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Peer reviewed

# A systematic review of the management of postoperative scars with silicone gel-based products in randomized controlled trials

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#### **Abstract**

Although postoperative scarring may be considered a cosmetic concern, it can greatly impact a patient's quality of life. This extends beyond psychosocial burden influenced by hypertrophic scars and keloids, as patients also experience discomfort and pain. This systematic review evaluates the efficacy of silicone gel (SG)-based products in preventing postoperative abnormal scar formation. Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a PubMed search was performed to find randomized, controlled trials investigating the effect of SG-based products on postoperative wound healing. The search yielded 359 publications, but only 30 studies published between 1991-2022 were found to fit the inclusion criteria. Outcomes were extracted from the literature and subsequent quality and risk of bias assessments performed. Most studies improvement of at least one quality of the scar with the use of SG-based products. The greatest potential variable increasing bias was an inadequate control group. Studies also suffered from small sample sizes, use of unvalidated scar assessment scales, lack of double-blinding, and short follow-up periods. Overall, SG-based products demonstrated potential in preventing abnormal scar formation during postoperative healing, but further studies are required to validate the results of current literature.

Keywords: hypertrophic scar, keloid, silicone gel, wound healing

#### Introduction

The management of postoperative wounds greatly influences the risk of abnormal scarring [1] and patients may even forgo essential procedures or decide between types of procedures based on potential cosmetic outcome rather than efficacy or safety [2]. The aesthetic outcome after surgery has important implications on a patient's quality of life [3,4] and scarring not only decreases a patient's quality of life but also their satisfaction with medical care, which may influence their future compliance [4-6]. Despite literature highlighting the influence of postoperative scarring on a patient's psyche, scar prevention and treatment is often underperformed due to the accompanying cost. Recent studies suggest that use of silicone gel (SG) and SG sheets (SGS) provide a potential preventative treatment for postoperative scars while remaining affordable and easily accessible [7,8].

Hypertrophic scars and keloids are commonly formed postoperative scars and are usually first observed after three months [9]. Hypertrophic scars are typically firm, red or pink, and raised, but they are usually no greater than four mm above the skin and do not exceed the margins of the wound area unlike keloids [10]. Hypertrophic scars often regress over time and are considered keloids if they do not improve or resolve within 6 months [11]. Pathological scars have been reported to decrease quality of life due to anxiety and depression related

to cosmesis and self-esteem; patients also experience functional disability through severe itching, tenderness, and even pain [3,4,6].

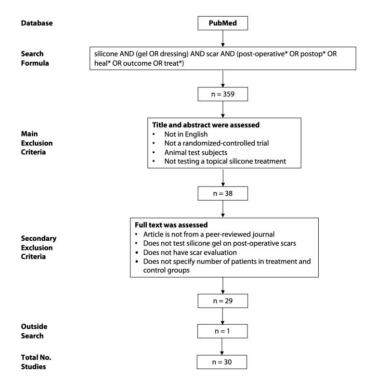
Several risk factors increase the risk of scar formation after trauma including excessive transepidermal water loss and wound tension. Although the epidermis regenerates after trauma, the immature stratum corneum allows excessive transepidermal water loss, which induces fibroblasts in the wound matrix to release more collagen fibers [11,12]. mechanical forces in the wound environment induce cell proliferation and increase collagen production, which may lead to fibrosis and abnormal scarring [13]. Silicone gel and SGS mimic the occlusive properties of a healthy stratum corneum to normalize hydration of wounded skin [12]. Silicone gel sheets further minimizes scar formation by transferring wound tension to the lateral edges of dressings resulting in reduced applied mechanical forces [11,12].

During the healing process, there are currently multiple treatments to minimize scar formation including dressing to minimize wound tension, topical treatments, radiation, laser, and intralesional injections of corticosteroids or botulinum toxin A [14]. Although there is conflicting evidence regarding the efficacy of each treatment, SG is the recommended first line treatment modality according to the International Advisory Panel on Scar Management and is preferred by many healthcare providers because it is an easily applied noninvasive therapy [12].

This current study aims to systematically review randomized, controlled trials comparing the efficacy of SG and SGS to other available treatments for scar prevention and to assess the quality of current literature to guide future studies. A meta-analysis was not conducted due to limitations found across studies, including lack of heterogeneity in reported outcome measurements.

