



# Elastic Silicone Occlusive Sheeting Versus Silicone Occlusive Sheeting in the Treatment of Scars: A Randomized Controlled Trial

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## ABSTRACT

**Introduction:** Hypertrophic scarring caused by conventional open thyroidectomy is prevalent among Asians and published trials have proved that silicone occlusive sheeting is a useful treatment for hypertrophic scarring. However, silicone occlusive sheeting does not effectively prevent scar widening. Here, we report elastic silicone occlusive sheeting as a new type of silicone application. In this study, we compared the effects of elastic silicone occlusive sheeting on scar width and appearance after conventional open thyroidectomy with those of silicone occlusive sheeting.

**Methods:** In this prospective, randomized, assessor-blinded study, a total of 74 patients

who underwent conventional open thyroidectomy were recruited to undergo elastic silicone occlusive sheeting and silicone occlusive sheeting on the healed wound. Scar width, Vancouver scar scale, pain/itching visual analogue scale, and patients' subjective degree of satisfaction with the scar, during the patients' 6-month review.

**Results:** A total of 61 patients completed the study. Scar width, Vancouver scar scale score, and patients' subjective degree of satisfaction indicated that elastic silicone occlusive sheeting was associated with narrower scars and significant improvement in scar appearance. The two methods did not differ significantly with regard to pain/itching visual analogue scale.

**Conclusions:** Our findings highlight elastic silicone occlusive sheeting as an effective treatment for scarring, resulting in narrower and better scars after conventional open thyroidectomy. The use of elastic silicone occlusive sheeting after conventional open thyroidectomy may minimize the formation of hypertrophic scars in the early postoperative period.

**Trial Registration:** ChiCTR2100049740.

**Keywords:** Scar; Scar width; Tension; Silicone occlusive sheeting; Elastic silicone occlusive sheeting; Conventional open thyroidectomy

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### Key Summary Points

Hypertrophic scarring caused by conventional open thyroidectomy is prevalent and an effective treatment is badly needed.

Silicone occlusive sheeting is not highly efficient at reducing scar width while various clinical trials have shown that it effectively prevents pathological scarring.

Elastic silicone occlusive sheeting is a relatively new form of silicone application that combines occlusion and tension offloading but no study has found this combination to be more effective than either strategy alone.

The study compared the effects of elastic silicone occlusive sheeting versus silicone occlusive sheeting on scar width and appearance after conventional open thyroidectomy.

#### *What was learned from the study?*

Elastic silicone occlusive sheeting overcomes the shortcomings of the silicone occlusive sheeting, which has limited capacity to reduce scar width.

Scar width and scar appearance especially in the terms of vascularity and pigmentation are improved by using elastic silicone occlusive sheeting compared with silicone occlusive sheeting.

## INTRODUCTION

Since the year 2000, the incidence of thyroid cancer is reported to be rising significantly. Thyroid cancer is mainly treated through conventional open thyroidectomy, which creates a large incision and forms a disfigured scar. Studies indicate that the risk of pathologic scarring is higher in Asian patients than in Caucasians [1, 2].

