Comparison of Efficacy of Herbal Extract Plus Silicone Gel and Silicone Gel for the Prevention Postburn Hypertrophic Scars

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Background: *Post-burn hypertrophic scar is one of the condition that cause functional and cosmetic problem for patients. Scar prevention gives better result treatment outcome.*
Objective: *This study was designed to compare the efficacy of post burn scar prevention between herbal extracts plus silicone derivative gel and silicone gel.*
Material and Method: *Forty patients who have second-degree burns more than 20% of total body surface area (TBSA) were selected and treated with three products; herbal extracts plus silicone derivative gel, silicone gel and placebo gel. Day 0 of this study was the day of wound closure with complete epithelialization. Each gel was applied on separated sites of wound twice daily for 24 weeks. The 10x10 cm^2 wound area was evaluated by using Modified Vancouver Scar Scale (MVSS) at 0, 1^{st}, 2^{nd}, 4^{th}, 8^{th}, 12^{th}, 16^{th}, 20^{th} and 24^{th} week.*
Results: *A total of 36 patients completed the study. In MVSS evaluation, the pliability score in silicone gel group was lower than placebo gel at 16^{th}, 20^{th} and 24^{th} week ($p = 0.0379$, 0.0027, and 0.0005, respectively). Vascularity silicone derivative gel was better than placebo at 16^{th}, 20^{th} and 24^{th} week ($p = 0.0135$, 0.0314, and 0.004, respectively). Silicone gel was better than placebo at 16^{th} week ($p = 0.0074$).*
Conclusion: *Both herbal extracts plus silicone derivative gel and silicone gel might be effective in preventing hypertrophic scar after burn injury and should consider to be used early after dermal burn wound healing especially in patients who have risk to develop postburn hypertrophic scar.*

Keywords: *Silicone gel, Herbal extract plus silicone gel, Burn scar, Scar gel*

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Deep second-degree burns need secondary wound healing modalities because it is inadequate epithelialization during healing which can cause wound contraction. Generally, the prevalence of scar formation after burn injury is about 30 to 90%[1-3], whereby hypertrophic scar is 40 to 70%[1,4] and contracted scar is 3 to 15%[1]. Burn scarring is a challenging problem for clinicians and patients who are concerned not only with cosmetic result but also impaired quality of life with the decreased range of motion, pain or itching. At the present time, there is no standard treatment for burn scar prevention.

There are many published regimens for the treatment or prevention of scars such as silicone gels, silicone gel sheet[5-10], direct pressure to the wound (massage), cryotherapy, steroid injection, radiation, immunosuppressive agent, laser, excision or herbal treatment (onion extract[2-3]). But there is no single therapy which can be considered as a satisfactory treatment[9,11-17]. Silicone sheet is used worldwide, especially in western countries, and it seem to decrease scar formation and hypertrophic scar, and mostly used for small wounds[7]. Patients who received this regimen may experience itching and discomfort symptoms from using silicone sheet. So silicone gel was developed to solve this problem, for easier in application[10,18-21]. This study compared the efficacy of postburn hypertrophic scar prevention between herbal extracts plus silicone

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derivative gel (Cybele scagel®, Bangkok Botanica Co., Ltd) and silicone gel (Dermatix®, Invida Pharmaceuticals Ltd).

Material and Method

Forty of second-degree burn wound cases with more than twenty percentage of total body surface area (TBSA) between age of 17 to 80 years old were enrolled. The wounds sized more than 10x10 cm^2 and located across the joint were excluded from the study. One patient had at least three extremities wounds. Each wound (size less than 10x10 cm^2 and site not involving joint and completely recover from secondary healing without any treatment) were randomized to receive topical treatment with derivative silicone gel plus herbal extracted (Cybele scagel®, Bangkok Botanica Co., Ltd), silicone gel (Dermatrix®, Invida Pharmaceuticals Ltd) or placebo gel. Instructions were provided by well-trained burn care nurses to each patient. Three topical gels (placebo, Scagel®, Dermatix®) were double blinded randomized for application on each extremity wound. Day 0 of this study was the day of wound closure by complete epithelialization and also be the first day of topical gel treatment. The gels were applied on each wound twice daily. The follow-up visits for burn wound scar evaluation were at 0, 1, 2, 4, 8, 12, 16, 20 and 24 weeks with Modified Vancouver scar scale (MVSS)[22] on 6 parameters (vascularity, pliability, pigmentation, height, pain, itching, Table 1).

