Original Article

Effectiveness of Silicone Gel Combined with Pressure Garment for Prevention of Post-Burn Hypertrophic Scar: A Randomized Controlled Trial

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Background: The objective of post-burn hypertrophic scar prevention is to improve patient quality of life. Many treatments have been employed to obviate hypertrophic scarring, but the optimal treatment has not yet been identified. Several studies have demonstrated the potential of silicone gel in scar prevention.

Objective: To investigate the efficacy of silicone gel combined with pressure garment for prevention of post-burn hypertrophic scar.

Materials and Methods: This randomized controlled trial included patients with completely epithelialized post-burn wound injury that were recruited from the Burn Unit of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Study patients were allocated to the pressure garment alone group (control) or the pressure garment with silicone gel group (study). Gel was applied to scar tissue twice daily after bathing, and the pressure garment was worn for 23 hours each day for 24 weeks. Scars were evaluated using the Vancouver Scar Scale (VSS) at 2, 4, 12, and 24 weeks of treatment.

Results: Fifty patients (25 per group) were included. The average age of patients and size of wound was 39.74±10.75 years and 95.95±29.30 cm^2, respectively. Most patients (72%) were male. There was no significant difference between groups for age, gender, size of burn wound, or infection. The study group demonstrated significantly lower pigmentation (at week 24, $p<0.05$), increased pliability (at weeks 12 and 24, $p<0.05$), and decreased height (at week 24, $p<0.05$) than the control group; however, no significant difference was observed between groups for vascularity, pain, or itching. Total modified VSS score was significantly lower in the study group than in the control group at 12 and 24 weeks ($p<0.05$).

Conclusion: The present study demonstrated the statistically significant benefit of combining silicone gel with pressure garment for post-burn hypertrophic scar prevention compared to pressure garment alone.

Keywords: Effectiveness, Silicone gel, Pressure garment, Burn wound, Hypertrophic scar

J Med Assoc Thai 2020;103(Suppl. 5): 39-43
Website: http://www.jmatonline.com

The survival rate among burn patients continues to increase due to continuously developing knowledge and management; however, burn patients routinely suffer from wound complications, especially post-burn hypertrophic scarring[1,2]. These lesions present as raised and erythematous skin, they are a cause of cosmetic concern to patients, and they last at least 6 to 12 months. Pain and itching also occur around the scar area. In cases of severe complication, the contracture can cause increased morbidity, increased time and cost of treatment and rehabilitation, and reduced quality of life[3].

The pathophysiology of hypertrophic scar involves augmentation of vascularity, cellularity, and connective tissue when compared with normal scar. In addition, the pattern and arrangement of collagen fibers in hypertrophic scars differs from those of normal scars[2,4]. Scar formation usually develops in the dermis layer of wound involved skin, so it forms in both partial-thickness and full-thickness burn wounds. Most partial-thickness burn wounds or second-degree burn wounds can heal naturally by epithelialization within 14 to 21 days. Hyperpigmentation generally develops after complete wound healing. Previous studies reported that about 30% of post-burn wounds would progress to hypertrophic scar as a result of abnormal wound healing process[2,4,5]. Patients with a full-thickness burn injury that did not spontaneously heal within three weeks were found to have a 70% or greater risk of scar aggravation[6].

Although various modalities are used to prevent and manage post-burn hypertrophic scar, such as pressure garment, silicone gel, silicone sheet, intralesional steroid injection, radiation therapy, laser therapy, and surgery[2,7,8], a resounding treatment of choice has not yet been established[2]. The treatment used at most burn centers is pressure garment therapy, and this treatment has been used for several decades. The exact mechanism(s) of this treatment are still unclear,

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How to cite this article: Muangman P, Kongkor A, Namviriyachote N, Sirikun J. Effectiveness of Silicone Gel Combined with Pressure Garment for Prevention of Post-Burn Hypertrophic Scar: A Randomized Controlled Trial. J Med Assoc Thai 2020;103(Suppl.5): 39-43.

but its positive effects in scar management have been reported in many studies. Pressure garments may reduce some cytokines such as IL-1β, tumor necrosis factor-α, and epylisin, and this may positively affect the creation and arrangement of collagen[2,9].

