

Does the form of dressings matter?

A comparison of the efficacy in the management of postoperative scars between silicone sheets and silicone gel: a randomized controlled trial

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Abstract

Background: Silicone sheet is commonly used for scar management but hard to apply to irregular surfaces or mobile areas, and difficult to conceal. On the contrary, silicone gel is easy to apply and nearly unnoticeable. Therefore, we conducted this study to compare their effectiveness.

Methods: Patients undergoing horizontal cesarean section were included. Surgical wounds were divided into 2 halves. Patients randomly applied silicone sheets and silicone gel on either side of their wounds for 3 months. The wounds were assessed at 1, 3, 6, and 12 months after surgery. We used the Vancouver Scar Scale (VSS) for an objective evaluation and the visual analog scale (VAS) for a subjective evaluation.

Results: There was no statistical significance between the silicone sheet and silicone gel groups with respect to VSS score. The silicone sheet group showed a statistically significant higher VAS score for itch at 1 month follow-up (1.18 ± 2.04 vs 0.35 ± 0.85 , $P = .01$). However, the difference was less than 1 on a scale of 10, so it might not be clinically meaningful.

Conclusion: Silicone sheet group showed statistically significant worse VAS score in terms of itch. However, the difference was too small to be clinically meaningful.

Abbreviations: VAS = visual analog scale, VSS = Vancouver Scar Scale.

Keywords: postoperative scar, silicone gel, silicone sheet

1. Introduction

Postoperative section scar is annoying but unavoidable. Scientists have left no stone unturned in the search for ways to prevent or reduce scar formation. Currently, silicone therapy has been a tried and true option for scar management.^[1] Among all forms of preparations, silicone sheet is one of the most common delivery methods, and its efficacy has been proven in a variety of clinical studies.^[2] However, it is difficult to fix, or hard to be unnoticeable. Silicone gel, introduced later

than sheet, has been gaining its popularity because it was easy to apply to all types of wound surfaces, and effortless to conceal.^[3] Its clinical efficacy has also been proven in several studies.^[4–6] To the best of our knowledge, there are 2 published studies comparing their effectiveness.^[7,8] However, the wounds of interest were not standardized, and the dressings were compared among 2 different groups of patients. To reduce potential bias, we conducted this study including head-to-head comparisons on the same patients to evaluate the effectiveness of silicone sheet and silicone gel in the management of postoperative section scars.

2. Patients and methods

This randomized controlled study was approved by the institutional review board of our hospital (ID: VGHKS97-051) and registered at ClinicalTrials.gov (NCT00849004). It was conducted at a medical center in southern Taiwan. Patients undergoing horizontal cesarean section (Pfannenstiel incision) were recruited. Patients with wound infection, those with a long-term use of systematic steroids, those using herbal agents, those with a history of an allergy to silicone, and those who could not tolerate the duration of dressing were excluded (Fig. 1). The wound of each patient was divided into 2 halves: right and left. Silicone sheet (CICA-CARE; Smith & Nephew, UK) was applied to one side and silicone gel (Cimeosil; Allied Biomedical, CA) was applied to the other side. We randomly assigned an allocation ratio of 1 to 1, and performed the randomization using a computerized random sequence generator with a block of 4. The use of each dressing was started 1 week postoperatively and persisted for 3 months. Each dressing was expected to be applied