Statistical analysis

SPSS software version 17 was used for analysis of the results. The MVSS were analyzed with ANOVA and Point Pair's t-test. The *p*-value of <0.05 is considered as significant. The descriptive data was reported in mean and standard deviation.

Results

A total of thirty-six patients were analyzed (male 28, 77.78%). Four patients were excluded because of no adherence with appointments (2 males and 2 females). Mean age was 36.33±11.55 years (18-56). Mean %TBSA burn was 37.52±10.53%. Flame burn was 83.33% and scald burn was 16.66% of cases.

This study showed that overall MVSS of derivative silicone gel plus herbal extract (Cybele scagel®) and silicone gel (Dermatix®) were statistically significant (*p*-value <0.05) better than placebo at 8-24 week (Fig. 1A-C). But there was no statistic difference (*p*-value = 0.61) between derivative silicone gel plus herbal extract (Cybele scagel®) group and silicone gel (Dermatix®) group.

Only the vascularity and pliability parameters were statistically significant (*p*-value <0.05). Vascularity of derivative silicone gel plus herbal extract group was

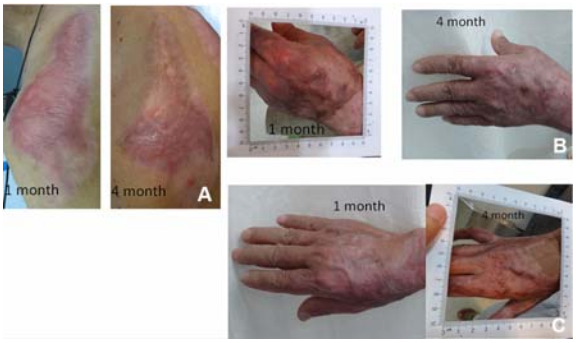

Fig. 1 A) Topical derivative silicone gel plus herbal extract treatment. B) Topical silicone gel treatment. C) Placebo gel treatment.

Table 1. The modified's Vancouver scar scale (MVSS)

Feature	Characteristics	Score	Feature	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			
	Supple	1	Height	Normal (flat)	0
	Yielding	2		<2 mm	1
	Firm	3		<5 mm	2
	Banding-rope	4		>5 mm	3
	Contracture	5			
Pain	0 = none, 1 = occasional, 2 = require medication				
Itching	0 = none, 1 = occasional, 2 = require medication				

significantly better than placebo group at 16, 20 and 24 week (p-value = 0.0135, 0.0314, 0.004, respectively), silicone gel group was significantly better than placebo group at 16 week (p-value = 0.0074). Pliability, silicone gel group was significantly better than placebo group at 16, 20 and 24 week (p-value = 0.0379, 0.0027, 0.0005, respectively). There was no significant difference in the results from derivative silicone gel plus herbal extract, placebo and silicone gel group in pigmentation, height, pain and itching (p-value >0.05). The overall of parameter scoring was demonstrated in Fig. 2-8.

Discussion

The efficacy of topical derivative silicone gel plus herbal extract (Cybele scagel®) and topical silicone gel (Dermatix®) demonstrated the role of scar

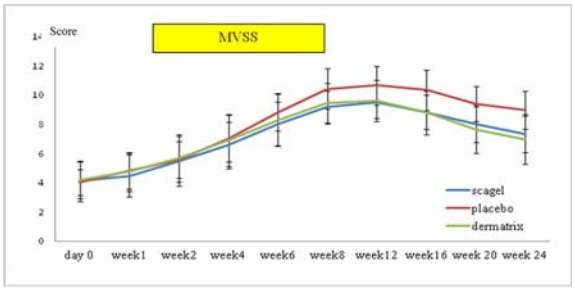

Fig. 2 Overall Modified vancouver scar scale (MVSS).

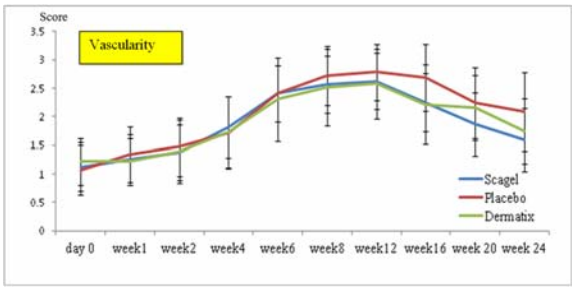

Fig. 3 Vascularity score.