## **Methods**

PRISMA guidelines were followed to conduct this systematic review (**Figure 1**). A literature search of



**Figure 1**. Flowchart depicts selection process for publications. n, number of publications.

the PubMed database included all publications in English that use human subjects from earliest records to August 2022 using the search formula: "silicone AND (gel OR dressing) AND scar AND (post-operative\* OR postop\* OR heal\* OR outcome OR treat\*)."

#### Inclusion and exclusion criteria

A pair of independent reviewers (AN and CH) performed an initial screening protocol and removed any publications that were duplicates or met the following exclusion criteria: not in English, not a randomized controlled trial, not using human subjects, or not including a topical treatment containing SG. Afterwards, the reviewers screened the remaining publications for eligibility based on the following inclusion criteria: article is from a peer-reviewed journal, study investigates the efficacy of SG or SGS on post-operative scars, and study must include a form of scar evaluation. In the case of disagreement, a third reviewer (SP) made the decision after reviewing the study.

# Measure of literature's quality & risk of bias

Two independent reviewers (AG and AN) assessed the quality of each publication in accordance with the methodological index for non-randomized

studies (MINORS) quality assessment tool [12]. There were eight criteria used to assess the quality and risk of bias including: clearly stated aim, prospective collection of data according to a protocol established at the study's beginning, clearly stated criteria for outcome evaluation, unbiased endpoint assessment or an explanation for lack of blinding, appropriate follow-up period, loss less than 5% of study population at endpoint, adequate control for treatment, and adequate statistical analysis. A follow-up period of at least three months was adequate because studies have considered demonstrated that it takes at least one month for hypertrophic scars, and at least three months for keloids to develop [15]. Each publication was then reviewed and assigned a score of 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate) for each criterion. The individual score of each criterion was subsequently summed to generate an overall score for each study with an ideal score of 16. A third reviewer (SP) decided the final score after reviewing any disagreements in scoring.

#### Measure of patient outcome

For the purpose of this study, treatment success was defined as statistically significant (P<0.05) improvements of scarring based on the scar assessment scale used by the authors. Adverse effects were identified and recorded when available to determine the efficacy and safety of the treatment.

#### Results

# **Patient demographics**

Our initial search yielded 359 articles. After review, 30 articles met the inclusion criteria and were included in this systematic review. One additional article was identified and included through outside search. Among these 30 studies, only 7 studies focused on cosmetic surgeries and two studies focused only on pediatric patients [16,17]. The number of participants in each study ranged from 7-160 with an age range of 6 months to 85 years of age.

#### Study design

<u>Table 1</u> summarizes the study design for publications included in this systematic review.

Twenty studies compared SG or SGS to a control group with six studies examining the efficacy of SG used in conjunction with additional ingredients [17-24]. The other ten studies compared SG or SGS to other forms of treatments. Of those ten studies, five studies directly examined the efficacy of SG or SGS to another form of treatment including onion extract [25,26], tretinoin cream [27], methylprednisolone cream [28], and flashlamp-pulsed dye laser [29]. Two studies in particular compared silicone gel sheets to silicone gel [30,31], whereas two other studies compared different types of SG or SGS to each other [22,32].

Treatment length ranged from 1-6 months except for one study that used SG for 12 months [22]. The longest follow-up assessment was a one-year postoperative period. The Modified Vancouver Scar Scale (VSS) was the most widely used scale for scar assessment followed by the Visual Analog Scale (VAS) and Patient and Observer Scar Assessment Scale (POSAS).

Most of the studies excluded participants with comorbidities including diabetes, scleroderma, and autoimmune disorders. Patients with allergies or hypersensitivity reactions to silicone were also excluded. Additionally, participants who experienced postoperative wound infections or were taking drugs that would interfere with wound healing were also excluded. Additional exclusion criteria were history of hypertrophic scars and keloids, history of prolonged wound healing, symptoms of dermatitis, inability to comply or attend follow up visits, smoking, and pregnancy.

#### The effect of silicone gel in scar formation

There was no consensus on the efficacy of SG and SGS on scar outcome (Table 2). Although most studies found that using SG or SGS improved at least one aspect of scar outcome, six studies found that it did not significantly improve scar outcome, and two studies reported that it may even worsen scar outcome. There was no difference in scar outcome when using SG or SGS based on the results of two different studies [30,31], and different types of SGS also did not affect scar outcome [32].