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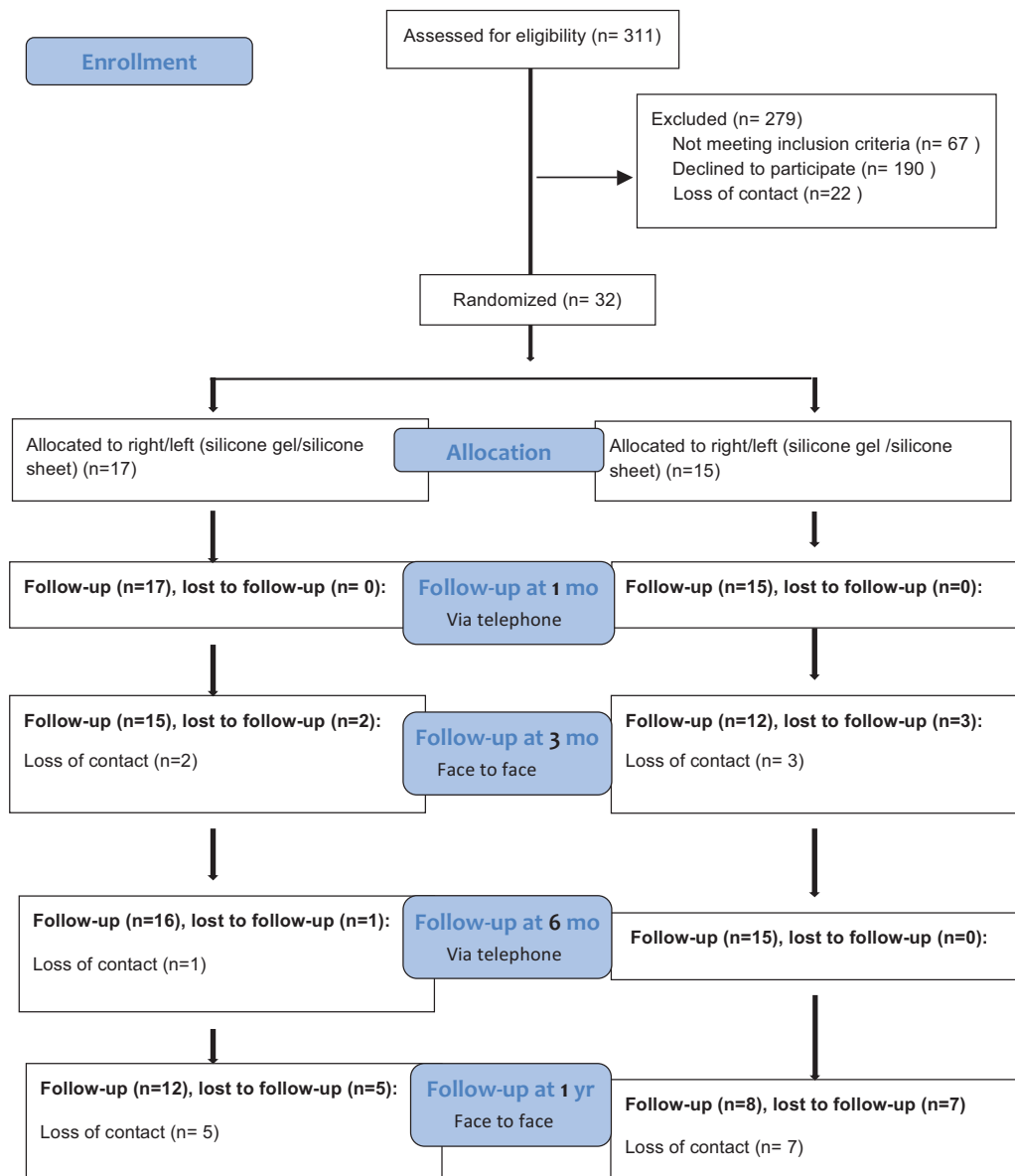


Figure 1. Flow chart.

for 24 hours/day, except while showering. For silicone gel, patients applied it twice daily in the morning and after shower. For silicone sheet, patients removed the sheet before shower, and reapplied it after it was washed clean. To ensure the patients' compliance during the trial period, the patients who had any difficulty using the dressings as our protocol would be excluded. The surgical scars were assessed at 1, 3, 6, and 12 months postoperatively. At 1 and 6 months postoperatively, a telephonic inquiry was conducted, whereas an in-person assessment was performed at a 3 and 12 months' follow-up. During the in-person follow-up, scars were evaluated and scored by the evaluators based on the Vancouver Scar Scale (VSS),^[9] composed of 4 parameters, pliability, height, vascularity, and pigmentation. At each of the 4 follow-up time points, patient-reported evaluations were performed on the basis of the visual analog scale (VAS) in terms of itch, pain, and scar appearance. For itch and pain, the higher score means the worse; For scar appearance, the higher score means the better. We used Stata 9.1 (StataCorp, Inc.,

College Station, TX) for statistical analysis. Estimated sample size calculation was performed with the following assumptions: power, 0.8; alpha, 5%; sampling ratio, 1:1; standard deviation, 3; and effect size, 2. The choice of 2 as effect size is because we plan a superiority trial and it is a more clinically meaningful difference.^[10,11] The estimated sample size was 36. Per-protocol analysis was adopted. Patients with missing data were excluded. A paired *t* test was used to compare the differences in mean scores of VAS at different time points. A Chi-squared test was used to compare the differences in each aspect of VSS. For subgroup analysis, Fisher exact test was used. A *P* value of <.05 was considered statistically significant.