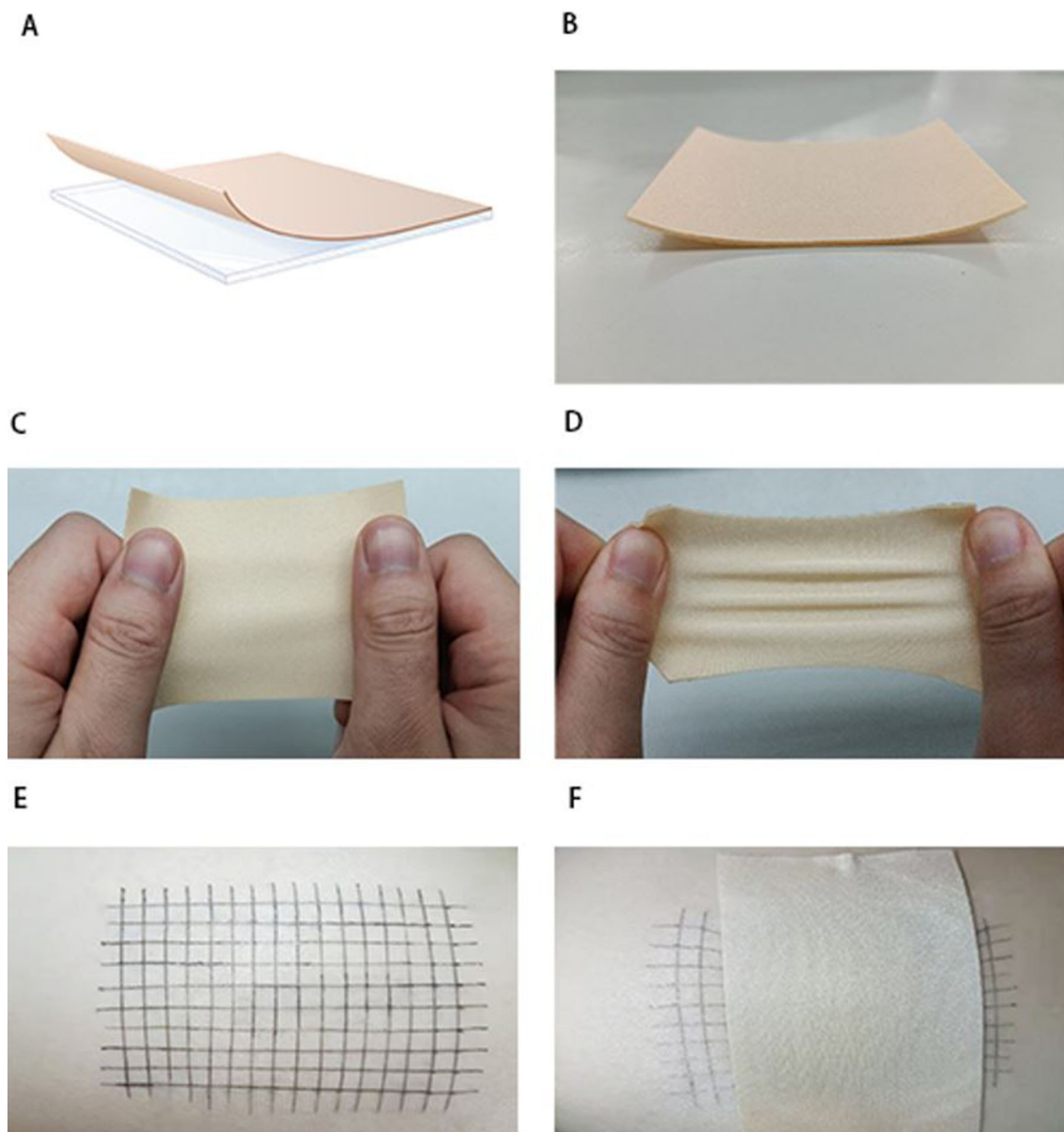
Pathologic scars include hypertrophic scars, which remain within the boundaries of the original lesion, and keloids, which tend to expand beyond the boundaries of the original lesion. It is widely accepted that the tension acting on the wound edges is a major contributor to the disfiguring caused by scars. Wounds in areas of high tension, such as the manubrium, scapula, and joint, have a higher likelihood of developing wide pathological scars [3]. The neck is an area of frequent movement and high tension, which increase the risk of pathologic scarring. Although a wide range of treatments have been proposed for the prevention and minimization of pathological scarring, treatments capable of reducing tension around the wounds are limited.

Although various randomized clinical trials have shown that silicone occlusive sheeting effectively prevents pathological scarring [4–6], it is not highly efficient at reducing scar width. Clinically, tension offloading devices are used to reduce tension around the wound. However, tension offloading devices do not improve scar height, pigmentation, and pliability. To improve scar appearance, anti-scar treatments like silicone gels are often used. Additionally, the use of tension offloading devices is associated with a high rate of skin maceration, which limits wider clinical use of the device. Thus, more effective approaches are needed for the treatment of scar pathogenesis. Elastic silicone occlusive sheeting is a relatively new form of silicone application that combines occlusion and tension offloading. To date, no study has found this combination to be more effective than either strategy alone. Here, we compared the effects of elastic silicone occlusive sheeting versus silicone occlusive sheeting on scar width and appearance after conventional open thyroidectomy.

## METHODS

### Elastic Silicone Occlusive Sheeting and Comparator

The elastic silicone occlusive sheeting has an elastic backing layer on one side and a silicone