#### Silicone gel versus control

Seven studies investigated the efficacy of SG with varying results. Three studies reported statistically significant improvement in scores for scar outcome with SG use [33-35]. One study reported no significant difference in VAS scores or objective measurements between SG use and no treatment [36]. Two studies found that SG use improved different aspects of the scar, but the only common criterion with improvement was height. Kong et al. reported decreased pigmentation while Shirazi et al. reported decreased vascularity and increased pliability with SG use [37,38]. Another study examined the effect of SG on patients at low-risk and high-risk of abnormal scar formation and found that there was only a statistically significant decrease in the incidence of abnormal scar formation in high-risk patients with SG use [39].

#### Silicone gel sheet versus control

Six studies examined the efficacy of SGS and similarly found varying results. Four studies reported statistically significant improved scar outcomes with SGS use [40-43], whereas one study found that SGS significantly improved only pliability pigmentation [44]. In particular, Choi et al. examined the expression of growth factors in skin treated with SGS and untreated skin and found that SGS-treated skin had statistically significant decreased expression of transforming growth factor (TGF)-β1 and platelet-derived growth factor (PDGF), which are implicated in abnormal scar formation [40]. Similarly to SG, one study reported that the SGS increased the width of scars [16].

Silicone gel and silicone gel sheet versus other scar treatments

Of the five studies comparing SG or SGS to a different treatment, four studies found no statistically significant difference between SG or SGS plus onion extract [25,26], tretinoin cream [27], and lashlampulsed dye laser [29]. Meseci et al. did report better modified VSS scores for patients treated with methylprednisolone cream in comparison to SG, although both treatments had better outcomes than patients in the control group who did not receive any preventative treatment [28].

Combined effect of silicone gel-based products with other scar treatments.

Eight studies examined the efficacy of SG used in conjunction with other scar treatments. One study demonstrated that SG with onion extract and SG with vitamin C improved the total and individual components of VSS and POSAS scores compared to baseline [24]. Three studies reported statistically significant improvement of scar outcome when onion extract [17], herbal extract [20], or vitamin C [23] was added to SG in comparison to a control group. Four other studies further examined if SG with additional ingredients performed better than SG alone and reported varying results. Of the four with studies, only treatment SG plus microencapsulated recombinant human epidermal growth factor (Me-EGF) demonstrated statistically significant improvement in overall scar outcome in comparison to SG alone [18]. Three other studies reported statistically significant improvement in only some aspects of the scar. Tanini et al. reported improved height, vascularity, and pigmentation with Top Surgery Scar go (TSSgo), which includes spironolactone, alfa bisabolol, and silicone gel [22]. Pangkanon et al. found no difference in overall POSAS score but statistically significant improved pliability in patients treated with SG plus onion extract and aloe vera (SGOE), [19] Surakunprapha et al. reported statistically significant improved height and pliability in scars treated with SG and herbal extract [21].

#### Adverse effects of silicone gel

Adverse effects were mostly limited local skin reactions such as rashes, pruritus, superficial wound infections, dermatitis, and hyperpigmentation. The most severe side effect was the formation of a pustule after the use of onion extract in silicone gel derivative which resolved with topical antibiotic treatment [17]. Most participants either resumed treatment after the side effects diminished or never ceased treatment because side effects were minimal, but one participant was excluded following severe pruritus around the silicone gel sheet [40].

# Quality and risk of bias in the literature

Quality assessment scores for all 30 studies ranged from 12-16 (**Table 3**) with six studies receiving the

**Table 3**. Methodological index for non-randomized studies (MINORS) quality assessment (ideal score=16).

Publications	Total Score
Napavichayanun et al. [24]	14
Kao et al. [18]	16
Pangkanon et al. [19]	15
Hassanpour et al. [25]	15
Surakunprapha et al. [20]	15
Surakunprapha et al. [21]	16
Tanini et al. [22]	15
Shirazi et al. [38]	16
Cadet et al. [45]	16
Lin et al. [30]	13
Song et al. [26]	15
Meseci et al. [28]	15
Braam et al. [16]	15
Choi et al. [40]	16
Kim et al. [31]	12
Kong et al. [37]	16
Kwon et al. [27]	15
Lim et al. [41]	16
Chittoria et al. [34]	15
Riedel et al. [36]	14
Wananukul et al. [17]	16
Yun et al. [23]	15
Maher et al. [44]	14
Markl et al. [32]	14
de Giorgi et al. [35]	15
Signorini et al. [43]	13
Maján [42]	15
Chan et al. [33]	16
Gold et al. [39]	13
Wittenberg et al. [29]	16

maximum score of 16 [17,21,27,29,40,45]. All studies demonstrated a clearly stated aim and criteria for outcome evaluation, prospective collection of data, and loss of less than 50% of participants to follow-up. Additionally, all but one study had an adequate statistical analysis [39].