3. Results

A total of 32 eligible patients were recruited from October 25, 2008, to October 24, 2013. All patients were Asians. Supplemental Table 1, <http://links.lww.com/MD/C383> presents

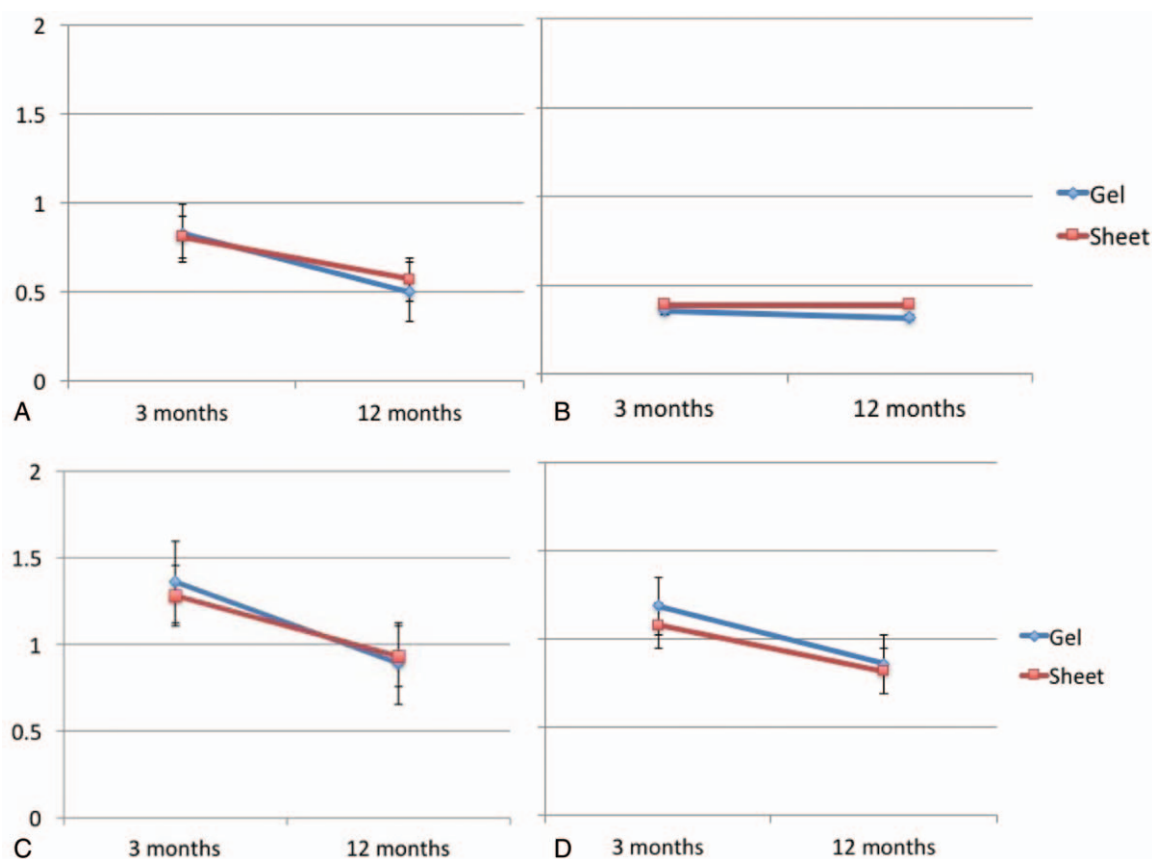


Figure 2. Comparison of Vancouver Scar Scale scores between silicone gel (Gel) and silicone sheet (Sheet) (A: Pliability; B: Height; C: Vascularity; D: Pigmentation); No statistical significance in either aspect; y-axis: Vancouver Scar Scale.