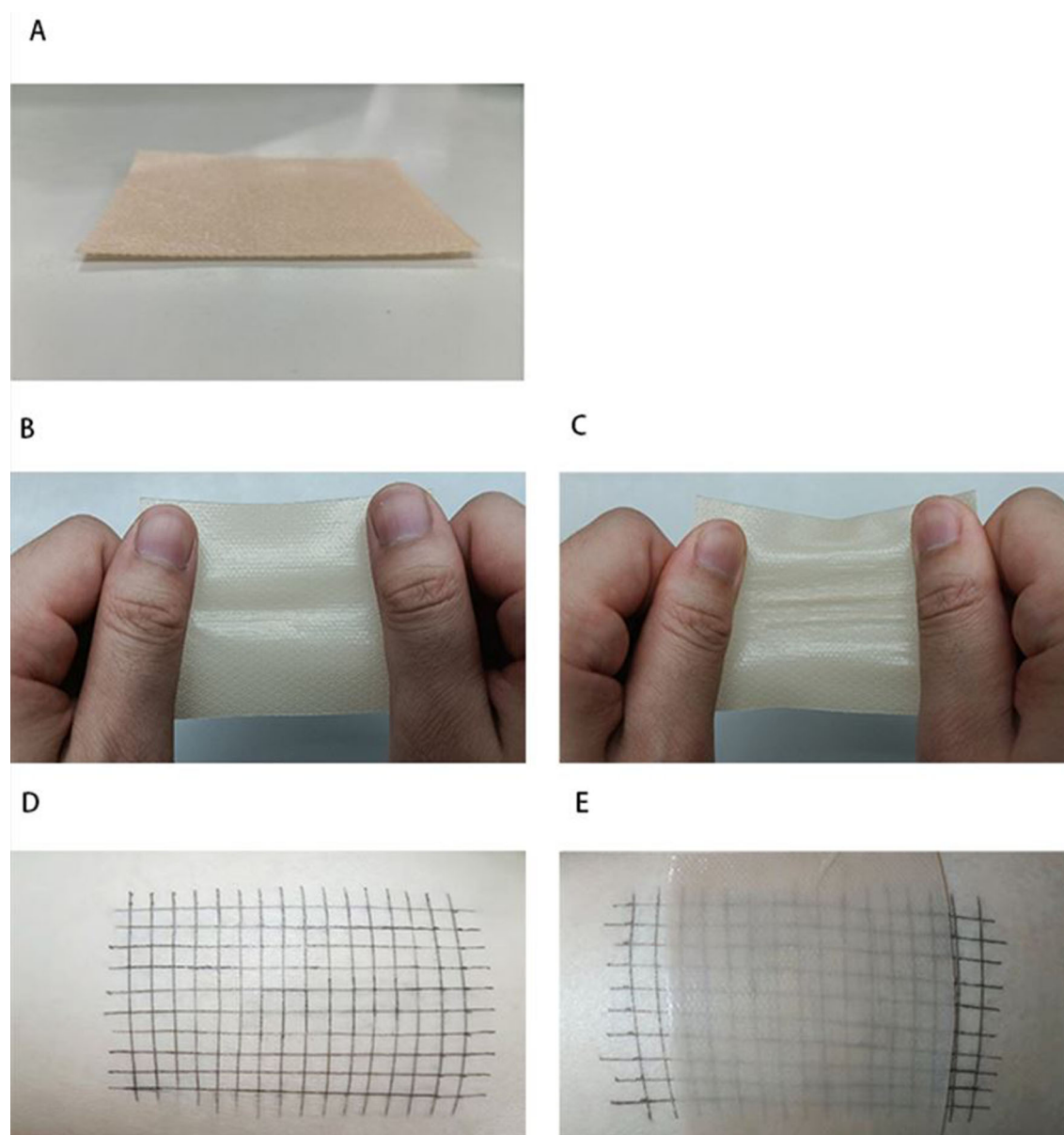


**Fig. 1** The elastic silicone occlusive sheeting. **A** An illustration of an elastic layer on the upper side and a silicone gel structure on the inferior side of the elastic silicone occlusive sheeting used as the experimental group. **B** The actual shape of the elastic silicone occlusive

sheeting. The thickness, width, and length are 0.9 mm, 60 mm and 80 mm, respectively. The elastic silicone occlusive sheeting **C** before and **D** after stretching. Elastic silicone occlusive sheeting **E** before and **F** after application on the skin

gel structure on the other. Its underlying principle is based on stress and strain, ensuring enough elasticity and resilience to reduce tension around the wound. Elastic silicone occlusive sheeting has very high elastic and resilient forces. The elastic silicone occlusive sheeting

used in this study was 0.9 mm thick, 60 mm wide, and 80 mm long (Fig. 1). The sheeting was stretched before use and then applied around the scar areas in order to occlude them and offload tension around them. This strategy can be applied on necks, arms, legs, and trunks.

