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Submitted for publication May 3, 2019. Accepted in revised form July 28, 2019.

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Smart Scar Care Pad: An Innovated Silicone-Based Insert That Improved Severe Hypertrophic Scar by Integrating Optimal Pressure and Occlusion Effects

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Objective: Inserts are typically used in conjunction with pressure garment to improve the outcomes of hypertrophic scar (HS) treatment. However, the types of insert materials currently available have many limitations, thus hindering their therapeutic effect. An innovative insert material, the Smart Scar Care Pad (SSCP), was invented to maximize treatment outcomes through enhanced compression and occlusion. The study aimed to investigate the properties of the SSCP and its efficacy to serve as a suitable insert material for HS management.

Approach: The physical properties and biocompatibility of SSCP were examined. A self-controlled clinical study of 45-day intervention using SSCP in comparison with Plastazote was conducted on 25 subjects with HS. Study outcomes included scar parameters measured both subjectively and objectively and patient feedback questionnaire.

Results: The SSCP demonstrated equivalent and even superior performance when compared with commercial products in tests of biological safety and physical properties. Both arms demonstrated significant time effects on Vancouver Scar Scale total score ($p=0.000$), melanin score ($p=0.042$), pliability ($p=0.039$), and hydration score ($p=0.013$). Significant intervention and time interaction effect was found in the pliability ($p=0.048$). From the feedback questionnaire, patients reported that SSCP was more conformable and there was less displacement during movement ($p=0.040$) compared with conventional insert.

Innovation: The SSCP is the first insert that combined the pressure enhancing effect of a traditional pressure insert and occlusion effect of silicone insert.

Conclusion: The SSCP can serve as a safe and effective insert material in HS treatment, especially in improving HS pliability.

Keywords: hypertrophic scar, conservative treatment, silicone therapy, pressure therapy

INTRODUCTION

HYPERTROPHIC SCAR (HS) is a fibroproliferative disorder of dermal tissue after skin injuries such as surgery, trauma, and burns.¹ They are elevated rigid scars with differ-

ent skin pigmentation that are confined within the border of the original wound.² HSs are observed in ~30–91% of wounds after burns.³ It is reported that the Chinese population display a higher incidence of HS than

the Caucasian population.⁴ Patients who develop HS usually suffer from functional and psychological problems because scar contractures could affect physical movements² and are difficult to manage. They could also suffer from itchiness, tenderness, pain, sleep disturbance, depression, and anxiety that severely affect their daily activities.² Psychological problems such as loss of self-esteem and stigmatization have led to a diminished quality of life.

The effectiveness of pressure therapy (PT) in HS treatment is widely supported.^{5–7} Pressure garments have been used to apply mechanical pressure to flatten the scar by accelerating collagen maturation and reducing capillary perfusion pressure.⁸ Adequate pressure dosage is essential for the clinical treatment effect of PT. However, maintaining adequate pressure dosage through pressure garment alone is usually uncomfortable as the garment might be felt too tight. Sometimes it is impossible, especially over bodily concave area. Therefore, pressure inserts are used in conjunction with pressure garment to increase local pressure.⁹

Thermoplastic polyethylene foam, Plastazote, displays preferable properties and thus is used as inserts in some countries.^{10,11} Because of its thermoplasticity, this material can conform to different body contours. However, its rigidity also hinders body movements. Furthermore, under prolonged compression from pressure garment, foam could shrink in thickness after long-term wear, resulting in insufficient pressure and frequent replacement during the course of treatment is often required.¹² Because of its nonadhesive feature, it often creates friction on the HS upon movement, thus inducing blisters and erosions or even ulcerations of skin especially during movement. Some studies have documented the usage of neoprene and spacer fabrics as pressure insert materials, but they are not widely adopted in clinical practice because of its limited clinical evidence.^{13,14}

Silicone gel sheeting (SGS) is a type of gel-based insert commonly used in combination with PT.^{15–17} Cochrane review on SGS found statistical significance in the reduction of scar thickness and the improvement scar color.¹⁸ It is suggested that SGS reduces HS through occlusion.^{18–22} Research suggested that occlusion restored homeostasis of stratum corneum of HS by controlling excessive trans-epidermis water loss (TEWL) and recreating normal water-holding capacities.^{23,24} Gel-based inserts are mainly used for small scars or surgical scars. They are generally costly and thin in physical form, rendering them incapable of exerting sufficient pressure.