the baseline demographic characteristics. The average age was 33 ± 5.7 years. Only 1 patient (3.1%) had a history of diabetes mellitus. In terms of the objective VSS score, no statistically significant difference was found between the 2 groups with respect to pliability, height, vascularity, and pigmentation at postoperative 3 (Supplemental Table 2, <http://links.lww.com/MD/C383>) and 12 (Supplemental Table 3, <http://links.lww.com/MD/C383>) months' follow-ups (Fig. 2). In terms of the subjective VAS score, no statistically significant difference was found between the 2 groups with respect to pain or scar appearance at any of the follow-up time points, but the silicone sheet group had statistically significantly higher scores than the silicone gel group at 1 month's follow-up with respect to itch (1.18 ± 2.04 vs 0.35 ± 0.85 , $P = .01$) (Fig. 3). However, the statistical difference was less than 1 on a scale of 10, which might not be meaningful in the clinical context. In the subgroup with a history of keloid or hypertrophic scar, no statistically significant difference was found between the 2 dressings at any of the follow-up time points in terms of either VSS score (Fig. 4) or VAS score (Fig. 5).

4. Discussion

Postoperative scar formation is unavoidable. If the scars occur in a hypertrophic form, or accompanied with intractable itching sensation, patient's quality of life could be drastically jeopardized. Numerous treatment options have been developed to tackle this scar issue, such as corticosteroid injection,^[12] silicone sheet, silicone gel, paper tapes,^[13] laser

therapy,^[14,15] surgery,^[16] pressure therapy,^[17] radiotherapy,^[18] and cryotherapy.^[19] Among them, silicone-based dressing is currently considered the first-line option for scar management. A variety of possible mechanisms have been proposed, such as increased surface temperature,^[20] increased oxygen tension,^[21] hydration,^[22] or increased negatively charged static-electric field.^[23]

Silicone sheet, one of the most widely used forms of silicone-based dressings, was first found to be an effective treatment in 1983 for burn scar management.^[3] Several clinical trials have been conducted to prove the efficacy of silicone sheets.^[2] Despite its popularity, however, it is difficult to stay fixed in some irregular surfaces or mobile areas, and is easily noticeable. The need for additional taping to fix the silicone sheet is likely to cause irritation or excessive sweating over the surrounding skin, leading to discomfort and lower compliance. Silicone gel, on the contrary, could be easily applied to any irregular scar surfaces, any size of scar, and mobile parts such as joints. Its transparency could also alleviate patients' cosmetic concern. Its efficacy for scar management has also been proven in several studies. However, silicone gel still has some downsides. For example, it needs to be applied multiple times during the day because it could be wiped out by clothes after sweating. It is also better to combine with sunscreen to prevent hyperpigmentation. So far, 2 studies had been published to compare the effectiveness between silicone sheet and gel,^[7,8] but a head-to-head comparative study has been lacking. Therefore, we conducted this randomized controlled trial to tackle this issue.