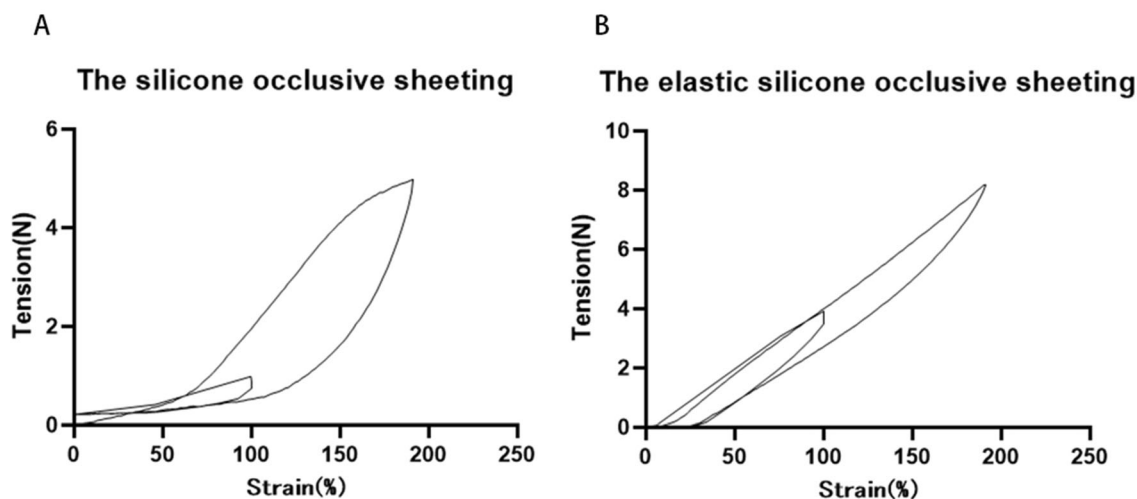


**Fig. 2** The silicone occlusive sheeting. **A** The actual shape of the silicone occlusive sheeting used as the control with a thickness of 0.3 mm. **B** An illustration of the silicone

occlusive sheeting before stretching. **C** The silicone occlusive sheeting after stretching. Silicone occlusive sheeting **D** before and **E** after application on the skin

Because adhesion is limited, elastic silicone occlusive sheeting can maintain a length of 80–93 mm on the skin after being stretched. Silicone occlusive sheeting, a self-adhesive silicone patch (0.3 mm thick, Fig. 2), was used as a comparator. The elastic silicone occlusive sheeting stretches easily (tensile modulus of elasticity 0.45 N/mm<sup>2</sup>, Fig. 3). It also has very

good resilience that can generate a tensile elasticity of up to 3.95 N when placed on the skin while stretched to 93 mm. Comparatively, the silicone occlusive sheeting is hard to stretch. However, when stretched, it can reach a tensile modulus of elasticity of 0.64 N/mm<sup>2</sup>. Additionally, its resilience declines, which limits its ability to reduce tension around the healed



**Fig. 3** Testing and features of the elastic silicone occlusive sheeting and the silicone occlusive sheeting. The stress–strain curve of the **A** silicone occlusive sheeting and **B** elastic silicone occlusive sheeting

wound. In conclusion, although the tensile modulus of elasticity of the elastic silicone occlusive sheeting is lower than that of the silicone occlusive sheeting, its resilience is better than that of silicone occlusive sheeting, which enables elastic silicone occlusive sheeting to reduce skin tension around the healed incision.

### Study Design and Ethical Approval

This single-center, prospective, randomized, assessor-blinded, and split scar trial was conducted at the Department of Breast Surgery. Patients were continuously enrolled from August to October 2021. Ethical approval for the study was granted by the Ethics Committee of the First Affiliated Hospital of Army Medical University, PLA, before the study started. All patients gave written informed consent, and the study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

### Identification of Patients

Inclusion criteria were (a) patients with a healed wound on the neck following conventional open thyroidectomy, (b) patients aged at least 18 years old, (c) patients able to give informed

consent, and (d) a healed wound length of at least 4 cm.

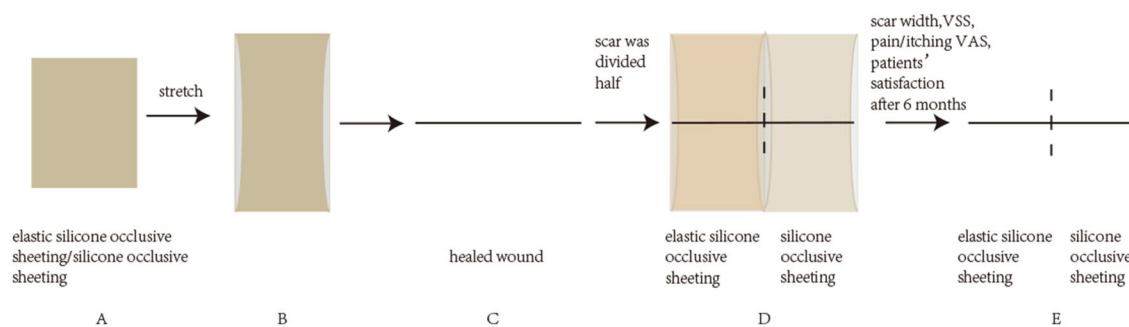
Exclusion criteria were (a) intellectually challenged patients, (b) patients unable to understand written and oral Chinese, (c) patients who were unwilling or unable to return for follow-up, (d) pregnant women, (e) known history of allergy to the silicone occlusive sheeting, (f) patients with healed wounds with lengths of less than 4 cm, and (g) patients with other anti-scar treatment.

### Patient Sample Size

Scar widths were used as the primary outcome measures for power analysis. A priori power analysis indicated that the study would need to enroll 74 patients in order to detect a difference of 0.7 mm, assuming  $\alpha = 0.05$ , a power of 90, a standard deviation of 1.67, and a 20% patient dropout rate [7].