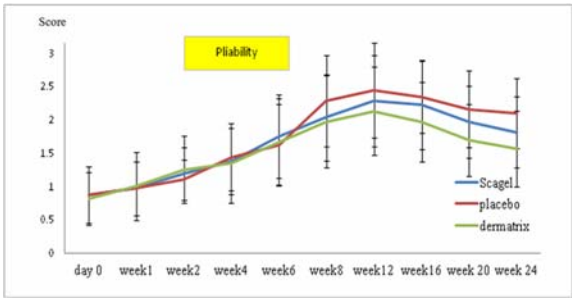

Fig. 4 Pliability score.

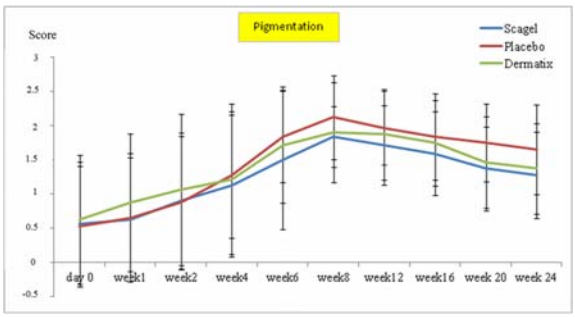

Fig. 5 Pigmentation score.

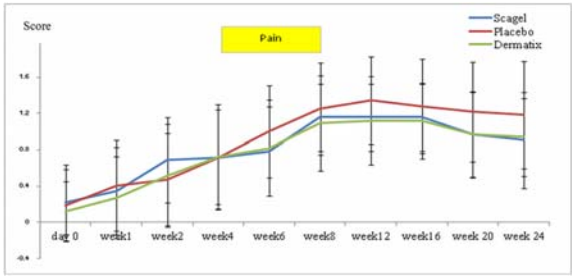

Fig. 6 Pain score

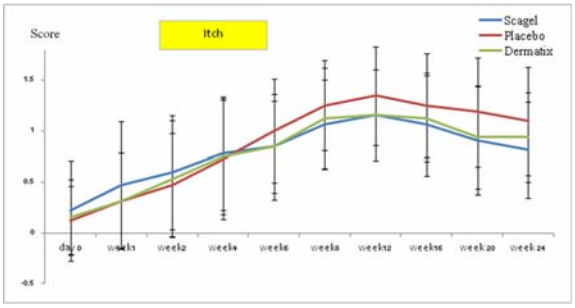

Fig. 7 Itching score.

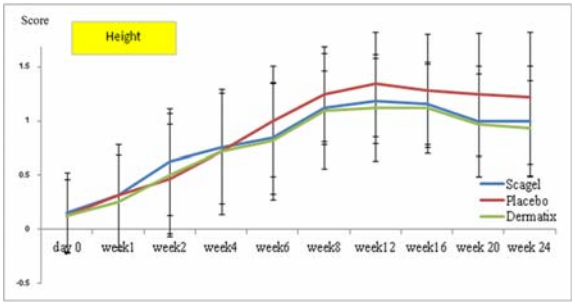

Fig. 8 Height score.

prevention from previous studies[6,22]. It may be concluded that their ingredient has efficacy in the prevention of scar formation. Higher silicone ratio may cause Dermatix® to have better pliability than Cybele scagel® and placebo. Silicone could moist wound environment in the prevention of epithelial dehydration and thus resulting in decrease of fibroblast activity and collagen production[7,23,24]. Cybele scagel® reduces itching and vascularity better than others but it's not significant. These effects may be from the herbal extracts (onion extract could decrease inflammation and itching via inhibit prostanoid releasing, Quercetin in onion extract could inhibit signal from Insulin-like growth factor (IGF)[25], decrease collagen synthesis). Asiaticoside from *Centella asiatica* also suppress collagen synthesis via inhibit TGF-β Smad signaling[26]. Mulberry and Tamarind extract could decrease skin pigmentation[27,28].

Conclusion

The authors concluded that both type of topical agents including the derivative silicone gel plus herbal extract (Cybele scagel®) and Silicone gel (Dermatix®) demonstrated benefit on postburn hypertrophic scar prevention. They cause significant decrease in overall MVSS, pliability and vascularity of the wound when compared to the placebo group.This study proved that both groups of topical agents should consider to be used early after dermal burn wound healing especially in patients who have high risk to develop postburn hypertrophic scar.