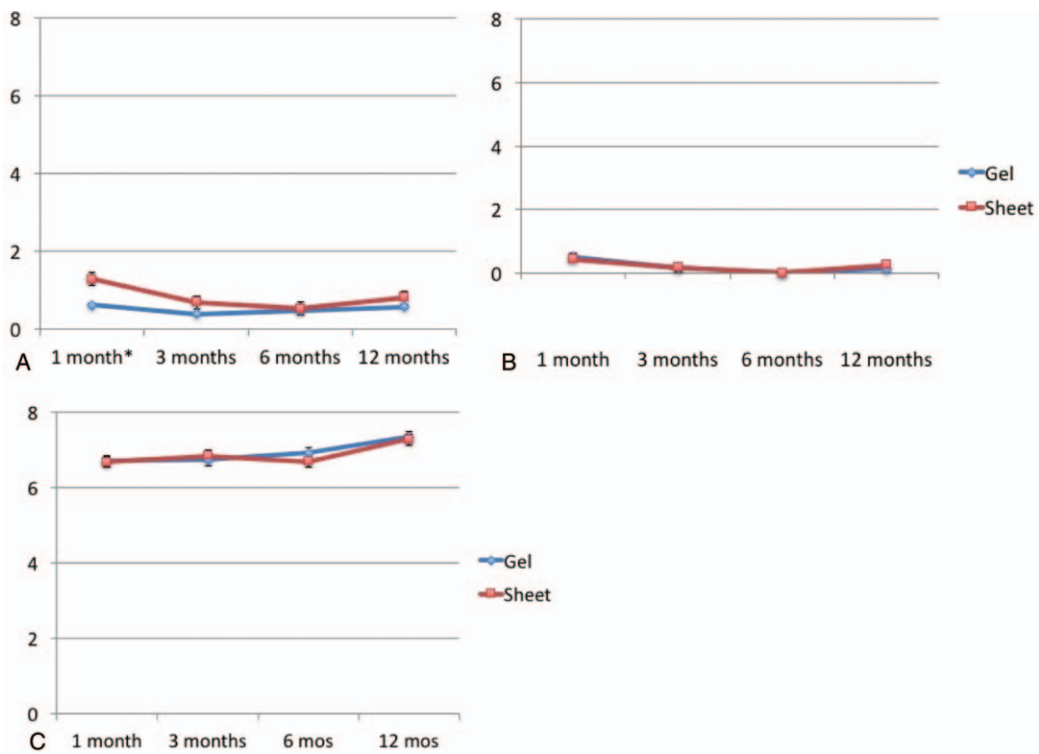


Figure 3. Comparison of visual analog scale (VAS) scores for itch (A), pain (B), and scar appearance (C) between silicone gel (Gel) and silicone sheet (Sheet); * $P < .05$; y-axis: Visual analog scale. For itch and pain, the higher score means the worse; For scar appearance, the higher score means the better.

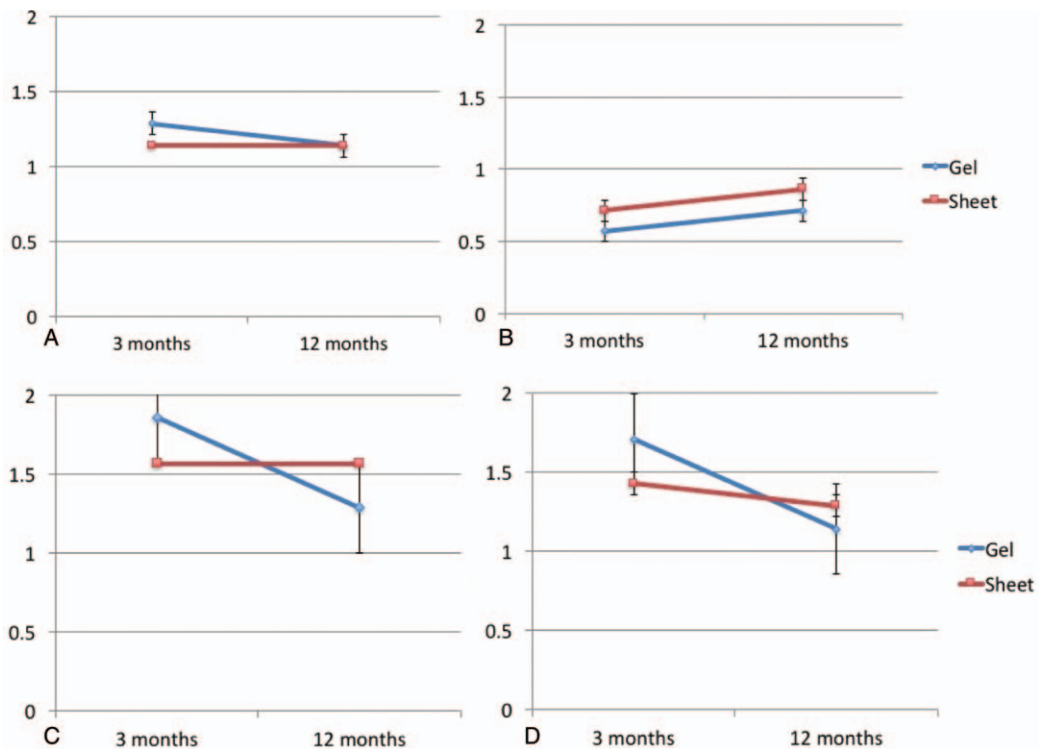


Figure 4. Comparison of Vancouver Scar Scale scores between silicone gel (Gel) and silicone sheet (Sheet) in the subgroup with a history of keloid or hypertrophic scar (A: Pliability; B: Height; C: Vascularity; D: Pigmentation); No statistical significance in either aspect; y-axis: Vancouver Scar Scale.