The most significant deficiency was the inclusion of an adequate control group with 18 studies lacking an adequate control group. Other limitations included inadequate follow-up period along with lack of blinding or satisfactory reasoning for absence of blinding. Seven studies did not follow patients for at least three months [16,18,33-35,37,38]. Five studies did not use a double-blinded design with two studies single-blinding evaluators [32,36] and three studies using no blinding at all [30,43,44]. One study

did not report if outcome assessors were blinded [31]. Both Lin et al. and Maher et al. explained that they could not blind their participants based on the study design, but neither study blinded their evaluators [30,44].

#### **Discussion**

# Silicone gel-based products demonstrate potential in preventing scar formation

Although current studies have varying results, SG-based products demonstrate viability as a therapy for scar reduction. Reported adverse effects were generally mild and related to skin irritation, which is a potential problem in any topical treatment. Overall, most studies suggested that SG-based products helped improve at least some cosmetic aspect of postoperative wounds, but they differ on aspects of wound healing that were improved upon.

In some studies, the difference in overall subject scar assessment scores was not statistically significant, but specific criteria of the scores were significantly different between SG-based products and the control group. This may be a potential result of the mechanism by which SG-based products work. Choi et al. found that SGS-treated skin had decreased expression of TGFβ1 and PDGF, which are found in high levels in skin that heals abnormally [40]. This suggests that SGS may play a role in preventing abnormal scar formation, not just improving the cosmesis of normal wound healing. This is further supported by the findings of Gold et al. in which there was only improvement in the scar of high-risk patients who previously developed either a hypertrophic or keloid scar [39]. This result could explain why studies that excluded patients with a history of hypertrophic or keloid scarring showed less significant scar improvements with SG [25,27-29]. Further studies are required to elucidate the potential benefit of SG-based products in preventing abnormal scar formation in those at high-risk because most studies excluded patients who had a history of hypertrophic scars or keloids.

Only two studies did not find improvement from the use of SG-based products. One study found no significant difference between SG use and no

treatment [36], whereas another study found that SGS use actually resulted in significantly wider scars with longer use [16]. Braam et al. theorized that the wider scar may be a result of a skin reaction to the constant cycle of application and removal of SGS [16]. A recent study by Lin et al. demonstrated that there was no difference in outcome between SG and SGS-treated wounds [30], but the results of the studies in this systematic review suggest that SG may be a safer treatment option than SGS because it does not demonstrate risk of causing irritation that may result in worse outcomes. Further studies are needed with larger sample sizes to better determine if SG and have different outcomes. Standardized application regimens may also help differentiate whether the manner in which SG and SGS are applied influence poor outcomes similar to the widening of scars from application cycling reported by Braam et al. [16].

# Comparing silicone gel to other treatments in reducing scar formation

The results of studies comparing SG-based products to other treatments including onion extract [25,26], tretinoin cream [27], **FLPDL** [29], and methylprednisolone cream [28] suggest that any of these treatments may help reduce abnormal scar formation. Except in the case of methylprednisolone cream, none of these treatments demonstrated a statistically significantly improvement in cosmesis of wound healing in comparison to SG-Silicone gel-based based gel. products demonstrated few adverse effects beyond skin irritation whereas topical corticosteroids may also cause skin atrophy [46] and topical retinoids are avoided in pregnant patients due to teratogenic potential [47].

Treatments used for abnormal scars that were not investigated in this systematic review include radiation, laser, intralesional corticosteroids, and botulinum toxin A [14]. Most treatments targeting abnormal scar formation require multiple treatments, so the cost effectiveness of a treatment can play a role in its selection. Although SG-based products can be purchased over the counter at an average price of \$16.25 [48], other treatment options

with reported costs within the literature may be significantly more expensive for patients such as radiotherapy (\$512.38-\$844.20), [49], intralesional triamcinolone (\$433-\$776.93), [50], and botulinum toxin (\$5.25 per unit), [51]. Moreover, not all patients may be able to commit to the follow-up visit frequency required for optimal efficacy of these treatments and may not be able to tolerate the pain associated with these treatments. Consequently, the optimized treatment modality for each patient may vary based on socioeconomic limitations along with treatment tolerance. Provider understanding of when to use each modality along with their side effect profiles may broaden the range of patients who can benefit from postoperative scar severity reduction.