### Randomization

After patient enrollment, the wound was divided in half. The left (superior) half and right (inferior) half of the wound were labeled A and B, respectively. Treatment method was assigned using a random integer generator [8], which generated zeroes and ones, which represented



**Fig. 4** Treatment algorithm. **A** The elastic silicone occlusive sheeting and the silicone occlusive sheeting have a width of 60 mm and length of 80 mm. **B** Illustration of stretching the elastic silicone occlusive sheeting and the silicone occlusive sheeting before use. **C** The elastic silicone occlusive sheeting and the silicone occlusive sheeting were applied when the wound had healed and the scab of the

wound had completely peeled off. **D** The wound was divided in half. If one side was designated for treatment using silicone occlusive sheeting, the other side received elastic silicone occlusive sheeting. **E** After 6 months, scar width, the Vancouver scar scale, the pain/itching visual analogue scale, and patients' subjective degree of satisfaction were measured

left/superior and right/inferior, respectively. If side A was designated for treatment using silicone occlusive sheeting, side B received elastic silicone occlusive sheeting (Fig. 4).

### Usage Procedure

The elastic silicone occlusive sheeting and the silicone occlusive sheeting were applied when the scab of the wound had completely peeled off. To ensure offloading around the wound, both the elastic silicone occlusive sheeting in the intervention group and the silicone occlusive sheeting in the control group were stretched before application, and used for almost 5 months after application. In week 1, the sheetings were applied for 8–12 h each day. From week 2 onward, they were applied for 24 h a day.

### Clinical Assessments

The primary outcome measure of scar appearance was scar width. The secondary outcomes of scar appearance included the Vancouver scar scale, the pain/itching visual analogue scale, and patients' subjective degree of satisfaction with the scar. Patients were evaluated 6 months after surgery, with an acceptable window for

follow-up of 2 weeks before or after the assessment period.

### Scar Width

A Vernier caliper was used to measure scar widths 1.5 cm from the midline on each side.

### Vancouver Scar Scale

The Vancouver scar scale, a validated scar evaluation tool, was used as secondary outcome measure for power analysis. The Vancouver scar scale is based on four scar criteria (vascularity, pigmentation, height, and pliability; Table 1). Standardized digital images were taken with a labeled standard scale (centimeters and millimeters) next to each scar. Two blinded plastic surgeons, who were not involved in the intervention, evaluated the scar using the same scale for scar vascularity, pigmentation, thickness, and pliability [9].

### Visual Analogue Scale

At the same time, the pain/itching visual analogue scale was used to assess pain and pruritus intensity [10, 11]. The pain/itching visual analogue scale score is based on a 10-cm line representing the patient's intensity of pain and itching ("no pain/itching", score = 0 and "worst imaginable pain/itching", score = 10 [10-cm scale]). The pain/itching visual analogue scale

**Table 1** Vancouver scar scale

Characteristic	Description
Vascularity	
0	Normal
1	Pink
2	Red
3	Purple
Pigmentation	
0	Normal
1	Hypopigmentation
2	Hyperpigmentation
Pliability	
0	Normal
1	Supple
2	Yielding
3	Firm
4	Banding
5	Contracture
Height	
0	Normal
1	< 2 mm
2	2–5 mm
3	> 5 mm

was self-completed by the patient. To this end, the patient was asked to place a line perpendicular to the visual analogue scale at the point that represented their pain/itching intensity.

#### ***Patients' Subjective Degree of Satisfaction with the Scar and Side Effects***

Patients were surveyed about their overall degree of satisfaction using the following response choices in a grading scale: grade 1 (very dissatisfied), grade 2 (not satisfied), grade 3 (moderately satisfied), grade 4 (satisfied), grade 5 (very satisfied). Patients also reported any side effects of treatment, including allergy, erythema, and infection.

#### **Statistical Analysis**

Scar widths, the Vancouver scar scale, the pain/itching visual analogue scale, and patients' subjective degree of satisfaction with the scar are presented as mean  $\pm$  SD. Differences between the groups for the parameters, scar width, Vancouver scar scale, the pain/itching visual analogue scale, and patients' subjective degree of satisfaction with the scar were statistically compared using paired *t* tests. Statistical analysis was done using SPSS version 26 (IBM).  $P \leq 0.05$  indicated statistical significance.