PT and silicone therapy are recommended as first-line noninvasive treatments for HS, according to guidelines of the International Society of Burn Injuries.²⁵ In clinical practice, therapists must trade off the pressure effect from thermoplastic form with the occlusion effect from SGS, as it is impractical to have two separated layers of inserts stack together with pressure garments because displacement between two inserts could affect the pressure effect. Thus, the limitations of the currently available inserts compromise HS treatment outcomes.

With the aforementioned expectations, we recently developed a new insert material: The Smart Scar Care Pad (SSCP; Patent No. CN 103070744 A&B).^{26,27} The design is given in Fig. 1. The outer layer was made of silicone rubber that is stiff enough to generate pressure, yet more elastic and durable than thermoplastic form upon compression. The rubbery silicone stiffener layer consists of a thin layer of silicone rubber sheet whose surface is covered with numerous studs aligned in a honeycomb pattern (Fig. 1b). By trimming the individual studs into gradient heights according to different bodily contours, one can create a tailor-made localized pressure environment on skin while maximizing conformability and comfort. The inner layer below the silicone rubber was made of medical-graded SGS that directly adheres to HS to limit TEWL and reduce friction. Based on their properties, the combination of both layers should be biocompatible and induce occlusion and pressure effect to improve various HS parameters such as color, thickness, and pliability. Therefore, the aim of this study was to (1) investigate the physical properties and biocompatibility of SSCP to determine if it is suitable as a new insert for scar management, and (2) conduct a self-controlled clinical study to evaluate its clinical efficacy on HS in comparison with the thermoplastic form insert that was used conventionally in hospitals.

CLINICAL PROBLEM ADDRESSED

Although to combine PT and silicone therapy is the first-line conservative treatment for HS, it is difficult to implement this treatment strategy because of the various shortcomings of conventional insert materials as described in the previous sections. The limitations of these inserts will hinder the treatment outcomes, some even create complications upon prolong wear. In this article, we intend to address this problem by introducing a newly invented insert material that could enhance the pressure, ensure the occlusion effect,

Figure 1. Schematic illustration of SSCP: (a) SSCP is composed of a rubbery silicone stiffener layer and a medical-grade silicone gel layer. (b) Rubber silicone stiffener layer is a thin layer of silicone rubber sheet designed with numerous studs aligned in a honeycomb pattern to enhance conformability. (c) In addition to occluding HS tissue, the SSCP creates a tailor-made localized pressure environment, especially over concave areas, by selection of different stud heights and by cutting the individual studs into gradient height. HS, hypertrophic scar; SSCP, Smart Scar Care Pad. Color images are available online.

and at the same time improve the level of comfort and ease of wear.

MATERIALS AND METHODS

Experimental procedures examining biological safety

Three-dimensional human epidermis culture model. Human keratinocyte-derived EpiSkin (Lyon, France) resembling human skin was purchased and cultured on a collagen matrix at the air-liquid interface to maintain a three-dimensional shape. The EpiSkin was initially equilibrated in the maintenance medium at 37°C, 5% CO₂, 24 h before assay.²⁸

Samples. The SSCP was prepared using medical-grade silicone gel precursor purchased from Bluestar Silicones Germany (Lübeck, Germany). The silicone rubber stud sheet that we designed was fabricated by a company in China.

Cytotoxicity, irritation, and sensitization tests. The SSCP and Cica Care (Smith & Nephew), a commercial SGS product, were tested for cytotoxicity, irritability, and oxidative stress (sensitiza-

tion test). The gel sheets were cut into 8 mm gel disks by biopsy punch (Kruuse) and autoclaved before assays. Each gel disk was applied directly on the surface of EpiSkin for 15 min. In positive and negative controls, EpiSkin was treated with phosphate-buffered saline (PBS) solution (pH 7.4; Gibco) and PBS with 5% sodium dodecyl sulfate (SDS), respectively. The EpiSkin cultures were further incubated in fresh assay medium for 42 h before proceeding. All experiments were performed in triplet.