#### Potential mechanisms of action of silicone gel

Studies have been conducted to elucidate the mechanism of action of SG-based products, but the exact mechanisms are still unknown. Injury to the epidermis, particularly the stratum corneum, results in abnormally high transepidermal water loss, stimulating keratinocytes to produce cytokines that signal for increased collagen production and subsequently scar formation [11]. The benefit of SG-based products may lie in its ability to maintain proper hydration in healing skin, preventing upregulation of inflammatory cytokines and increased production of collagen synthesis and deposition.

Studies have demonstrated that SG is more effective than petrolatum at maintaining hydration and decreased hypertrophic scar formation as a result [52]. In vitro experiments have shown that proper hydration of keratinocytes modifies cytokine levels and reduces collagen secretion [53]. Further in vivo studies have shown that SGS modify the abnormal growth factor levels in wound healing, which normally increase formation of hypertrophic scars and keloids [40]. Increased PDGF and  $TGF\beta1$  have been implicated in the pathogenesis of keloid formation, but immunohistochemistry of punch biopsies demonstrated that SGS-treated scars had more normalized levels of these growth factors in both the epidermis and dermis [40].

#### Potential risk of bias in the current literature

In this systematic review, all studies demonstrated adequate quality in reporting their aim, methods of data collection, follow-up period, and statistical analysis. However, some studies suffered from small sample sizes, poor choice of outcome evaluation, short follow-up periods, lack of double blinding, and inadequate controls. **Figure 2** summarizes the risk of bias for each criterion across studies.

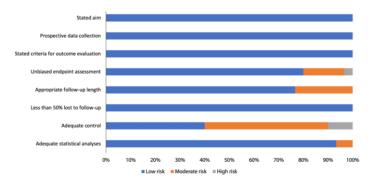
#### Control groups

The treatment group had an average of 38 (6-80) subjects. Eight studies had fewer subjects in the control group than treatment group even though previous literature has recommended at least one control subject for every subject in the treatment group [54].

Of the 16 studies that lacked a control group, five were comparative studies. The other 11 studies used no treatment as their control, which does not allow them to account for the effect of the inert vehicle in SG and traditional occlusive dressings in SGS. Since both have been shown to improve wound healing alone [55-57], it is important for studies to include an adequate control to minimize bias and prevent confounding inflation of treatment effect.

#### Double-blinding

In many cases blinding was not possible in patients because the control was no treatment, but several studies lacked adequate blinding when it was possible to include in the study design or did not provide an explanation for absence of blinding. Of the three studies that lacked double blinding, two acknowledged that this increased bias in outcome evaluation. In both cases, it was impossible to blind the patients because one was a comparative study and applied SGS dressing and topical SG to each half of a surgical incision [30] whereas the other used no treatment as their control group [44]. However, neither study blinded the evaluators, which could have been accomplished by removing any dressings or treatments before outcome evaluation. Two other studies used a single-blinded study design. Markl et al. assessed pain in patients using a 10-point VAS and used this measure to determine which type of SGS decreased pain the most [32], but a previous meta-



**Figure 2.** Risk of bias for each methodological index for non-randomized studies (MINORS) criterion presented as a percentage across all studies.

analysis demonstrated that placebos can have an analgesic effect with high risk of bias [58].

#### Follow-up period

Seven studies had a follow-up period of less than three months, which does not allow for adequate determination of abnormal scar formation. In one study, investigators found that scar width increased significantly from two months to 6 months in both treatment and control groups [16], demonstrating that wounds can continue changing over the first few months after surgery and longer follow-up periods are needed to determine the effect of SG-based products on scar formation.

#### *Method of outcome evaluation*

Although every study adequately established a protocol for data collection and outcome evaluation, two studies did not use a validated scar assessment scale [35,39]. Instead, these studies had dermatologists look for abnormal scar alterations. Although these dermatologists are trained to diagnose and treat abnormal scar formation, a validated scar assessment scale allows not only more nuanced assessment but also more reliable assessment not subject to interrater variability since validated scar assessment scales such as the VSS have been tested for interrater reliability [59,60].

#### Criteria for patient recruitment

Six studies excluded any patients with a history of hypertrophic scars or keloids [22,25,27-29,42]. Patients with a history of abnormal scar formation are more likely to continue developing abnormal scars and are therefore the group that would most benefit from any scar treatments if efficacious. Their

exclusion may have affected the success rate of the studied treatments. In fact, an investigation into the effects of SGS on high-risk patients with a history of abnormal scarring in comparison to low-risk patients showed that SGS benefitted high-risk patients more [61].

