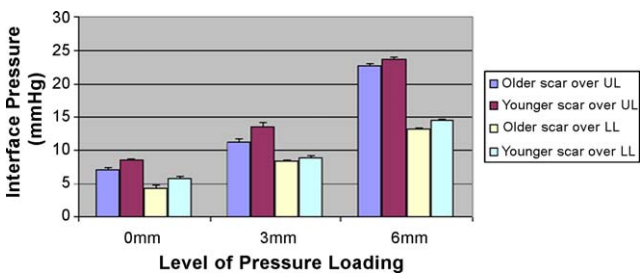

Fig. 4 – Comparisons between younger and older hypertrophic scars.

Interface pressure of at least 15 mmHg is recommended in previous studies [14,18,41]. However, the PG fabricated in this experiment could not generate pressure higher than 10 mmHg. To provide sufficient and uniform pressure for effective hypertrophic scar management, additional padding with good conformation power may be considered.

In clinical measurements, the Pliance X system was found to be quite user-friendly. It is easy to administer by therapists or technicians with one or two sessions of training. The readings generated could be exported to other software system for data analysis. Base-line zero pressure could be set before any loading applied. Multiple measurements over various body regions are allowed with connection of additional sensors to the matrix configuration.

5. Limitations of the study

The experiment was conducted on body regions with relatively flat skin surface without addressing the concavity or convexity of body contours. Therefore, results obtained may not apply to skin surfaces with high concavity such as face and ear. Samples of scar tissues might also be insufficient to show variations of pressure changes. Moreover, the interface pressure reading was currently exploited in static means, however, physical activities and movements predictably alter the pressures significantly. Dynamic pressure effect on the sensor accuracy remains unexamined.

6. Conclusion

It is important to monitor pressure dosage in management of hypertrophic scar. Empirical observations in current clinical practice, however, were too subjective in manipulating pressure and previously available techniques to measure pressure had their limitations. In this study, a newly available device, the Pliance X System, was tested for its feasibility of measuring interface pressure between skin and pressure garment. Results demonstrated its potential as a clinical tool in measuring pressure in an objective manner. Its feasibility in low pressure measurement was supported with its superior technical performances in laboratory tests. Its clinical applicability also revealed by its good discriminant ability under diverse loadings in static manner. Slightly reduced sensor sensitivity, however, appeared during low pressure measurement below 10 mmHg. Further investigations were recommended to evaluate its response to concave skin surfaces and dynamic movements.

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