For the cytotoxicity test, the cell viability of EpiSkin was determined by MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide] assay. EpiSkin was pulsed with MTT at a final concentration of 0.3 mg/mL for 3 h at 37°C before incubating with 500 μ L acidic isopropanol (0.04 N) overnight at room temperature. The supernatant samples were then measured for optical density reading at 570 nm using a Victor3 microplate reader (Perkin Elmer). For the irritation test, the level of proinflammatory cytokine interleukin (IL)-1 α released from the culture was evaluated using the IL-1 α human ELISA (enzyme-linked immunosorbent assay) Kit (Abcam) according to the manufacturer's manual. For sensitization test, CellROX Oxidative Stress Reagents (Molecular

Probes) was used to detect reactive oxygen species. EpiSkin was incubated with 5 μ mol of CellROX Green dye in culture medium for 30 min and washed three times with PBS before the sample gel disks were loaded on top for 30 min. For positive control, the construct was treated with cigarette smoking for 30 min.²⁹ The fluorescent signals were measured at Ex/Em of 485/520 nm.

Measurement of physical properties

Measurement of water vapor transmission rate. Water vapor transmission rate (WVTR) test was used to evaluate the occlusive properties of material.^{30,31} The WVTR of the SSCP and the commercial SGS were measured and compared according to BS7209:1990 standard.³²

Measurement of tensile properties. The tensile property of the SSCP was tested for its conformability and compared with a conventional thermoplastic foam, Plastazote (3 mm; Zotefoams). Both SSCP and the thermoplastic foam were cut into rectangular shapes of the same size ($n=5$). The specimens were gripped and stretched in vertical

orientation with a velocity of 600 mm/min using an Instron 5566 tensile tester (Instron). The Young's modulus, the yield strength, and the tensile strain at yield were recorded automatically for comparison.

Clinical effect of the SSCP on the HS

A self-controlled clinical study design. The clinical study was conducted in several hospitals to examine the clinical efficacy of SSCP on patients with postburn HS and compared with the ones of the conventional insert (Plastazote), which was commonly used to increase local pressure on HS.³³ The assessments on clinical characteristics were conducted at baseline, and after a 45-day intervention.³⁴ The study design is given in Fig. 2. Written consent was obtained from the subjects of each study before their engagements. The study was approved by the ethics committee of The Hong Kong Polytechnic University (HKPolyU), Hong Kong. All interventions and assessments were provided by certified occupational therapists to ensure a unified and standard treatment and assessment.

Figure 2. The study design of the clinical study.

Study population. Patients between 20 and 70 years of age with HS resulting from burn injury were screened using the Vancouver Scar Scale (VSS).³⁵ The maximum score is 15 and normal skin score zero. Patients with a total score of VSS ≥ 8 ; and score of each item of the VSS ≥ 1 were included for the study; and other inclusion criteria are as follows: (1) existing HSs grew on either upper limbs or lower limbs; (2) with a history of delayed wound closure (>21 days); (3) size reached $4 \times 4 \text{ cm}^2$ or above; and (4) cooperative and had good compliance with treatment. At least two scars with similar burn depth, size, healing time, and preferably from adjacent area were selected in each subject. Patients were excluded from this study if (1) the HSs have open wound or infection; (2) the HSs treated with steroid injections or other intervention before the study; or (3) subjects with medical conditions that might affect wound healing, for instance, diabetes mellitus.