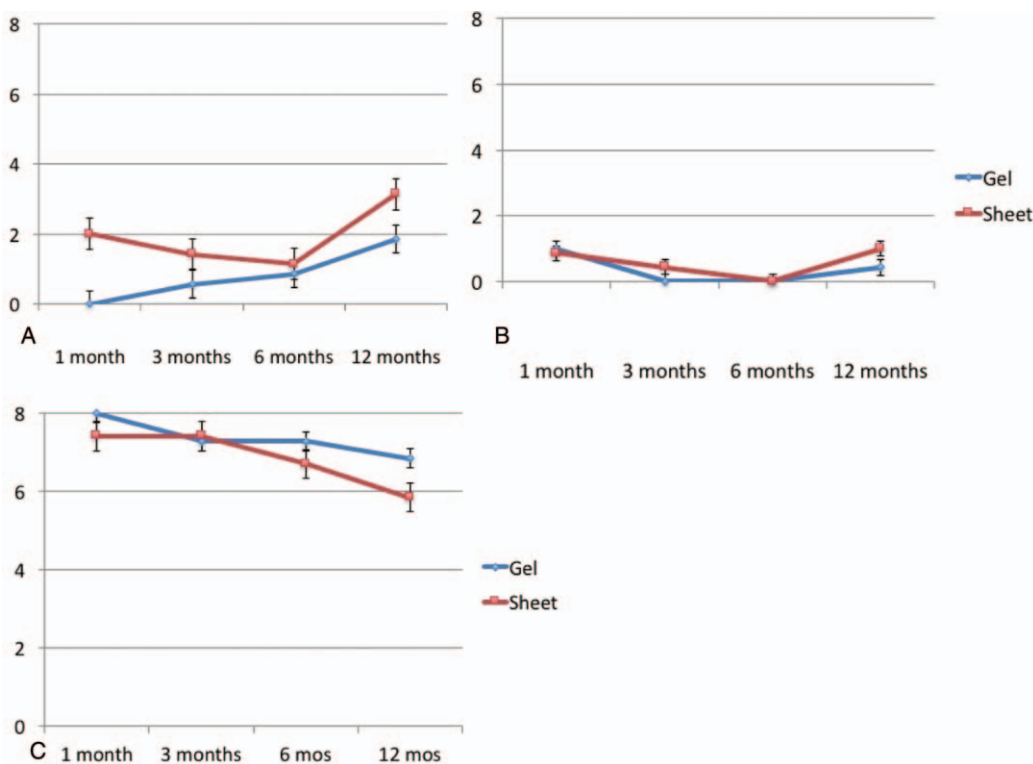


Figure 5. Comparison of visual analog scale (VAS) scores for itch (A), pain (B), and scar appearance (C) between silicone gel (Gel) and silicone sheet (Sheet) in the subgroup with a history of keloid or hypertrophic scar; No statistical difference was noted at each time point.; y-axis: Visual analog scale. For itch and pain, the higher score means the worse; For scar appearance, the higher score means the better.

Our study revealed no statistically significant difference in VSS score at 3 months (Supplemental Table 2, <http://links.lww.com/MD/C383>) and 12 months (Supplemental Table 3, <http://links.lww.com/MD/C383>). On the basis of the VAS score, our study revealed statistically significant differences in terms of itch at 1 month's follow-up (Fig. 3). The possible explanation is that we started the study 1 week postoperatively, when the wound just healed. In this period, patients were more likely to feel itchy. The form of gel was more likely to provide some cool feelings, which could help alleviate the itchiness during this period. After the first month, when the wounds became more stable and less itchy, neither silicone gel nor sheet could have significant effects on itchiness alleviation. In addition, despite observing statistically significant differences during the follow-up period, the differences in the scores were less than 1 on a scale of 10, which were too small to be clinically significant for most patients. The statistical differences might be only meaningful for some extremely appearance-conscious patients.

In our study, both dressings were applied on the same patient. The benefit of such a design is that all the confounding factors between individuals can be removed. In addition, the duration of scar maturation is approximately 6 months to 1 year, so our 12-month follow-up should be long enough to prove the effect of dressings on scars. Some people might argue that the horizontal cesarean section wounds were less scar-prone because they were parallel to Langer lines. However, on the basis of our experience, most of our patients, made up of Asian, were still widely annoyed by the postpartum scar problems (Fig. 6). Therefore, this study implemented on the cesarean wounds was still of its clinical importance. For those patients with a history of keloid or hypertrophic scar, our subgroup analysis did not find any statistically significant difference between the 2 dressings in any of the follow-up time points (Figs. 4 and 5). The small sample size (n=7) in this subgroup might result in insufficient power to analyze effectively, so further study could focus on this specific group of patients.