Recent studies described the benefits of silicone gel for treatment and prevention of hypertrophic scar, including reduced scar formation and severity[10]. The mechanism of action was reported to be enhanced moisture in the stratum corneum layer, which protects against dehydration and regulates keratinocyte-dermal fibroblast interactions[6,11]. However, other studies suggested that it might associate with static electrical charge or the oxygen tension occlusion effect[12,13].

Continued study to identify an optimal treatment for preventing or reducing post-burn hypertrophic scarring would improve patient outcomes and quality of life. Accordingly, the aim of this study was to compare the efficacy of combination silicone gel and pressure garment with the efficacy of pressure garment alone for the prevention of post-burn hypertrophic scarring.

Materials and Methods

This prospective randomized controlled trial included patients with completely epithelialized post-burn wound injury that were recruited from the Burn Unit of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. A flow diagram showing the patient enrollment, allocation, and treatment process is shown in Figure 1. Patients with a second-degree burn wound larger than 10% of their body surface area (10% BSA) that was completely epithelialized were eligible for enrollment. Patients having one or more of the following were excluded: age less than 18 years of age or greater than 70 years of age, scar formation for longer than 6 months, wound at face or perineum, known or suspected contact allergy to silicone gel, family history of hypertrophic or keloid scar, and/or received immunosuppressive agents, chemotherapy, or radiation therapy. All eligible and willing patients provided written informed consent to participate. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) (COA No. 309/2016).

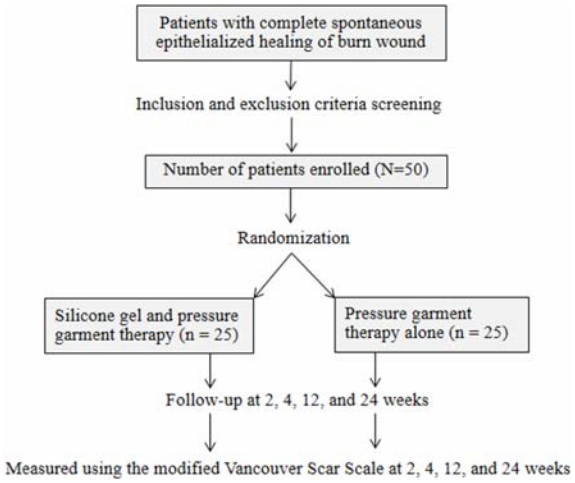

Figure 1. Protocol of this study.

Enrolled patients were randomly assigned to receive one of two treatments for 24 weeks. Patients assigned to the study group received silicone gel (Scagel® Si, Bangkok Botanica Co., Ltd., Thailand) combined with pressure garment therapy. Patients assigned to the control group received pressure garment therapy only. Silicone gel was applied to patients in the study group twice daily after bathing. All patients in both groups were followed-up at the 2-, 4-, 12-, and 24-week treatment time points.

The modified Vancouver Scar Scale (mVSS) was used to assess six scar-related parameters, including pigmentation, vascularity, pliability, height, pain, and itching. Scoring of the mVSS is shown in Table 1. The total mVSS represents the sum of all six parameter scores. Scar evaluation was conducted by an experienced surgeon who was blinded to the treatment allocation.

Statistical analysis

Quantitative data, such as mVSS score and age, were reported as mean±standard deviation, and qualitative data, such as gender and location of wound, were reported as frequency and percentage. Levene's test for equality of variances or t-test for equal means was used to compare values between groups. SPSS Statistics program (version 22) (SPSS, Inc., Chicago, IL, USA) was used for all data analyses. A *p*-value less than 0.05 was regarded as being statistically significant.

Results

Fifty patients were enrolled and equally divided into two groups of 25 patients each. The average age of patients and size of wound was 39.74±10.75 years and 95.95±29.30 cm^2, respectively. Most patients were male (36 patients, 72%), and the most common type of burn was flame burn (31 patients, 62%). More patients were burned at the upper extremities than at the lower extremities (29 patients, 58% vs. 21 patients, 42%, respectively). There was no significant difference between groups for age, gender, size of burn wound, or infection (Table 2). All patients in both groups were able to tolerate their assigned treatment for the full 24-week study period.