What is already known on this topic?

Previous studies were confirmed the benefit of silicone gel in post burn scar prevention.

What this study adds?

This study offered the new product of choice in post burn scar prevention by using topical agents including the derivative silicone gel plus herbal extract (Cybele scagel®) that showed comparable efficacy of treatment.

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Potential conflicts of interest

None.

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การเปรียบเทียบประสิทธิภาพของเจลซิลิโคนที่มีอนุพันธ์ผสมกับสารสกัดสมุนไพรกับเจลซิลิโคนในการป้องกันการเกิดแผลเป็นภายหลังบาดเจ็บแผลไหม้

โกสินทร์ นิ่มปุญญกำพงษ์, เลิศพงศ์ สมจริต, นันทพร นามวิริยะโชติ, บรรเจิด ประดิษฐ์สุขถาวร, กุสุมา ชินอรุณชัย, พรพรหม เมืองแมน

ภูมิหลัง: *แผลเป็นนูนหลังแผลไหม้ก่อปัญหาทั้งด้านการเคลื่อนไหวและความสวยงามให้ผู้ป่วย การป้องกันให้ผลการรักษาที่ดีกว่าการรักษาเมื่อเกิดแผลเป็นนูนแล้ว*

วัตถุประสงค์: *การศึกษานี้ออกแบบเพื่อเปรียบเทียบประสิทธิภาพของเจลที่มีอนุพันธ์ซิลิโคนผสมกับสารสกัดสมุนไพรกับเจลซิลิโคนในการป้องกันการเกิดแผลเป็นภายหลังบาดเจ็บแผลไหม้*

วัสดุและวิธีการ: *ผู้ป่วยจำนวน 40 รายที่ได้รับบาดเจ็บ แผลไหม้ระดับสองมากกว่าร้อยละ 20 ของพื้นที่ผิวร่างกาย ถูกคัดเลือกเพื่อรับการรักษาด้วยผลิตภัณฑ์สามแบบ เจลซิลิโคนที่มีอนุพันธ์ผสมสารสกัดสมุนไพร, เจลซิลิโคน และเจลหลอก วันที่ 0 ของการศึกษานี้หมายถึง วันที่แผลปิดโดยขบวนการงอกของเซลล์ผิวหนังโดยสมบูรณ์ เจลแต่ละชนิดใช้ทาแผลวันละสองครั้งเป็นเวลา 24 สัปดาห์ ในบาดแผลขนาด 10x10 ตารางเซนติเมตรจะได้รับการประเมินวัด Modified Vancouver Scar Scale (MVSS) ณ วันที่ 0, 1, 2, 4, 8, 12, 16, 20 และ 24 สัปดาห์*

ผลการศึกษา: *มีผู้ป่วย 36 รายได้รับการเก็บข้อมูลโดยสมบูรณ์ในการประเมินคะแนน MVSS คะแนนความแข็งของแผลในกลุ่มเจลซิลิโคนน้อยกว่ากลุ่มเจลหลอก ณ สัปดาห์ที่ 16, 20 และ 24 สัปดาห์ (p = 0.0379, 0.0027, 0.0005 ตามลำดับ) คะแนนของการมาเลี้ยงของเลือดบริเวณบาดแผลเจลซิลิโคนที่มีอนุพันธ์ผสมสารสกัดสมุนไพรรักษาได้ผลดีกว่าเจลหลอก ณ สัปดาห์ที่ 16, 20 และ 24 สัปดาห์ (p = 0.0135, 0.0314, 0.004, ตามลำดับ) เจลซิลิโคนให้ผลการรักษาดีกว่าเจลหลอก ณ สัปดาห์ที่ 16 (p = 0.0074)*

สรุป: *เจลซิลิโคนที่มีอนุพันธ์ผสมสารสกัดสมุนไพรและเจลซิลิโคนน่าจะมีประสิทธิภาพในการป้องกันแผลเป็นภายหลังได้รับบาดเจ็บแผลไหม้ และควรพิจารณาที่จะใช้ในระยะแรกเริ่มภายหลังการหายของบาดแผลไหม้ระดับลึกถึงชั้นหนังแท้ โดยเฉพาะอย่างยิ่งในผู้ป่วยที่มีปัจจัยเสี่ยงที่จะเกิดแผลเป็นภายหลังได้รับบาดเจ็บแผลไหม้*