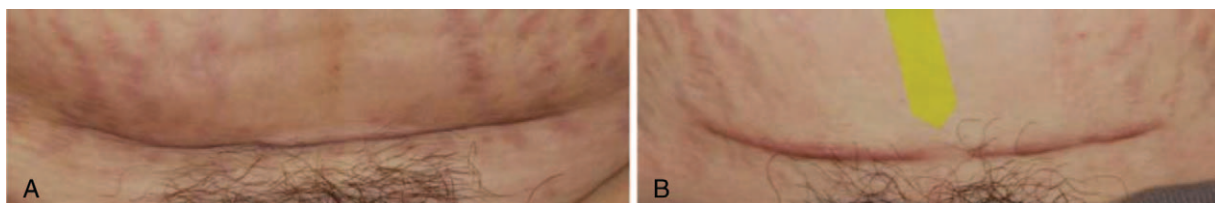


Figure 6. (A) Postoperative 3-month cesarean section scar (B) Postoperative 1-year cesarean section scar; For each photo, left half (from patient's perspective) scar was treated with silicone sheet, and right half scar was treated with silicone gel.

There was no denying that there were some limitations in this study. First, it was the lack of blinding; patients and evaluators were both aware of the type of dressing applied to each side of the wounds. For patients' side, it is nearly impossible to do the blinding. For evaluators' side, we might ask patients to remove the dressings before the evaluators come to assess the scars, which should be taken into consideration in further study design. Second, there was no control group. The ideal control group should be no treatment at all. However, this might be unethical for us to conduct this kind of trial and difficult for patients to comply with, as the scars resulting from cesarean section were usually obvious in Asian patients (Fig. 6). Third, our study was only conducted in Asian patients. It is widely known that ethnicity certainly plays an important role on scar formation. Caucasians are less likely to develop scar. On the basis of the study by Ince et al,^[24] wound location in the body, genetic characteristics of patients, and dermal thickness are well-known causes of hypertrophic scars. Therefore, further study might be implemented in a multiethnicity setting and in different locations in the body. Fourth, 3 research assistants were responsible for the assessment of VSS, which seemingly might lead to potential subjective bias. However, our study design was a head-to-head comparison between 2 dressings on the same patient. Unless the research assistants had different judgment standards for different dressings, the study result should not be largely affected. Lastly, there were loss of follow-ups; At each follow-up time point, we had a varying portion of patients whom we could not reach. However, every lost to follow-up patient contributed equally to the missing data for both the dressings, reducing the bias between groups. In addition, our original sample size estimation was based on the standard deviation of 3. However, most of our dataset had the standard deviation less than 2, which could compensate the power loss due to those lost-to-follow-up patients. In other words, despite a certain portion of patients lost to follow-up in some time points, we still have enough statistical power to detect any clinically meaningful difference, which was corroborated by our further power analysis revealing that the detectable minimal difference at each follow-up time points were less than 3.

Postoperative skin conditions such as scarring might be related to the menstrual cycles that contribute to hormonal fluctuation.^[25] Therefore, to follow-up at different phases of the menstrual cycle might have different scar presentations. In addition, for postpartum women, the return of the normal menstrual cycle is affected by the choice between breastfeeding and formula-feeding. Those information was lacking in our study. However, because we were comparing one half of the scar with the other on the same patient, the impact from this potential confounding factor should be limited.

5. Conclusion

Statistically speaking, silicone sheet is not different from silicone gel in any aspect of VSS at 3 and 12 months' follow-ups but is inferior to silicone gel in terms of itch in VAS at 1 month's follow-up. However, the statistical difference might be too small to be clinically meaningful. The clinical importance should be judged individually both by patients and clinicians.