#### **Conclusion**

Current literature demonstrates that SG-based products have the potential to improve postoperative healing and prevent abnormal scar formation. Because insurance often considers scar treatment as a cosmetic procedure, SG and SGS may

provide a cheaper and more easily accessible alternative for patients with financial limitations or those who cannot undergo time intensive therapies requiring multiple follow-up visits such as intralesional corticosteroids, laser, and radiation. Future studies should aim to improve study design by increasing their sample size relative to the current

literature, using validated scar assessment scales, single- or double-blinding, and adequate follow-up time.

## **Potential conflicts of interest**

The authors declare no conflicts of interest.

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 Table 1. Summary of study design.

Publications	Procedure	Scar assessment tools	Exclusion criteria
Napavichayanun et al. [24]	C-section	POSAS, VSS	Delivery > 1 month ago, C-section wound already healed
Kao et al. [18]	C-section with Pfannenstiel incision	VSS	Emergent c-section, underlying systemic diseases, pharmacotherapy that could affect outcome evaluation, scar treatment within 1-month, active infection, abdominal or pelvic tumors, treatments affecting lower abdominal wall or outcome evaluation, hypersensitivity to treatment
Pangkanon et al. [19]	NR	POSAS	Underlying systemic diseases; current infections, rashes, or discharging producing wounds; systemic or topical corticosteroids within 1-month; immunosuppressive drugs; hypersensitivity to treatment
Hassanpour et al. [25]	Upper extremity sharp injury repair	VSS	History of keloid or hypertrophic scarring in upper extremity, active dermatologic conditions, peripheral vascular disease, mental disorders, acute viral diseases, corticosteroid use, hypersensitivity to treatment
Surakunprapha et al. [20]	Median sternotomy	VSS	History of steroid and immunosuppressant usage, noncompliance with follow-ups
Surakunprapha et al. [21]	Median sternotomy	VSS	Symptoms of skin irritation or dermatitis
Tanini et al. [22]	Double incision mastectomy w/ NA grafts	mVSS	Pathologic scars, Western patients, 20-23 yo, normal BMI, Fitzpatrick Type II-III, smoking history, significant weight loss, chronic medical illness, pharmacotherapy affecting wound healing, hypersensitivity to treatment, noncompliance to treatment, not using compressive thoracic band during first 4 weeks and at least 12 hours during next 4 weeks, strenuous physical activity within 1-month of surgery, sun exposure
Shirazi et al. [38]	Surgical repair of hypospadias	VSS	Infected wounds, diabetes, collagen vascular disorder, history of skin hypersensitivity to any application
Cadet et al. [45]	Bilateral direct brow lift	POSAS	Hypersensitivity to silicone, wound infection, revision surgery
Lin et al. [30]	Cesarean section with Pfannenstiel incision	VSS, VAS	Hypersensitivity to silicone, wound infection, long term systematic steroid usage, herbal agents used, inability to tolerate duration of dressing
Song et al. [26]	Gynecologic laparoscopy	VSS, IPS, BIS, CS	Hypersensitivity to silicone or onion, active dermatologic conditions, contractive skin disorders, current chemotherapy or pharmacotherapy affecting wound healing, surgical complications, received nearly scar-free surgery
Meseci et al. [28]	Gynecological surgeries with Pfannenstiel incisions	mVSS	History of hypertrophic scars or keloids, underlying systemic diseases, history of abdominal incisions, systemic treatments in last 6 months
Braam et al. [16]	Totally implantable venous access device surgery	mVSS	Device removed secondary to infection or complications, radiotherapy at location of device scar
Choi et al. [40]	Debridement and scar revision surgery	Immunohistochemistry Three-point scale for staining of growth factors	Underlying systemic diseases, hypersensitivity to silicone, severe wound infection, unhealed wounds, blood abnormality, recent administration of oral steroids, pregnancy, old age

