Prospective Randomized Controlled Trial: Comparison Efficacy of Silicone Gel Sheets for Treatment of Post-Burn Hypertrophic Scars

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Background: *Post-burn hypertrophic scars are prevalent and they can cause significant functional and cosmetic impairment. Previous literatures has shown the beneficial effect of silicone gel sheet in treatment of hypertrophic scars but the literatures reported benefits in the original product which is more expensive and have the effects on financial burden of the patients that results in high cost of treatment.*
Objective: *To compare efficacy of silicone gel sheet between commercial brands of silicone gel sheet, Cicacare® and Actewound®, on post-burn hypertrophic scar.*
Material and Method: *Prospective randomized controlled trial was conducted in 30 patients with second to third degree burns with post-burn hypertrophic scar. Vancouver scar scale (VSS) was evaluated at 0, 2, 4, 8, 12, 16, 20, 24 weeks after treatment.*
Results: *No difference in pigmentation, pliability, pain, itching, vascularity, height, Vancouver scar scale (VSS) and satisfaction (physical appearance, adhesive properties, ease of application, patient comfort, uniform with skin, durability) between commercial brands of silicone gel sheet, Cicacare® and Actewound® groups ($p>0.05$). Both commercial brands of silicone gel sheets demonstrated comparable results; however the cost of treatment is less expensive with Actewound®.*
Conclusion: *Actewound® can be used as alternative, more affordable choice for management of post-burn hypertrophic scar.*

Keywords: *Silicone gel sheets, Hypertrophic scar, Post-burn scar, Scar treatment, Burns*

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Scar is an evitable damage of skin following by post traumatic, surgical procedure or after burn injury. It can cause significant functional loss and cosmetic problem as well as pain and pruritus that decrease the quality of life. Generally, 77% of post burn injury results in scars and develops hypertrophic scars (44%) and scar contracture (5%)[1].

Hypertrophic scar results from over production and abnormal arrangement of collagen in wound healing process. There are many modalities of the treatment of hypertrophic scar such as excision, laser, cryotherapy, topical agent (corticosteroid, vitamin A, vitamin E, herbal extract) and biophysical therapies[2].

The usefulness of silicone gel sheet in the management of hypertrophic scar has been reported in previous literatures[3,4]. The true mechanism is unknown but might be beneficial from maintaining a moisture environment in the wound healing process and helps in prevention and management of scar formation.

Cicacare® is an early brand of silicone gel sheet widely used in treatment of hypertrophic scar[4] but the cost of treatment is quite expensive and might not be appropriate for low income patients. In Siriraj hospital, the authors were interested in one commercial brand of silicone gel sheet called Actewound®, which is cheaper and easier to apply to the wound and which might also be useful in treatment of hypertrophic scar. This study was designed to compare two brands of silicone gel sheet Cicacare® and Actewound® in the efficacy and satisfactory aspects for treatment of hypertrophic scar post burn injury.

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Material and Method

This study was approved by Siriraj

Institutional Review Board (SIRB) committee to study in human research. This prospective, randomized control trial was performed in thirty second or third degree burn scar patients who were treated at Siriraj Burn Unit, Siriraj Hospital from September 2011 to September 2012. The exclusion criterias were age less than 18 years or more than 70 years, chronic scar over 6 months, history of allergy to silicone or history of keloid formation, wound at face and perineum and wound site infection.

Two wound areas that size less than 10x10 cm^2 in the post burn scar patients were selected for the treatment. The products (Cicacare® and Actewound®) were selected and randomized by box randomization. The silicone gel sheet was used to completely cover the wound. The sheet was observed by the patients and it was changed into the new one when it had loss the adhesive properties to stick on the wound.

Two experienced burn nurses who did not know the site of treatment were assigned to evaluate the burn scar. Demographic data were recorded; including age, sex, cause of injury, underlying disease and percentage of burn area to total body surface area. The modified Vancouver scar scale (VSS) which is composed of six parameters (pigmentation, vascularity, pliability, height, pain and itching) was used to assess the scar. The details of VSS were shown in Table 1. A digital camera was used to record serial change of the wounds during each follow-up. The heights of the wound were recorded as centimeters. The treatment and evaluated procedures started at week 0. Participants follow-up for observation were on 2, 4, 8, 12, 16, 20, 24 weeks. The scores of each product were compared during each follow-up. Patients' satisfactory was evaluated by a questionnaire including six parameters (physical appearance, adhesive properties, ease of application, patient comfort, uniform with skin color and durability). The questionnaire was evaluated by the patient at the end of study week 24.

SPSS software version 17 was used for analysis of the results. Significant differences of scar scale score parameters between two products were assessed by Paired t-test. A *p*-value of <0.05 was considered to be significant.