Compared to pressure garment alone, combining silicone gel with pressure garment was found to improve scar formation over the 24-week study period as measured by mVSS (Figure 2). The study group demonstrated significantly lower pigmentation (at week 24, $p<0.05$), increased pliability (at weeks 12 and 24, $p<0.05$), and decreased height (at week 24, $p<0.05$) than the control group; however, no significant difference was observed between groups for vascularity, pain, or itching. The total modified VSS was significantly lower in

Table 1. Modified Vancouver Scar Scale (mVSS) scoring for the six mVSS parameters

Parameter	Characteristics	Score	Parameter	Characteristics	Score
Pigmentation	Normal color	0	Vascularity	Normal color	0
	Hypopigmentation	1		Pink	1
	Mixed pigmentation	2		Red	2
	Hyperpigmentation	3		Purple	3
Pliability	Normal	0	Height	Normal(flat)	0
	Supple	1		<2 mm	1
	Yielding	2		<5 mm	2
	Firm	3		>5 mm	3
	Banding-rope	4			
	Contracture	5			
Pain	None	0	Itching	None	0
	Occasional	1		Occasional	1
	Required medication	2		Required medication	2

Table 2. Demographic and clinical characteristics compared between the study group (silicone gel + garment) and the control group (garment only) (n = 50)

Characteristics	Study group (n = 25)	Control group (n = 25)	*p*-value
Age (years), mean±SD	40.44±11.33	39.04±10.53	0.650
Male gender, n (%)	17 (68.0%)	19 (76.0%)	0.529
Size of wound (cm^2), mean+SD	94.55±28.14	97.35±30.94	0.640
Cause of burn, n (%)			
Flame	15 (60.0%)	16 (64.0%)	0.833
Scald	8 (32.0%)	8 (32.0%)	
Chemical	2 (8.0%)	1 (4.0%)	
Location of wound, n (%)			
Arm	14 (56.0%)	15 (60.0%)	0.774
Leg	11 (44.0%)	10 (40.0%)	
Infection, n (%)	2 (8.0%)	3(12.0%)	0.562

The *p*-value <0.05 indicates statistical significance

the study group than in the control group at both 12 weeks (6.0±1.5 vs. 7.0±1.4, $p = 0.02$) and 24 weeks (4.9±1.5 vs. 5.7±1.2, $p = 0.04$) (Table 3).

Discussion

Hypertrophic burn scars, which frequently occur in delayed wound healing, remain a challenge for both patients and healthcare providers. These scars can cause lifestyle-limiting problems, such as pruritus, pain, burning, stiffness, and contracture[14,15], that can adversely affect activities of daily living and reduce patient quality of life[16]. Silicone gel and pressure garment therapy have both been accepted treatments for burn scar management for over 40 years; however, there is minimal evidence to support their use[13].

The results of the present study demonstrate the significant benefit of combination silicone gel and pressure garment relative to pigmentation, pliability, and height, which is consistent with recent studies that reported improved scar coloration[17,18], hardness[19] and height[18,20]. Importantly and even though there was no significant difference between groups for pain, itching, and vascularity, the total mVSS score was statistically significantly different between groups at both the 12- and 24-week time points. In contrast, a previous study reported that combination topical silicone gel and pressure garment therapy demonstrated no benefit at six-months post-burn in children[21]. This difference in findings between studies may be due to continued growth in children compared to completed growth in adults. That group also reported less treatment compliance among their pediatric study population. Other positive findings of the use of silicone gel in a burn-related scar treatment setting were also published[19,22].

The strength of the present study is its prospective randomized controlled design. The notable limitation of this study is its inability to demonstrate the long-term outcome of this combination therapy in this clinical setting. A larger, longer-term study is needed to confirm these findings, and to identify the mechanisms of and factors associated with improvements in burn assessment parameters.

Conclusion

The present study demonstrated the statistically

significant benefit of combining silicone gel with pressure garment for post-burn hypertrophic scar prevention compared to pressure garment alone. Although there was no significant difference between groups for vascularity, pain, or itching, the combination therapy group had significantly lower pigmentation, pliability, and height than the pressure garment only group at 24-week time point.

What is already known on this topic?