Study interventions. For each pair of scars, one scar was assigned to the treatment arm and the other to the control arm. Scars were treated by SSCP in the treatment arm, whereas scars prescribed with conventional insert belonged to the control arm. Both inserts were secured by a standardized pressure garment named Smart Pressure Monitored Suit. Each patient was offered two sets of pressure garment to change and wash every day alternatively to maintain adequate pressure dosage. Selected scar sites were outlined by transparent plastic film and inserts were cut according to the film outlines. Patients were instructed to wear SSCP for 4 h/day for the first day and to increase 2 h every other day, until the total wearing time reached 23 h according to the international recommended wearing regime for SGS.³⁶ Patients were also instructed to clean the SSCP twice a day for hygienic measure. Its maintenance was also summarized on pamphlets. Patients were instructed to wear the conventional pad 23 h a day and only remove it during shower. The thermoplastic foam was wrapped with a gauge to absorb sweats, and the gauge was replaced regularly. Compliance toward wearing regimes was monitored closely by therapists. Interface pressure between pressure garment and the scar was measured by the Pliance-X system,^{33,37} so that optimal pressure was given to subjects after interventions were prescribed. According to previous research, we intended to achieve a pressure dosage of 20–30 mmHg.³⁸

Outcomes of the study. Each case was assessed by a research staff on a set regime. Demographic data of the subjects were collected including total

burn surface area (TBSA) and days postinjury. VSS was measured to reflect the change of global clinical outlook of scar conditions including pigmentation, vascularity, pliability, and height.³⁵ The scar thickness was assessed with the diagnostic ultrasound system; the DermaLab Combo (Cortex), was adopted to assess three HS characteristics: scar pigmentation (represented by melanin score), scar vascularity (represented by erythema score), and scar elasticity (represented by Young's modulus).^{39,40}

The outcome measurements also included objective assessment of the clinical characteristics of HS and end-users' feedback questionnaire. Scar dryness was measured by hydration score and stratum corneum function represented by TEWL.^{39–41} The improvement in redness was reflected by the decrease in erythema score and thus indicates reduction in vascularity. Feedback questionnaires were collected by telephone interview regarding the usage of both SSCP and thermoplastic foam. The questionnaire consisted of two sections with 9 five-point Likert items in total. The first section was on the cleansing of SSCP and it was not applicable to conventional insert because it cannot be washed. The second section contained six questions asking on the quality and application of the two inserts.

Statistical analysis. Demographical characteristics of subjects were reported using frequency distributions and descriptive statistics. Clinical characteristics of HS were analyzed using both descriptive statistics and inferential statistics. Patient who dropped out was not included in the analysis for clinical characteristics. Outliers (>2.5 standard deviation) were identified and excluded from the analysis. Paired *t*-tests were used to ensure baseline characteristics were the same between two arms. Repeated-measures analysis of variance (ANOVA) was used to compare the difference between arms over time. For the feedback questionnaire, descriptive statistics were used and paired *t*-tests were also used to compare the difference of inserts based on the second section of the questionnaires. Data analysis was performed using SPSS (version 25).

RESULTS

Cytotoxicity, irritation, and sensitization tests

In cytotoxicity test, if SSCP induced $>50\%$ reduction in cell viability when compared with the negative control, it will be considered cytotoxic. Whereas the positive control (5% SDS) induced significant reduction in cell viability, SSCP-treated EpiSkin samples exhibited $>80\%$ viability, which is

comparable with that of commercial SGS and negative control (Fig. 3a). In irritation test, elevation of IL-1 α expression level by >50 pg/mL than the negative control (*i.e.*, ≥ 79.94 pg/mL) would be considered irritant to skin. As demonstrated by the positive control, the IL-1 α expression was 1,883.69 pg/mL, which was far higher (>23-folds) than the negative control (Fig. 3b). Whereas the IL-1 α level released in the negative control (PBS) was 29.94 pg/mL, and the ones released from both the SSCP and commercial

SGS were even lower than the negative control. In sensitization test, no significant differences were observed among SSCP, the commercial SGS, and the negative control. Compared with the negative control, positive control induced a fourfold increase in fluorescence signals by EpiSkin (Fig. 3c).