Results

There were 30 patients including of 17 males and 13 females. The mean age group was 34 years (18 to 55 years). The causes of burns were mainly scald burns (50%), flame burns (33%), others were chemical burns (10%) and electrical burns (6.67%). Two patients had hypertension. The mean percentage of total body surface area burn was 28% (range 16 to 45%).

The pigmentation, pliability and vascularity parameters from VSS scores gradually increased until reaching the highest at week 12 then gradually decreased. The height, pain and itching score were highest at week 16 and then gradually decreased. All parameters of VSS score (pigmentation, vascularity, pliability, height, pain and itching) were not statistically significant between both groups ($p>0.05$) as shown in Fig. 1.

Patients' satisfactory between both groups was not statistically significant in physical appearance, adhesive properties, ease of application, patient comfort, uniform with skin, durability and overall impression ($p>0.05$).

Table 1. The modified's Vancouver Scar Scale (VSS)

Feature	Characteristics	Score	Feature	Characteristics	Score
	Normal color	0		Normal color	0
Pigmentation	Hypopigmentation	1	Vascularity	Pink	1
	Mixed pigmentation	2		Red	2
	hyperpigmentation	3		Purple	3
	Normal	0			
	Supple	1		Normal (flat)	0
	Yielding	2		<2 mm	1
Pliability	Firm	3	Height	<5 mm	2
	Banding-rope	4		>5mm	3
	Contracture	5			

Pain (0 = none, 1 = occasional, 2 = require medication); Itching (0 = none, 1 = occasional, 2 = require medication)