The pressure garment is a famous conventional therapy of hypertrophic scar prevention; however, the results are still not completely successful. Recent studies have

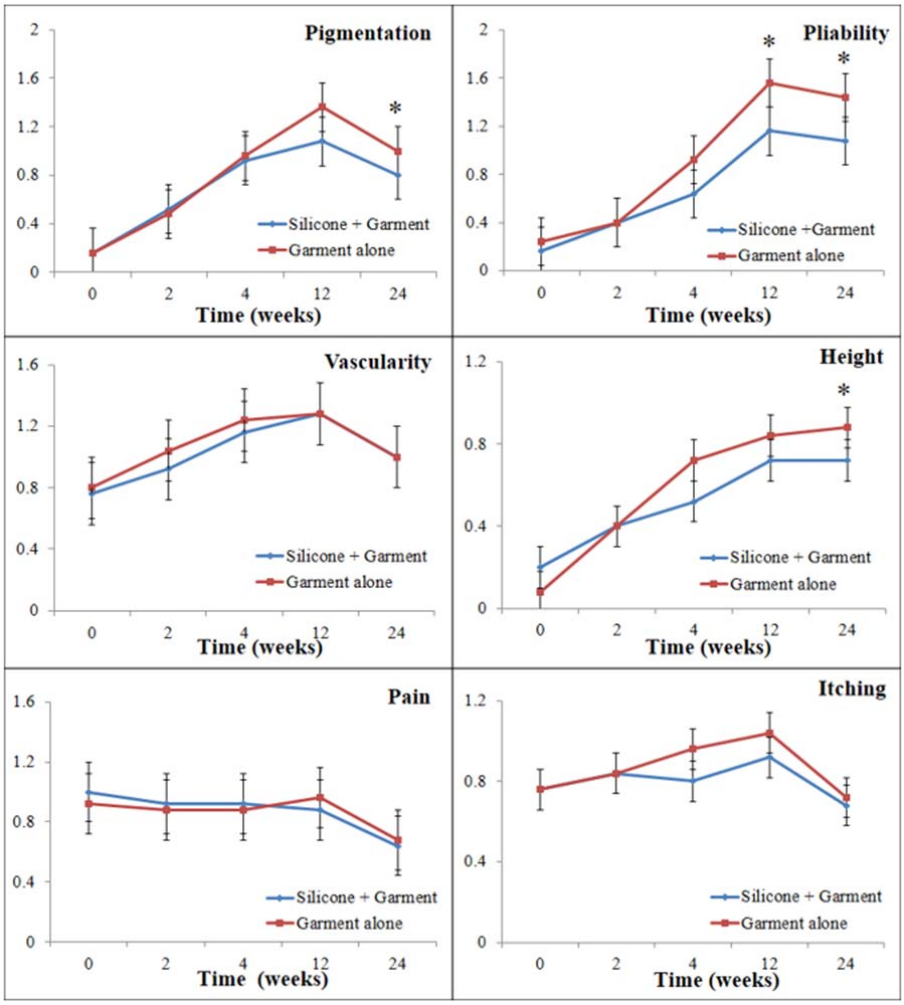

Figure 2. Comparison between silicone gel plus pressure garment and pressure garment alone in each parameter of mVSS score.

Table 3. Total modified Vancouver Scar Scale (mVSS) score compared between the study group (silicone gel + garment) and the control group (garment only) at 2, 4, 12, and 24 weeks

Total mVSS	Week 2	Week 4	Week 12	Week 24
Study group	4.1±1.5	5.0±1.3	6.0±1.5	4.9±1.5
Control group	3.9±1.5	5.6±1.8	7.0±1.4	5.7±1.2
p-value	0.64	0.21	0.02	0.04

The *p*-value <0.05 indicates statistical significance

reported the silicone gel offers efficiency in preventing scar formation.

What this study adds?

Using silicone gel combined with pressure garment therapy in adult patients has a potential in post-burn hypertrophic scar improvement than single treatment with pressure garment therapy.

Acknowledgements

The authors gratefully acknowledge the patients that agreed to participate in this study, Miss Suchada Kittidacha and nurses at Burn unit for assistance with data collection and statistical analysis.

Potential conflicts of interest

The authors declare no conflicts of interest.