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Kim et al. [30]	NR	VSS	History of surgery < 2 weeks or > 3 months; scar > 10x10 cm <sup>3</sup> ; age < 18 years, wound with infection or discharge, systemic illness; current use of anticancer, psychiatric, or steroid medications; psychiatric disorders	
Kong et al. [37]	Total knee arthroplasty	VSS, VAS, Knee Society score	Diagnosis other than primary osteoarthritis, previous knee surgery, sensory and motor disorders in operated limb	
Kwon et al. [27]	NR	mVSS	Personal and family history of hypertrophic scars or keloids, prolonged wound healing	
Lim et al. [41]	Scar revision surgery	VAS	Chronic or active skin disorder, collagen vascular disease, scleroderma, smoking, hypersensitivity to adhesives, inability to care for incision, did not qualify based on investigators' opinions	
Chittoria et al. [34]	Skin grafts	VSS	Donor scar <10 days or >3 weeks after surgery, underlying systemic disease, hypersensitivity to silicone, undergone full thickness skin grafting, wound infection at donor site, hormonal problems, hemolytic disorder, metastatic disease, skin infections, sun exposure, conditions or pharmacotherapy that may interfere with study results	
Riedel et al. [36]	Auricular reconstruction with autologous costal cartilage	VAS	Immunosuppression, hypersensitivity to silicone, comorbidities (DM, skin diseases, vascular disorders), granuloma formation or infection in the wound area after suture removal	
Wananukul et al. [17]	Median sternotomy	VSS	Immunosuppression, steroids	
Yun et al. [23]	Facial mass excision, primary repair of facial laceration, scar revision	mVSS	Hypersensitivity to silicone, noncompliance with treatment and follow-ups	
Maher et al. [45]	NR	VSS, POSAS	Age < 18 years; post-surgical scar is < 1 inch, nonlinear, and < 1 year old	
Markl et al. [32]	Split-thickness skin grafts	VSS	Immunosuppression, underlying systemic disease, dementia, hypersensitivity to treatment	
de Giorgi et al. [35]	Skin excisions	Fine brush test Physician observation	History of surgical excision of dermatofibromas, sebaceous cysts, and inflamed cutaneous lesions	
Signorini et al. [43]	Skin excisions, scar revisions, breast augmentation, breast reduction	4-point graded scale for elevation	NR	
Maján [42]	Breast reduction, mastoidectomy, gastroplasty	VSS	Underlying systemic disease, hypersensitivity to silicone, noncompliance with study procedures and follow-ups, history of keloid scars	
Chan et al. [33]	Coronary bypass surgery or cardiac valvular surgery	VSS	Wound infection, hypersensitivity to treatment	
Gold et al. [38]	Dermatologic surgeries	Physician observation Scaled photo analysis	NR	
Wittenberg et al. [29]	NR	Laser doppler, elastometer, polydimethyl vinyl siloxane material, punch biopsies	Treatment of the scar 2 months prior, keloidal scarring, and scar length less than 8 cm	

BIS, body image scale; C-section, cesarean section; CS, cosmetic scale; IPS, image panel scale; mVSS, modified Vancouver scar scale; NR, not reported; POSAS, patient observer scar assessment scale; VSS, Vancouver scar scale; VAS, visual analog scale; yo, year-old.

**Table 2**. Summary of treatment outcomes and reported adverse effects.

Publications	Treatments	Control	Treatment Length	Results	Adverse Effects
Napavichayanun et al. [24]	SG & OE (N=22) <sup>§</sup> SG & vitamin C (N=22) <sup>§</sup>		3 m	Both groups showed statistically significant improvement from baseline VSS scores	None
Kao et al. [18]	SG & me-EGF (N=20)* # SG (N=20)	Tape (N=20)	2 m	SG & Me-EGF had better VSS scores than SG. Both were better than control	NR
Pangkanon et al. [19]	SGS (N=20) SGOA (N=20)		12 w	SGS had better pliability than SGOA	None
Hassanpour et al. [25]	SG (N=40)* OE gel (N=40)*	No treatment (N=40)	4 m	SG and OE had better VSS scores than control. No statistically significant difference was found between SG and OE	NR
Surakunprapha et al. [20]	SG & HE (N=23) SG (N=23)		6 m	SG & HE had improved vascularity and pigmentation but not height and pliability	NR
Surakunprapha et al. [21]	SG & HE (N=24)	Placebo gel (N=24)	6 m	SG & HE had improved height and pliability but not vascularity and pigmentation	Irritation, dermatitis
Tanini et al. [22]	SG (N=15) TSSgo (N=15)		12 m	TSSgo improved height, vascularity, and pigmentation but worse pliability	None
Shirazi et al. [38]	SG (N=37)	Placebo gel (N=37)	2 m	SG improved vascularity, height, and pliability but not pigmentation	NR
Cadet et al. [45]	SG (N=12)§	Placebo gel (N=12)§	6 m	SG did not improve POSAS	None
Lin et al. [30]	SG (N=32) <sup>§</sup> SGS (N=32) <sup>§</sup>		3 m	No difference in VSS and VAS between groups	NR
Song et al. [26]	SG (N=30) OE gel (N=30)	No treatment (N=30)	12 w	No difference in VSS between groups	Pruritis, irritation
Meseci et al. [28]	SG (N=25)§ * Methylprednisolone cream (N=25)§ *	No treatment (N=25)	3 m	Methylprednisolone cream had better mVSS than SG. Both treatments had better mVSS than control	None
Braam et al. [16]	SGS for 2 months (N=12) SGS for 6 months (N=14)	No treatment (N=10)	2 m or 6 m	SGS did not improve hypertrophy and caused wider scar at 6 months than 2 months	Rash
Choi et al. [40]	SGS (N=7)§*	No treatment (N=7)§	14 w	Expression of TGF-B1 and PDGF in epidermis and dermis was significantly lower in SGS. Dermal expression of bFGF was higher in SGS	Pruritis
Kim et al. [31]	SG (N=15) SGS (N=15)		3 m	No difference in VSS score between both groups but patients reported increased convenience with SG use	None
Kong et al. [37]	SG (N=50)	Placebo gel (N=50)	1 m	SG had improved pigmentation and height in VSS, but vascularity and pliability were not significantly improved	NR