## **RESULTS**

### **Patient Demographics**

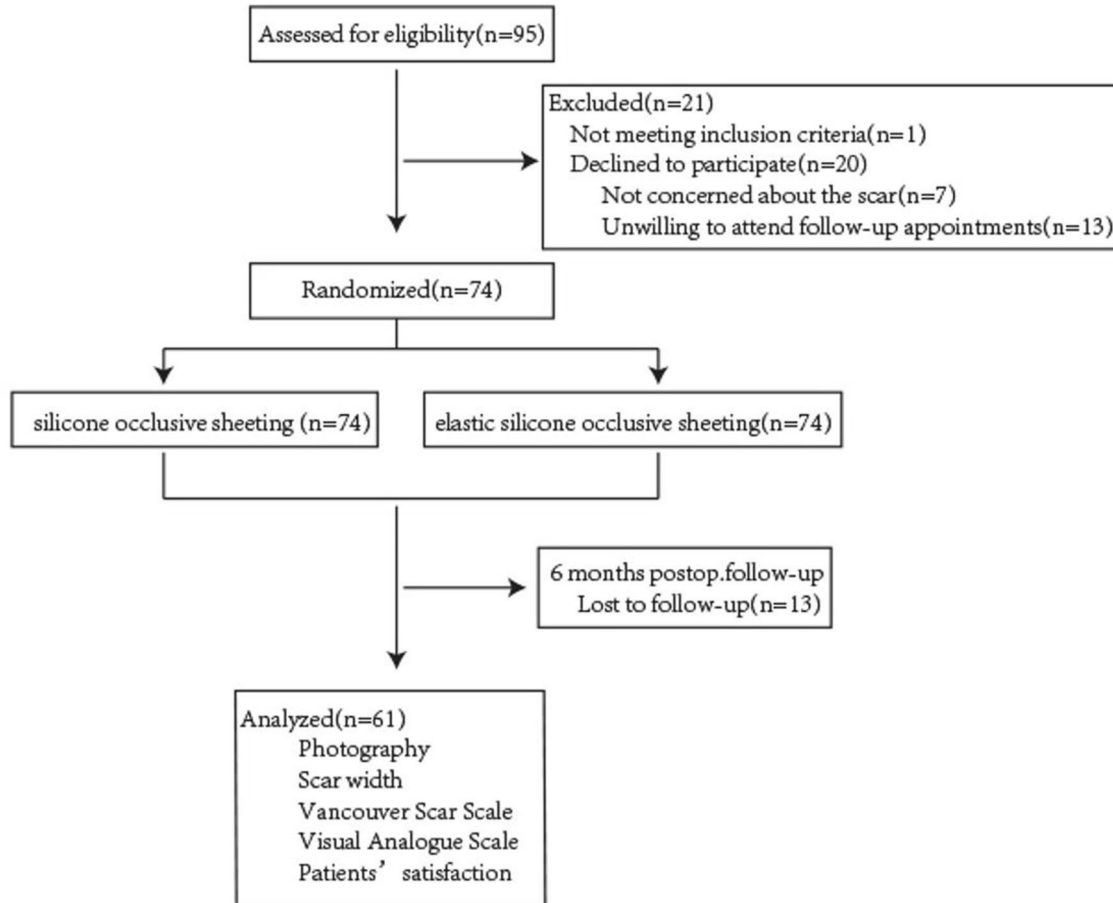
A total of 95 patients were screened and 74 of these were enrolled into the study. Of the 21 patients who were not enrolled, one did not meet inclusion criteria, while 20 declined to participate (7 were not concerned about the scar and 13 were unwilling to attend follow-up appointments) in the study. Of the 74 enrolled patients, 61 returned for their 6-month follow-up scar assessment (Fig. 5). The patients' ages ranged from 21 to 52 years (mean age 40.5 years). Of the participants, 54 were women (88.5%) and 7 were men (11.5%) (Table 2).

### **Objective Assessment of the Scar Based on Scar Width**

At the 6-month follow-up, mean scar width (our primary outcome measure) on the silicone occlusive sheeting side was significantly wider than the scar width on the elastic silicone occlusive sheeting side (1.02 mm versus 0.47 mm, respectively,  $P < 0.01$ , Table 3).

### **Subjective Assessment of the Scar Using the Vancouver Scar Scale**

The results of the secondary outcome measure, Vancouver scar scale score, are shown in Table 4. The Vancouver scar scale scores of the elastic silicone occlusive sheeting side were



**Fig. 5** Trial flow diagram

significantly better than those of the silicone occlusive sheeting side (mean 3.93 versus 4.49) at the 6-month follow-up (lower scores indicate better outcomes,  $P < 0.01$ ). Subcategory outcomes from the Vancouver scar scale score, such as scar vascularity, pigmentation, height, and pliability, are shown in Table 4. Pigmentation ( $P < 0.01$ ) and vascularity ( $P < 0.01$ ) scores for these scar characteristics were significantly different between the two sides, all favoring the better appearance of the elastic silicone occlusive sheeting side (Fig. 6). Moreover, the mean height score from the Vancouver scar scale was 0.98 for the elastic silicone occlusive sheeting side and 1.0 for the silicone occlusive sheeting side. Mean pliability score from Vancouver scar scale was 1.02 for the elastic silicone occlusive sheeting side and 1.03 for the silicone occlusive sheeting side. Scar height ( $P = 0.321$ ) and

pliability ( $P = 0.321$ ) did not differ significantly between the two sides.