References

1. Tompkins RG. Survival from burns in the new millennium: 70 years' experience from a single institution. Ann Surg 2015;261:263-8.
2. Stella M, Castagnoli C, Gangemi EN. Postburn scars: an update. Int J Low Extrem Wounds 2008;7:176-81.
3. Sanchez JL, Pereperez SB, Bastida JL, Martinez MM. Cost-utility analysis applied to the treatment of burn patients in a specialized center. Arch Surg 2007;142:50-7.
4. Aarabi S, Longaker MT, Gurtner GC. Hypertrophic scar formation following burns and trauma: new approaches to treatment. PLoS Med 2007;4:e234.
5. Mustoe TA, Cooter RD, Gold MH, Hobbs FD, Ramelet AA, Shakespeare PG, et al. International clinical recommendations on scar management. Plast Reconstr Surg 2002;110:560-71.
6. Mustoe TA. Evolution of silicone therapy and mechanism of action in scar management. Aesthetic Plast Surg 2008;32:82-92.
7. Arno AI, Gauglitz GG, Barret JP, Jeschke MG. Up-to-date approach to manage keloids and hypertrophic scars: a useful guide. Burns 2014;40:1255-66.
8. Monstrey S, Middelkoop E, Vranckx JJ, Bassetto F, Ziegler UE, Meaume S, et al. Updated scar management practical guidelines: non-invasive and invasive measures. J Plast Reconstr Aesthet Surg 2014;67:1017-25.
9. Reno F, Sabbatini M, Lombardi F, Stella M, Pezzuto C, Magliacani G, et al. In vitro mechanical compression induces apoptosis and regulates cytokines release in hypertrophic scars. Wound Repair Regen 2003;11:331-6.
10. Steinstraesser L, Flak E, Witte B, Ring A, Tilkorn D, Hauser J, et al. Pressure garment therapy alone and in combination with silicone for the prevention of hypertrophic scarring: randomized controlled trial with intraindividual comparison. Plast Reconstr Surg 2011;128:306e-13e.
11. Zurada JM, Kriegel D, Davis IC. Topical treatments for hypertrophic scars. J Am Acad Dermatol 2006;55:1024-31.
12. Mustoe TA, Gurjala A. The role of the epidermis and the mechanism of action of occlusive dressings in scarring. Wound Repair Regen 2011;19 Suppl 1:s16-21.
13. Stavrou D, Weissman O, Winkler E, Yankelson L, Millet E, Mushin OP, et al. Silicone-based scar therapy: a review of the literature. Aesthetic Plast Surg 2010;34:646-51.
14. Friedstat JS, Hultman CS. Hypertrophic burn scar management: what does the evidence show? A systematic review of randomized controlled trials. Ann Plast Surg 2014;72:S198-201.
15. Bloemen MC, van der Veer WM, Ulrich MM, van Zuijlen PP, Niessen FB, Middelkoop E. Prevention and curative management of hypertrophic scar formation. Burns 2009;35:463-75.
16. Richard R, Baryza MJ, Carr JA, Dewey WS, Dougherty ME, Forbes-Duchart L, et al. Burn rehabilitation and research: proceedings of a consensus summit. J Burn Care Res 2009;30:543-73.
17. Li-Tsang CW, Lau JC, Choi J, Chan CC, Jianan L. A prospective randomized clinical trial to investigate the effect of silicone gel sheeting (Cica-Care) on post-traumatic hypertrophic scar among the Chinese population. Burns 2006;32:678-83.
18. Goldberg DJ. Efficacy and safety of a novel 100% silicone scar gel treatment for early intervention in scar management. J Clin Aesthet Dermatol 2016;9:13-20.
19. Shirazi M, Mohammadi AA, Shamohammadi I, Mahboubi A, Makarem A. Efficacy of silicone gel in reducing scar formation after hypospadias repair: A randomized placebo-controlled trial. Res Rep Urol 2019;11:291-8.
20. Nimpoonyakampong K, Somcharit L, Namviriyachote N, Praditsuktavorn B, Chinaroonchai K, Muangman P. Comparison of efficacy of herbal extract plus silicone gel and silicone gel for the prevention postburn hypertrophic scars. J Med Assoc Thai 2017;100 Suppl 2:S126-31.
21. Wiseman J, Ware RS, Simons M, McPhail S, Kimble R, Dotta A, et al. Effectiveness of topical silicone gel and pressure garment therapy for burn scar prevention and management in children: a randomized controlled trial. Clin Rehabil 2020;34:120-31.
22. Puri N, Talwar A. The efficacy of silicone gel for the treatment of hypertrophic scars and keloids. J Cutan Aesthet Surg 2009;2:104-6.