Physical properties

The WVTR of the SSCP was 8.48 g/m²/day, whereas the WVTR of the commercial SGS was 11.91 g/m²/day, which was less occlusive than SSCP. The results of the tensile property of the SSCP and the thermoplastic foam are summarized in Fig. 4a–c. Compared with the thermoplastic foam, the SSCP had a much lower average Young's modulus (0.10 MPa) and yield strength (0.11 MPa), but greater tensile strain at yield (92.09%).

Figure 3. Graph of the biological effects of the SSCP on EpiSkin. **(a)** Results of the MTT assay show the metabolic activity of EpiSkin as an indication of tissue viability. **(b)** Expression level of IL-1 α (pg/mL) as an indication of irritation. **(c)** Fluorescence signals representing the abundance of reactive oxygen species on EpiSkin. EpiSkin was loaded separately with gel samples (SSCP and Cica-Care), PBS, 5% SDS (for **a**, **b**), and cigarette smoking (for **c**). The percentages of viability (in **a**), the concentration of IL-1 α (in **b**), and the fluorescence signal (in **c**) are expressed as mean ($n=3$) $\pm$ SEM as compared with the negative control (PBS). MTT, 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide; PBS, phosphate-buffered saline; SDS, sodium dodecyl sulfate; SEM, standard error of the mean.

Figure 4. Graph demonstrates the tensile properties of the SSCP as compared with Plastazote. **(a)** Young's modulus (MPa); **(b)** yield strength (MPa); and **(c)** tensile strain at yield (%). The values are presented as mean ($n=5$) $\pm$ SD. SD, standard deviation.

Table 1. Demographic Characteristics of Subjects in the Clinical Study

Variables	Complete cases (N = 25)	Dropout cases (N = 7)
Gender (%)		
Male	80.8	71.4
Female	19.2	28.6
Age (years), mean $\pm$ SD	37.23 $\pm$ 8.65	41.29 $\pm$ 10.63
TBSA (%), mean $\pm$ SD	37.56 $\pm$ 25.14	44.36 $\pm$ 27.00
DPI (days), mean $\pm$ SD	232.92 $\pm$ 142.48	180.86 $\pm$ 99.91

DPI, days postinjury; SD, standard deviation; TBSA, total burn surface area.

Clinical efficacy

Demographic characteristics. There were 32 subjects recruited in this 45-day assessment and 7 of them dropped out (21.2%). With two subjects contributing one more pair of scars, there were a total of 27 pairs of scar samples included in the analysis. The demographic characteristics of dropped out cases and completed cases were similar as given in Table 1. The majority of the subjects were middle-aged men and ~40% TBSA in average and 8 months postinjury.

Clinical characteristics. The descriptive statistics of clinical characteristics are summarized in Table 2 and the results of inferential statistics are summarized in Table 3. As shown in Table 3, paired *t*-tests showed no significant differences in clinical characteristics between both arms at the baseline. The results of repeated-measures ANOVA with within subject design are summarized in Table 3. There were significant time effects in VSS total score ($p=0.000$), melanin score ($p=0.042$), pliability ($p=0.039$), and hydration score ($p=0.013$). Significant intervention and time interaction effect were found in pliability ($p=0.048$). As given in Table 2, the average VSS total score of both arms were the same at the baseline and dropped more

Table 2. Descriptive Statistics of Treatment and Control Arm

Variable	Arm	Pre (mean $\pm$ SE)	Post (mean $\pm$ SE)
VSS total score (unit)	Treatment	11.38 $\pm$ 0.22	9.79 $\pm$ 0.43
	Control	11.38 $\pm$ 0.22	10.04 $\pm$ 0.39
Melanin (unit)	Treatment	57.10 $\pm$ 1.42	54.40 $\pm$ 1.27
	Control	56.68 $\pm$ 1.54	53.53 $\pm$ 1.21
Erythema (unit)	Treatment	17.55 $\pm$ 0.70	17.42 $\pm$ 0.63
	Control	17.27 $\pm$ 0.71	17.14 $\pm$ 0.55
Thickness (mm)	Treatment	4.91 $\pm$ 0.34	4.78 $\pm$ 0.32
	Control	4.28 $\pm$ 0.26	4.35 $\pm$ 0.26
Pliability (MPa)	Treatment	14.86 $\pm$ 1.43	12.05 $\pm$ 0.70
	Control	12.92 $\pm$ 0.65	12.44 $\pm$ 0.87
TEWL (g/m ² /h)	Treatment	15.56 $\pm$ 1.57	13.55 $\pm$ 1.15
	Control	13.78 $\pm$ 1.07	13.17 $\pm$ 1.18
Hydration (μ S)	Treatment	190.44 $\pm$ 21.05	146.52 $\pm$ 14.37
	Control	192.44 $\pm$ 19.13	141.59 $\pm$ 15.00