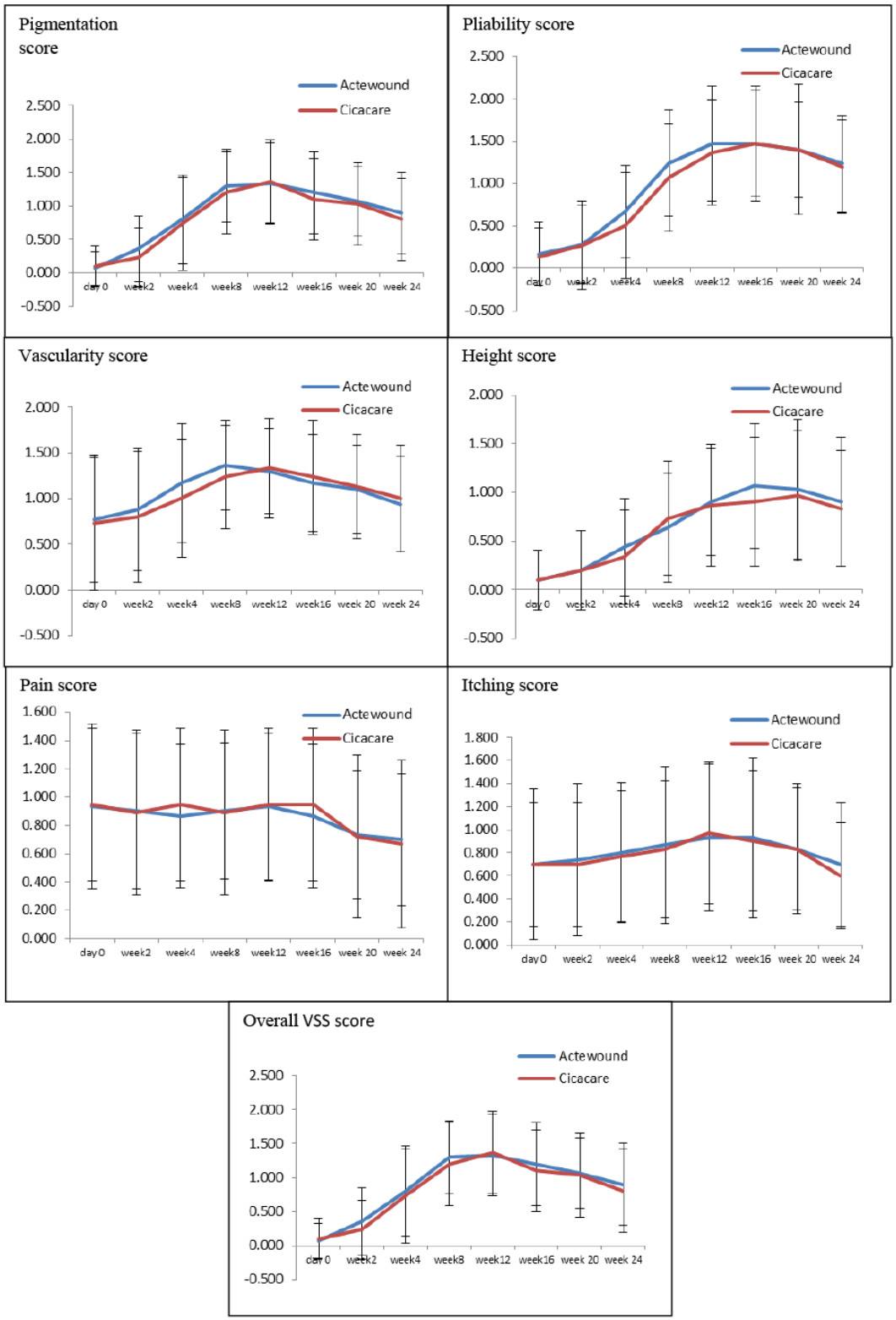

Fig. 1 The results of wound pigmentation, pliability, vascularity, height, pain, itching and total VSS score after treatment with Cicacare® and Actewound®.

Discussion

Silicone gel sheets are synthetic polymer that FDA approved for using in the management of hypertrophic scar since 1997[5]. They are believed to be effective for decreasing scar via wound hydration, increase statistic charge and modulation of growth factors, but they are not due to the pressure effect as garments[6-9]. There are many studies that reported the efficacy of silicone gel sheets and it is now one of the standard treatments for hypertrophic scars[6,8,10]. This study was a randomized controlled trial, whereby the limitation of the compounding factor of choice and selection of the wound in each patient to evaluate was excluded.

There was no statistically significant difference between the two brands of silicone gel sheets, Cicacare® and Actewound®, when modified Vancouver scar scale (VSS) was used to compare after treatment. It means that brands of silicone gel sheet are effective for treatment of post burn hypertrophic scar equally in benefit of treatment. In the current study, there was no control (no intervention group of patients) to compare with both intervention groups (silicone gel sheet groups), because authors believed that any hypertrophic scar should be treated more than let it be untreated. And the another reason was Cicacare®, the quite old brand silicone gel sheet, was studied and reported widely about its benefit in scar treatment that made it to be one of original and standard brand of silicone gel sheet using in burn scar treatment[4]. Patients' satisfactory of both groups had the same results. There was no statistically significant difference between Cicacare® and Actewound® in terms of physical appearance, adhesive properties, ease of application, patient comfort, uniform with skin color, durability and overall impression. The price of Actewound® is much lower than that of Cicacare® (2.85 bahts/cm^2 to 23.61 bahts/cm^2, respectively). Both commercial silicone gel sheets had comparable results in the management of post burn hypertrophic scar, however, the overall cost of treatment might be lower with Actewound®.

Conclusion

The commercial brand of silicone gel sheet, Actewound®, demonstrated comparable treatment results with the original and standard brand, however the total cost of treatment is less expensive in Actewound® group. It can be used as an alternative, cost saving choice for the management of post-burn hypertrophic scar.

What is already known on this topic?

Cicacare® was original and standard brand to be used to treat post-burn hypertrophic scar.

What this study adds?

Actewound® that is more cost saving from local made brand demonstrated comparable treatment results with the original and standard brand.

Potential conflicts of interest

None.

References

1. Gangemi EN, Gregori D, Berchialla P, Zingarelli E, Cairo M, Bollero D, et al. Epidemiology and risk factors for pathologic scarring after burn wounds. Arch Facial Plast Surg 2008; 10: 93-102.
2. Edriss AS, Mestak J. Management of keloid and hypertrophic scars. Ann Burns Fire Disasters 2005; 18: 202-10.
3. Poston J. The use of silicone gel sheeting in the management of hypertrophic and keloid scars. J Wound Care 2000; 9: 10-6.
4. 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.
5. Alster TS, West TB. Treatment of scars: a review. Ann Plast Surg 1997; 39: 418-32.
6. Meaume S, Pillouer-Prost A, Richert B, Roseeuw D, Vadoud J. Management of scars: updated practical guidelines and use of silicones. Eur J Dermatol 2014; 24: 435-43.
7. Mustoe TA. Evolution of silicone therapy and mechanism of action in scar management. Aesthetic Plast Surg 2008; 32: 82-92.
8. McCarty M. An evaluation of evidence regarding application of silicone gel sheeting for the management of hypertrophic scars and keloids. J Clin Aesthet Dermatol 2010; 3: 39-43.
9. Bleasdale B, Finnegan S, Murray K, Kelly S, Percival SL. The Use of Silicone Adhesives for Scar Reduction. Adv Wound Care (New Rochelle) 2015; 4: 422-30.
10. Muangman P, Aramwit P, Palapinyo S, Opasanon S, Chuangsuwanich A. Efficacy of the combination of herbal extracts and a silicone derivative in the treatment of hypertrophic scar formation after burn injury.Afr J Pharm Pharmacol 2011; 5: 442-6.