Kwon et al. [27]	SG (N=16)* Tretinoin cream (N=16)*	No treatment (N=16)	6 m	SG and tretinoin cream had better mVSS scores than the control. No statistically significant difference was found between SG and tretinoin cream	Burning sensation at application site
Lim et al. [41]	SGS (N=12)§ *	No treatment (N=12)§	12 w	SGS had better VAS scores	NR
Chittoria et al. [34]	SG (N=50) <sup>§</sup> *	Placebo gel (N=50)§	6 w	SG had smaller scars and better VSS scores	None
Riedel et al. [36]	SG (N=20) <sup>§</sup>	No treatment (N=20)§	3 m	SG had worst VAS scores	NR
Wananukul et al. [17]	SG & OE (N=39)§*	Placebo gel (N=39)§	6 m	SG & OE had decreased incidence of scarring and hypertrophic scar	Pustule
Yun et al. [23]	SG & vitamin C (N=41)*	No adjunct (N=39)	6 m	SG & vitamin C had decreased height, erythema, and pigmentation	Transient hyperpigment ation
Maher et al. [44]	SGS (N=10)§	No treatment (N=10)§	6 m	SG had improved pliability and pigmentation on VSS	Minor irritation
Markl et al. [32]	Mepitel (N=28) Suprathel (N=22) Biatain-lbu (N=27)		6 m	No difference in VSS for all types of SGS. Difference in cost and pain reduction	NR
de Giorgi et al. [35]	SG (N=65)*	Zinc oxide cream (N=45)	60 d	Decreased scar alterations in SG	None
Signorini et al. [43]	SG (N=80)*	Pressure dressing, ILK, or silicone sheets (N=80)	4 m	Self-drying SGS had improved scar quality	None
Maján [42]	SG (N=6)*	No treatment (N=5)	12 m	SGS had better VSS	Local skin irritation
Chan et al. [33]	SG (N=50) <sup>§</sup> *	Placebo gel (N=50) <sup>s</sup>	10 w	SG had better VSS scores, less pain, and itching	One small superficial wound infection
Gold et al. [39]	SGS low-risk	Topical antibiotic low- risk	6 m	Low risk group had no difference but high risk group had	NR
	SGS high-risk (N=17) Topical antibiotic high-risk (N=18)	decreased incidence of scar and keloid compared to control	Irritation to SGS		
Wittenberg et al. [29]	FLPDL (N=20)§ SGS (N=20)§	No treatment (N=20)§	FLPDL-40 w SGS-24 w	No difference in volume, elasticity, erythema, pruritus, burning compared to control	

<sup>\*</sup>Treatment success was statistically significant compared to control (p < 0.05)

BIS, body image scale; CS, cosmetic scale; d, days; FLPDL, flashlamp-pumped pulsed-dye laser; HE, herbal extract; IPS, image panel scale; ILK, intralesional Kenalog; mVSS, modified Vancouver scar scale; m, months; NR, not reported; OE, onion extract; POSAS, patient observer scar assessment scale; SG, silicone gel; SGS, silicone gel sheets; SGOA, silicone gel+onion extract+aloe vera; VSS, Vancouver scar scale; VAS, visual analog scale; w, weeks.

<sup>\*</sup>Treatment success was statistically significant compared to other treatments (p < 0.05)

<sup>§</sup>Treatments and/or controls were tested on the same group of patients

<sup>&</sup>lt;sup>b</sup>Low-risk group did not specify number of subjects in treatment or control arm, total N=31