SE, standard error; TEWL, trans-epidermis water loss; VSS, Vancouver Scar Scale.

Table 3. Results of Inferential Statistics

Variable	Paired <i>t</i> -test p Value (baseline)	Repeated measure ANOVA with within subject design			
		p Value (T)	Observed power	p Value (I $\times$ T)	Observed power
VSS total score (unit)	0.43	<0.001	0.99	0.39	
Melanin (unit)	0.99	0.04	0.54	0.69	
Erythema (unit)	0.61	0.82		0.99	
Thickness (mm)	0.06	0.90		0.36	
Pliability (MPa)	0.09	0.04	0.55	0.048	0.51
TEWL (g/m ² /h)	0.19	0.08		0.34	
Hydration (μ S)	0.85	0.01	0.73	0.58	

Bold signifies $p < 0.05$ values.

ANOVA, analysis of variance; I $\times$ T, intervention $\times$ time; T, time.

than one score by 45-day posttreatment, with the treatment arm having a lower VSS total score. Both arms demonstrated significant reduction in melanin score and improvement in scar pigmentation. The reduction in erythema score was also parallel in two arms during treatment period, but no significant time effect was found. There was no significant change in thickness in either group, although two arms demonstrated different trend. On the contrary, there was also a significant difference in the improvement of pliability between two arms, in which there was a nearly 3 MPa improvement of pliability in treatment arm, whereas the ones in control arm was not more than 0.5 MPa. For the hydration score, the drop of hydration level was significant yet comparable between the two arms after intervention and there was a borderline time effect in TEWL. Both arms showed reduction in TEWL, but the reduction in treatment arm was more than that of control arm. Photographs of pretreatment and posttreatment scars are given in Fig. 5a–d.

Feedback questionnaire. The responses of feedback questionnaire are summarized in Table 4. A total of 14 subjects answered the telephone interview and reported that SSCP were very easy to clean and dry, and the pressure exerted was considered to be well sustained. Patients reported that the SSCP was significantly more conformable to wear ($p=0.02$) and less displacement during movement ($p=0.040$). In addition, the durability of SSCP was slightly better with borderline *p*-value. Compared with thermoplastic foam, SSCP was easier to wear, less smelly, and less breathable, but no significant differences were observed statistically.

DISCUSSION

To our knowledge, the SSCP is the first insert that combined the pressure enhancing effect of a

Figure 5. Clinical photographs of HSs treated with the SSCP and thermoplastic foam. Circles indicate area of assessment. (a) HS treated with SSCP, pretreatment; (b) HS treated with SSCP, posttreatment; (c) HS treated with thermoplastic foam, pretreatment; and (d) HS treated with thermoplastic foam, posttreatment. Color images are available online.

traditional pressure insert and occlusion effect of silicone insert. This study investigated whether the SSCP can serve as a better alternative material for inserts for the treatment of HS. To serve as a material compatible for human skin, it is necessary