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References

- [1] Meaume S, Le Pillouer-Prost A, Richert B, et al. Management of scars: updated practical guidelines and use of silicones. *Eur J Dermatol* 2014;24:435–43.
- [2] O'Brien L, Pandit A. Silicon gel sheeting for preventing and treating hypertrophic and keloid scars. *Cochrane Database Syst Rev* 2006; CD003826.
- [3] Perkins K, Davey R, Wallis K. Silicone gel: a new treatment for burn scars and contractures. *Burns* 1983;9:201–4.
- [4] Chernoff WG, Cramer H, Su-Huang S. The efficacy of topical silicone gel elastomers in the treatment of hypertrophic scars, keloid scars, and post-laser exfoliation erythema. *Aesthetic Plast Surg* 2007;31:495–500.
- [5] Murison M, James W. Preliminary evaluation of the efficacy of dermatix silicone gel in the reduction of scar elevation and pigmentation., *J Plast Reconstr Aesthet Surg* 2006;59:437–9.
- [6] Chan KY, Lau CL, Adeeb SM, et al. A randomized, placebo-controlled, double-blind, prospective clinical trial of silicone gel in prevention of hypertrophic scar development in median sternotomy wound. *Plast Reconstr Surg* 2005;116:1013–20.
- [7] Kim S-M, Choi J-S, Lee J-H, et al. Prevention of postsurgical scars: comparison of efficacy and convenience between silicone gel sheet and topical silicone gel. *J Korean Med Sci* 2014;29:S249–53.
- [8] Karagoz H, Yuksel F, Ulkur E, et al. Comparison of efficacy of silicone gel, silicone gel sheeting, and topical onion extract including heparin and allantoin for the treatment of postburn hypertrophic scars. *Burns* 2009;35:1097–103.
- [9] Baryza MJ, Baryza GA. The Vancouver Scar Scale: an administration tool and its interrater reliability. *J Burn Care Rehabil* 1995;16:535–8.
- [10] Gassner HG, Brissett AE, Otley CC, et al. Botulinum toxin to improve facial wound healing: a prospective, blinded, placebo-controlled study. *Mayo Clin Proc* 2006; 81:1023–1028.
- [11] Quinn J, Wells G, Sutcliffe T, et al. Tissue adhesive versus suture wound repair at 1 year: randomized clinical trial correlating early, 3-month, and 1-year cosmetic outcome. *Ann Emerg Med* 1998;32:645–9.
- [12] Giovannini UM. Treatment of scars by steroid injections. *Wound Repair Regen* 2002;10:116–7.
- [13] Atkinson J-AM, McKenna KT, Barnett AG, et al. A randomized, controlled trial to determine the efficacy of paper tape in preventing hypertrophic scar formation in surgical incisions that traverse Langer's skin tension lines. *Plast Reconstr Surg* 2005;116:1648–56.
- [14] Bouzari N, Davis SC, Nouri K. Laser treatment of keloids and hypertrophic scars. *Int J Dermatol* 2007;46:80–8.
- [15] Chan HH, Wong DS, Ho W, et al. The use of pulsed dye laser for the prevention and treatment of hypertrophic scars in Chinese persons. *Dermatol Surg* 2004;30:987–94.
- [16] Kelly AP. Medical and surgical therapies for keloids. *Dermatol Ther* 2004;17:212–8.
- [17] Macintyre L, Baird M. Pressure garments for use in the treatment of hypertrophic scars—a review of the problems associated with their use. *Burns* 2006;32:10–5.
- [18] Dinh Q, Veness M, Richards S. Role of adjuvant radiotherapy in recurrent earlobe keloids. *Aust J Dermatol* 2004;45:162–6.
- [19] Har-Shai Y, Amar M, Sabo E. Intralesional cryotherapy for enhancing the involution of hypertrophic scars and keloids. *Plast Reconstr Surg* 2003;111:1841–52.
- [20] Musgrave MA, Umraw N, Fish JS, et al. The effect of silicone gel sheets on perfusion of hypertrophic burn scars. *J Burn Care Rehabil* 2002; 23:208–14.
- [21] Gilman TH. Silicone sheet for treatment and prevention of hypertrophic scar: a new proposal for the mechanism of efficacy. *Wound Repair Regen* 2003;11:235–6.

- [22] Suetake T, Sasai S, Zhen Y-X, et al. Effects of silicone gel sheet on the stratum corneum hydration. *Br J Plast Surg* 2000;53: 503–7.
- [23] Hirshowitz B, Lindenbaum E, Har-Shai Y, et al. Static-electric field induction by a silicone cushion for the treatment of hypertrophic and keloid scars. *Plast Reconstr Surg* 1998;101:1173–83.
- [24] Ince B, Dadaci M, Oltulu P, et al. Effect of dermal thickness on scars in women with type III–IV fitzpatrick skin. *Aesthetic Plast Surg* 2015;39: 318–24.
- [25] Oranges CM, Meier C, Schaefer DJ. Surgical timing and the menstrual cycle affect wound healing in young breast reduction patients. *Plast Reconstr Surg* 2016;138:547e.