### Subjective Assessment of the Scar Using the Pain/Itching Visual Analogue Scale

The pain/itching visual analogue scale scores at 6-month follow-up are shown in Table 5. The mean pain visual analogue scale score was 0.77 for the silicone occlusive sheeting side and 0.82 for the elastic silicone occlusive sheeting side. Visual analogue scale score for pain on the silicone occlusive sheeting side did not differ significantly from that of the elastic silicone occlusive sheeting side ( $P = 0.083$ ). Moreover, the mean itching visual analogue scale score was 0.31 on the silicone occlusive sheeting side versus 0.36 on the elastic silicone occlusive



**Table 2** Study demographics

Characteristics	Value
Patients, <i>n</i> (%)	
Enrolled	74
Completed 6-month follow-up	61 (82.4)
Age, years, mean (SD)	40.5 (7.52)
Sex, <i>n</i> (%)	
Male	7 (11.5)
Female	54 (88.5)
BMI	24.1 (3.59)
Wound closure length, cm, mean (SD)	6.87 (1.36)
6-month assessment time, months, mean (SD)	6.30 (0.16)

SD standard deviation

**Table 3** Scar width at 6-month follow-up

Scar width <sup>a</sup> , mm, mean (SD)		<i>P</i> value
Silicone occlusive sheeting	Elastic silicone occlusive sheeting	
1.02 (0.64)	0.47 (0.25)	< 0.01

<sup>a</sup>Measured 1.5 cm from midline

sheeting side. Pruritus visual analogue scale scores did not differ significantly between the two sides (*P* = 0.083).

**Subjective Assessment of the Scar Using Patients’ Subjective Degree of Satisfaction**

From the patients’ perspective, the average degree of satisfaction with the scar was 4.25 in the elastic silicone occlusive sheeting group and 3.79 in the silicone occlusive sheeting group. There was significant statistical difference (*P* < 0.01). The results are outlined in Table 6.

**Table 4** Vancouver scar scale score for the silicone occlusive sheeting and the elastic silicone occlusive sheeting

	Silicone occlusive sheeting	Elastic silicone occlusive sheeting	<i>P</i> value
VSS score	4.49 (0.96)	3.93 (0.93)	< 0.01
Subdomains			
Pigmentation	1.25 (0.51)	1.07 (0.51)	< 0.01
Vascularity	1.21 (0.58)	0.89 (0.52)	< 0.01
Height	1 (0)	0.98 (0.13)	0.321
Pliability	1.03 (0.18)	1.02 (0.13)	0.321

Lower Vancouver scar scale scores indicate better outcomes  
SD standard deviation



**Fig. 6** Representative photos showing the scar outcome at 6-month follow-up. The elastic silicone occlusive sheeting was used on the left half side and the silicone occlusive sheeting was used on the right half side

**Table 5** Visual analogue scale score for the silicone occlusive sheeting and the elastic silicone occlusive sheeting

VAS score	Silicone occlusive sheeting	Elastic silicone occlusive sheeting	<i>P</i> value
Pruritus	0.31 (0.47)	0.36 (0.48)	0.083
Pain	0.77 (0.42)	0.82 (0.50)	0.083

Lower visual analogue scale scores indicate better outcomes  
*SD* standard deviation

**Table 6** Patients' subjective degree of satisfaction with the scar

Degree of satisfaction		<i>P</i> value
Silicone occlusive sheeting	Elastic silicone occlusive sheeting	
3.79 (0.80)	4.25 (0.47)	< 0.01

Higher scores indicate better outcomes

## Side Effects

Both the elastic silicone occlusive sheeting and silicone occlusive sheeting were not associated with any side effects in the 61 patients.

## DISCUSSION

Hypertrophic or keloid scarring after conventional open thyroidectomy is a ubiquitous but challenging phenomenon. Concerns over hypertrophic scarring in the neck area are a major psychological obstacle for patients considering whether to undergo conventional open thyroidectomy. Although methods like laparoscopic thyroidectomy minimize postoperative scarring, their surgical indications are limited. Thus, effective strategies for improving scar appearance are urgently needed.