Table 4. Results of Feedback Questionnaires

Questions	Treatment	Control	p
Question 1: Is the padding material easy to clean?	4.29		
Question 2: Is the padding material easy to dry?	4.00		
Question 3: Is the padding material able to sustain pressure after wash?	4.50		
Question 4: Comparing with the other, is the padding material easy to wear?	3.71	3.20	0.21
Question 5: Comparing with the other, is the padding material smelly?	3.93	4.30	0.26
Question 6: Comparing with the other, is the padding material breathable?	2.93	3.60	0.13
Question 7: Comparing with the other, is the padding material conformable after use?	4.29	3.40	0.02
Question 8: Comparing with the other, is the padding material durable in general?	4.71	4.20	0.09
Question 9: Comparing with the other, is there any displacement noticed during usage?	4.71	3.90	0.04

for the material to be free of notorious biological effects. Our results demonstrated that the performance of SSCP in the tests for cytotoxicity, irritation, and sensitization on EpiSkin model was basically comparable with commercial SGS and the control treatment (PBS). Our study also showed that the occlusive property of SSCP was comparable with that of commercially purchased SGS and its texture and elasticity were favorably better than a conventional thermoplastic insert.

From a clinical perspective, this study is also the first clinical trial in the field to examine the clinical efficacy of the inserts on severe HSs. It has been observed that inserts were able to improve overall HS rating reflected by the decrease of VSS score, HS pliability, and HS color reflected by decreased melanin score. When examining the clinical efficacy of SSCP on HS and compared with the ones of thermoplastic foam, the results have shown that SSCP is able to improve HS pliability, possibly by exerting compression and occlusion. SSCP also demonstrated better conformability and lesser tendency of displacement as reported by patients, rendering it a

superior insert material compared with the conventional material such as thermoplastic foam.

An ideal insert material should maintain sufficient rigidity and thickness to increase local pressure, while remaining sufficient softness and elasticity to conform to different body contours and allow joint movements. The material should be remoldable when the scar changes in size and contours upon maturation. The material should be adhesive to the scar surface to provide occlusion effect and with certain level of extensibility to reduce the friction during movement. The material should be friendly to skin, comfortable, durable, and easy to clean, so that the patient can adhere to the prolonged wearing regime. The material should provide optimal pressure to control the growth of the HS while maintaining the occlusive property to soften the scar, thus achieving maximal clinical outcomes. Finally, the material should not impose any toxic, irritating, or sensitizing effects on the skin.

Based on our biocompatible tests according to ISO 10993 standards,^{42,43} SSCP induced no cytotoxicity, irritating, and sensitizing effects on the EpiSkin model and comparable with commercial SGS and the saline control. All these data indicated that SSCP is not harmful to humans and unlikely to irritate or react on the skin of patients. Because the sole composite of SSCP is silicone, our tests concurred with previous literatures that silicone is an excellent biocompatible and nontoxic material for medical devices.^{12,44,45} Patients who wore SSCP in the 45-day clinical trial had no complaints regarding skin irritation. That further illustrated the biocompatibility of SSCP and its suitability to be used for treatments.

SSCP also received better patient feedback in the items of conformability and tendency of displacement. According to the patients' feedback in the clinical study, SSCP was superior to thermoplastic foam in terms of conformability and adhesiveness during movements. Tensile tests of SSCP have shown its lower Young's modulus and higher tensile strain than thermoplastic foam, rendering it less stiff and more deformable on the transverse plane. Our tensile tests of SSCP strongly reflected patient feedback.

With better design of the SSCP, SSCP improved the overall HS rating reflected by the decrease of VSS score, HS pliability, and HS color reflected by the decreased melanin score. Based on our physical test on the WVTR, it was shown that SSCP has the ability to induce occlusion effects, which is comparable with commercial SGS. The lower WVTR of SSCP has indicated that SSCP could reduce the excessive TEWL and normalize the stratum corneum functions.^{23,24}

This could also be reflected by the decreased TEWL of the experimental arm. Moreover, although both arms demonstrated reduction of the hydration level of stratum corneum, experimental arm retained more water than the control arm.