การศึกษาแบบสุ่มไปข้างหน้าเปรียบเทียบประสิทธิภาพของการการใช้แผ่นซิลิโคนเจลรักษาแผลเป็นนูนหลังบาดเจ็บแผลไหม้

พรพรหม เมืองแมน, วุฒิกร วงษ์ศิลาทัย, จตุพร ศิริกุล, กุสุมา ชินอรุณชัย, กฤษณ์ แก้วโรจน์

ภูมิหลัง: *ปัญหาแผลเป็นนูนหลังการบาดเจ็บไฟไหม้น้ำร้อนลวกเป็นปัญหาที่พบบ่อยและก่อให้เกิดปัญหาด้านการเคลื่อนไหวและด้านความสวยงาม งานวิจัยก่อนหน้านี้พบว่าการปิดแผ่นซิลิโคนเจลช่วยรักษาแผลเป็นนูนได้แต่แผ่นซิลิโคนตามที่ใช้ในงานวิจัยเป็นผลิตภัณฑ์ที่มีราคาแพง และผลจากงานวิจัยอ้างถึงผลการรักษาเฉพาะ จากผลิตภัณฑ์ที่ใช้ศึกษาในงานวิจัยเท่านั้น ทำให้ผู้ป่วยต้องแบกรับภาระค่าอุปกรณ์การรักษาที่มีราคาแพง*

วัตถุประสงค์: *การศึกษาวิจัยเพื่อเปรียบเทียบผลการรักษาแผลเป็นนูนหลังการบาดเจ็บแผลไหม้ระหว่างการใช้แผ่นซิลิโคนเจลที่ใช้กันทั่วไปและเป็นยี่ห้อที่อ้างอิงถึงจากงานวิจัยคือ cicacare กับแผ่นซิลิโคนเจล actewound ซึ่งเป็นผลิตภัณฑ์ที่ผลิตขึ้นในประเทศไทยและมีราคาถูกกว่าแบบดั้งเดิม*

วัสดุและวิธีการ: *ผู้ป่วยแผลเป็นนูนหลังการบาดเจ็บแผลไหม้ที่มีขนาดบาดแผลน้อยกว่า 10 ตารางเซนติเมตรถูกสุ่ม เพื่อแบ่งผู้ป่วยเข้ากลุ่มการรักษาด้วยการปิดแผลด้วยแผ่นซิลิโคน 2 ชนิดคือ cicacare และแผ่นซิลิโคนเจล actewound หลังจากนั้นผู้ป่วยจะติดตาม modified Vancouver scar scale (VSS) ตั้งแต่ก่อนเริ่มการใช้และที่ 2, 4, 8, 12, 16, 20, 24 สัปดาห์หลังได้รับการรักษา*

ผลการศึกษา: *มีผู้ป่วยแผลเป็นนูนหลังการบาดเจ็บแผลไหม้จำนวน 30 รายที่เข้าร่วมการวิจัยนี้ ผลการศึกษาไม่พบความแตกต่างของระดับของการเกิดแผลเป็นนูน (ความเข้มของสี ความนุ่ม ระดับความปวด อาการคัน การมีเลือดมาเลี้ยง (vascularity) และความสูง) ผลที่ประเมินด้วย modified Vancouver scar scale (VSS) และความพึงพอใจของผู้ป่วย (ลักษณะของแผ่นปิด การยึดเกาะของแผ่น ความยากง่ายในการลอกแผ่นออก ความสะดวกสบายในการใช้ การยึดติดของแผ่นกับผิวหนังและความทนทานของแผ่น) ต่อการใช้แผ่นซิลิโคนเจลยี่ห้อ actewound ที่เป็นผลิตภัณฑ์ใหม่เมื่อเทียบกับผลิตภัณฑ์ cicacare ที่เป็นผลิตภัณฑ์มาตรฐานที่ใช้รักษาแผลเป็นนูนอยู่ในปัจจุบัน ($p>0.05$)*

สรุป: *แผ่นปิดแผลซิลิโคนเจล actewound มีผลการรักษาแผลเป็นนูนเทียบเท่ากับแผ่นซิลิโคนเจลมาตราฐาน cicacare ในราคาที่ย่อมเยากว่าจึงสามารถนำมาใช้ทดแทนกันได้ในการรักษาแผลเป็นที่เกิดขึ้นภายหลังได้รับบาดเจ็บแผลไหม้*