Multiple factors contribute to undesirable scars, including the patient's ethnic background, the anatomical location of the incision, local mechanical tension, surgical technique, and postoperative infections [12]. The neck is prone to pathologic scarring because of its

frequent movement and local high tension. Moreover, tension acting on the neck is a major cause of scar disfigurement. Here, we describe a relatively new silicone-based strategy that combines occlusion and a tension offloading device. Using scar width, the Vancouver scar scale, the pain/itching visual analogue scale, and patients' subjective degree of satisfaction analyses, we show that elastic silicone occlusive sheeting can narrow the scar and improve scar appearance following conventional open thyroidectomy. Elastic silicone occlusive sheeting and silicone occlusive sheeting differed significantly with regard to scar width and Vancouver scar scale scores. Scar width on the elastic silicone occlusive sheeting side was narrower when compared with that of the silicone occlusive sheeting. The mean Vancouver scar scale score of the elastic silicone occlusive sheeting was lower than that of the silicone occlusive sheeting. Additionally, scar vascularity, pigmentation, height, pliability, and Vancouver scar score of the elastic silicone occlusive sheeting were improved whereas there was no statistical difference of the pliability and height, probably because the size of patients was not enough and the minimum score of scar height in the Vancouver scar scale was 1 representing 2 mm height which cannot reflect the true differences.

The highly significant differences of scar width between the elastic silicone occlusive sheeting-treated portions and the silicone occlusive sheeting-treated portions are supported by basic science research on mechanotransduction and fibrosis [13–15]. Continuous muscular relaxation induced by elastic silicone occlusive sheeting could reduce movement and tension around a healing wound. This tension relief may help prevent scar widening, hypertrophy, and hyperpigmentation. Moreover, skin stretching around the wound by elastic silicone occlusive sheeting did not increase the incidence of skin maceration, which happens when using a tension offloading device.

Various randomized clinical studies have shown that silicone has a positive effect on the healing process of hypertrophic scars. Silicone has been used in various forms, including gel, gel sheets, spray, cream compounds, and silicone oil with or without additives [16, 17].

Studies indicate silicone gel sheeting may exert therapeutic effects via hydration and occlusion [18, 19]. Thus, we hypothesize that improvements in scar appearance result from the better hydration offered by elastic silicone occlusive sheeting, which is thicker than silicone occlusive sheeting. However, the excessive hydration may increase the incidence of skin maceration. Here, we did not observe increased risk of maceration which means the hydration level of elastic silicone occlusive sheeting is appropriate. Additionally, the pain/itching Vancouver scar scale scores did not differ significantly between the two interventions, which increased patients' compliance.

To our knowledge, this is the first attempt to combine silicone with a tension offloading device. This new form of silicone sheeting overcomes the shortcomings of the silicone occlusive sheeting, which has limited capacity to reduce scar width, as well as the shortcomings of the tension offloading device, which is characterized by a high incidence of skin maceration, and does not improve scar height, pigmentation, and pliability.

The strengths of our study include its split scar comparison, randomized design, blinded evaluation, and use of an objective evaluation index and validated scar outcome instrument. Using the same patient as control allowed direct comparison of scar morphology, and enabled matching of the control and intervention groups by age, sex, anatomic location, variation in individual healing, and variable susceptibilities to scar formation. Thus, this strategy avoids the common confounding factors and biases encountered during patient selection.

It is worth mentioning that the final endpoint for this study was 6 months. This time point was chosen on the basis of our understanding of how scars change over time. We reasoned that 6 months met the criteria for the minimum acceptable time at which scar analysis should be performed, which is consistent with other studies [20, 21].

The limitation of this study is that the anatomical location is limited to the neck. The variety of anatomical locations could also have influenced tension offloading.

The strategy described here is applicable for patients undergoing conventional open thyroidectomy. To our knowledge, this strategy of elastic silicone occlusive sheeting is the first to combine the merits of silicone with a tension offloading device. The highly statistically significant differences including scar width, the Vancouver scar scale, and patients' subjective degree of satisfaction with the scar between the elastic silicone occlusive sheeting-treated scars and the silicone occlusive sheeting-treated scars strongly indicate that the observed differences are real and not attributable to chance.

## CONCLUSION

These results have important implications in conventional open thyroidectomy. Although it is hard to accurately estimate the number of patients that are unhappy with scars worldwide, the efficacy of the strategy described here suggests that elastic silicone occlusive sheeting can address an important unmet need and offer an alternative option to surgeons and patients undertaking scar management.

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**Authorship.** All authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work

as a whole, and have given their approval for this version to be published.

**Author Contributions.** Min Jiang, Jiaping Zhang and Yi Zhang designed the study; Min Jiang, Yi Zhang and Qiang Xiang enrolled the patients; Qilin Luo and Fengxia Wen performed the follow-up; Min Jiang, Xupin Jiang, Jie Liu, Chao Wu and Ze Zhang analyzed the data; Jiaping Zhang supervised the experiments; Min Jiang and Jiaping Zhang wrote the manuscript.

**Disclosures.** Min Jiang, Yi Zhang, Qiang Xiang, Qilin Luo, Fengxia Wen, Xupin Jiang, Jie Liu, Ze Zhang, Chao Wu and Jiaping Zhang have nothing to disclose.

**Compliance with Ethics Guidelines.** This study was approved by the Ethics Committee of the First Affiliated Hospital of Army Medical University, PLA. It was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All patients gave written informed consent.

**Data Availability.** The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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