The primary working mechanism of pressure inserts used in this study is to increase interfacial pressure dosage by increasing the radius of curvature of the selected HS sites and thus ensure adequate pressure applied to that site without inducing much discomfort.^{10,33} Classical theory proposes local mechanical pressure is able to mitigate abnormal wound healing, including reducing edema, suppressing local blood flow, and facilitating collagen remodeling.^{46,47} Recent studies have also suggested that deformation and elongation of local HS tissue under pressure could reduce the tension between HS and surrounding tissues, thus promoting the wound healing process through mechanomodulation.^{48,49}

This study was the first clinical trial on pressure and silicone intervention that adopted objective assessment to measure scar parameters comprehensively, not only traditional scar parameters, but also parameters indicating stratum corneum functions. With the implementation of objective measurements, infinitesimal changes of the HS parameters could be identified. Previous investigations have suggested that uncertainty lied in the effectiveness of pressure or silicone intervention's effect on scar pliability because of the lack of the usage of objective measurement in pliability assessment.^{5,18} Using the objective measurement of HS parameters, the effect of SSCP on HS pliability was able to be documented and served as the solid proof on the effect of a combined adequate PT with silicone gel therapy.¹⁷ This finding corresponded with our previous study in which HS pliability was measured subjectively.

There are several limitations in our study. First, the duration of this study was restrained and only lasted for 45 days. Longer follow-up period should be applied in future study to observe HS thickness. Moreover, the recommended wearing regime for SSCP might delay the outcome of the treatment because it took patients 2 weeks to wear the insert 23 h/day, which suggested that the whole-dose intervention for this study was just 1 month. In addition, the study was designed as a self-control clinical study to minimize the differences between different subjects. However, we realized that some subjects had replaced the SSCP with the conventional inserts to the control arm once they realized that it was more effective. Thus, the outcomes of the study were affected. Despite close supervision by the local

staff, the noncompliance of subjects could saturate the outcomes of treatment arm and drive research results toward null. For this reason, between-subject group design instead of self-control design is recommended in future study.

INNOVATION

The innovative design of the SSCP enables evidence-based practice in HS treatment up-to-date by sustaining adequate pressure and occlusive effect simultaneously, which is difficult to achieve previously. The SSCP also overcomes the shortcomings of traditional inserts. Its adhesiveness and flexibility ensures conformability and comfort in both static and dynamic circumstances, which are also reflected on the positive feedbacks from patients. With these special features, the SSCP improves various HS outcomes and proves to be effective in improving the pliability in severe HS as measured by objective assessment tool.

ACKNOWLEDGMENTS AND FUNDING SOURCES

This research work was supported by the Innovation and Technology Fund of the Innovation and Technology Commission, the Government of the Hong Kong Special Administrative Region (grant No. GHP/020/13, year 2014–2016). The authors acknowledge the support from the Institute of Textile and Clothing, the HKPolyU, the Guangdong Work Injury Rehabilitation Hospital, Chengdu No. 2 Hospital and the Southwest Hospital of China. The authors thank Dr. Raymond Chung, the Senior Scientific Officer of the Department of Rehabilitation Sciences, the HKPolyU, for his valuable advice on statistical analysis.

DISCLAIMER

Any opinions, findings, conclusions, or recommendations expressed in this material/event (or by members of the project team) do not reflect the views of the Government of the Hong Kong Special Administrative Region, the Innovation and Technology Commission, or the Panel of Assessors for

KEY FINDINGS

- SSCP is safe and effective to use as an insert material for HS treatment.
- Biological tests suggest the SSCP is biocompatible and nontoxic and its physical properties ensured a constant adequate pressure and occlusion effect.
- It was more conformable to wear and there was less displacement during movement than thermoplastic foam.
- The clinical study suggested the SSCP to improve HS overall VSS rating, color, and most importantly pliability, with a possible effect to inhibit thickness growth.

the Innovation and Technology Support Programme of the Innovation and Technology Fund.

AUTHOR DISCLOSURE AND GHOSTWRITING

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ABBREVIATIONS AND ACRONYMS

HKPolyU = Hong Kong Polytechnic University
HS = hypertrophic scar

MTT = 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide
PBS = phosphate-buffered saline
PT = pressure therapy
SDS = sodium dodecyl sulfate
SGS = silicone gel sheeting
SSCP = Smart Scar Care Pad
TBSA = total burn surface area
TEWL = trans-epidermis water loss
VSS = Vancouver Scar Scale
WVTR = water vapor transmission rate