



## The Efficacy of Topical Silicone Gel in Keloids and Hypertrophic Scars Treatment: A Systematic Review and Meta-Analysis

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**Abstract Background:** Keloids and Hypertrophic scars emerge because of abnormal wound healing. A variety of treatment modalities have been used, with topical silicone gel being one of the most widely recommended non-invasive options for both treatment and prevention. Despite its common use in clinical practice, there remains a need to clarify its overall effectiveness. **Objectives:** The aim of the study is to evaluate the efficacy of topical silicone gel in improving scar outcomes (including scar scales and VSS domains), as well as its safety profile, in comparison to placebo, no treatment or alternative topical therapies. **Methods:** A systematic review according to PRISMA guidelines was performed utilizing PubMed, Web of Science and ProQuest. Studies were accepted for inclusion if they had patients with hypertrophic scars or keloids who received topical silicone gel, other topical therapy or a placebo and provided outcome data. The analysis of data was conducted with Review Manager and Comprehensive Meta-Analysis v3 software. **Results:** Eight studies encompassing 464 patients with hypertrophic scars or keloids. Four articles used silicone gel for post-burn scars, with the remaining for post-operative scars. The age range of patients is 18 to 85 years, from both genders. The likelihood of an excellent response was higher in the silicone gel group (OR = 2.79), although this did not reach statistical significance (95% CI: 0.84-9.23,  $p = 0.09$ ). In the Vancouver Scar Scale domains, the mean pliability score was lower in the silicone gel group (SMD = -0.55,  $p = 0.005$ ). No statistically significant differences were observed in other Vancouver Scar Scale domains, including height, pigmentation and vascularity. **Conclusion:** Topical silicone gel is a well-tolerated non-invasive option that may improve scar pliability, although overall efficacy across all scar outcomes remains uncertain in both post-burn and post-operative scars.

**Key Words** Hypertrophic Scar, Keloid, Silicone Gel, Topical Onion Extract, Vancouver Scar Scale

### INTRODUCTION

Keloids and Hypertrophic scars appear because of an abnormal process of wound healing characterized by inflammation, increased fibroblast proliferation and an excessive accumulation of extracellular matrix proteins. These scars can lead to significant physical discomfort, pruritus, pain and psychological distress due to their appearance and possible functional limitations [1-3].

Histologically, both Keloids and Hypertrophic scars represent a spectrum of fibroproliferative disorders in the reticular dermis. While hypertrophic scars typically remain within wound margins, keloids extend beyond and rarely regress. Both conditions lie on a clinical-histological

spectrum, with genetic, systemic and environmental factors contributing to their development. Ethnic differences affect prevalence and diagnostic tendencies: keloids are more common in African populations and less so in European populations, which can lead to regional variability in diagnosis [4].

Globally, scarring affects approximately 100 million patients annually in developed countries. Of these, 55 million cases result from elective surgeries, while 25 million stem from post-trauma operations [5]. Burn wounds represent another major cause of pathological scarring, including hypertrophic scars and contractures. Reported prevalence rates for hypertrophic scarring following

burns vary widely, ranging from 8% to 67%, with recent prospective studies identifying an incidence closer to 8% [6].

Keloids affect an estimated 2-4% of the global population, amounting to 150-300 million people worldwide [7]. Patients are considered high-risk if they have scars in keloid-prone areas (e.g., the lower face, prosternum, pectoral area, upper back, ears, neck and deltoid region of the upper arms) or a personal history of keloid formation [8].

A variety of treatment modalities have been used to manage hypertrophic scars and keloids, such as surgical excision, laser therapy, cryotherapy corticosteroid injections, laser, pressure therapy and silicone. Silicone is available in several formulations, including traditional sheets, topical gels and newer spray or stick formulations. Among these modalities, topical silicone gel is considered one of the most widely recommended non-invasive options for both prevention and treatment [1,3]. Compared to herbal-based therapies (e.g., onion extract), topical silicone gels demonstrate superior clinical efficacy, broader evidence support and more favorable safety profiles in managing scars [9]. Silicone gel has the advantage of becoming transparent and dry within a few minutes and is believed to hydrate scar tissue and regulate fibroblast activity, which may help to improve scar appearance and symptoms [10,11]. Additional proposed mechanisms include modulation of cytokine expression, reduction of capillary activity and regulation of collagen synthesis, although these pathways remain incompletely understood.

Multiple Randomized Controlled Trials (RCTs) and clinical studies have investigated the efficacy of topical silicone gel but their findings differ due to variations in measured outcomes, study quality and treatment protocols. Therefore, despite its common use in clinical practice, there remains a need to clarify its overall effectiveness and to summarize the available evidence on its benefits and safety.

This systematic review aims to assess the effectiveness of topical silicone gel in the treatment of keloids and hypertrophic scars, providing an updated and evidence-based overview to guide clinical practice.

Previous systematic reviews have reported inconsistent findings, due to heterogeneity in scar types, treatment duration and comparator interventions. This study aims to provide an updated synthesis focusing exclusively on randomized controlled trials to improve the reliability of the evidence.

## METHODS

### Protocol and Registration

We adhered to the PRISMA 2020 guidelines during this review to guarantee transparency and consistency [12]. The protocol for this study was registered in PROSPERO with the registration number CRD420251055406.

### Search Strategy

A thorough literature search utilizing PubMed, Web of Science and ProQuest was conducted in May 2025. The search methodology was as follows: ("hypertrophic scar" [Title/Abstract] OR "keloid" [Title/Abstract] OR "scar"

[Title/Abstract] AND ("silicone gel" [Title/Abstract] OR "topical silicone" [Title/Abstract]) AND ("randomized controlled trial" [Publication Type] OR "randomised controlled trial" [Title/Abstract] OR RCT [Title/Abstract]). Furthermore, we manually examined the bibliographies of all selected articles throughout the full text review to guarantee the thorough inclusion of all relevant publications.

### Study Selection

The Rayyan cooperation platform was utilized to screen the studies based on title and abstract (<https://www.rayyan.ai/>) [13]. The studies were qualified for inclusion in this systematic review and meta-analysis if they satisfied the following criteria:

### Inclusion Criteria:

- Studies are conducted as randomized controlled trials
- Studies involving patients with various types of cutaneous scars, including hypertrophic scars, keloids and post-surgical scars
- Studies assessing our intervention of interest, specifically topical silicone gel as a monotherapy
- Studies published in the English language must have accessible full-text articles for data extraction

### Exclusion Criteria:

- Non-randomized controlled trials, encompassing observational research, case series, case reports, reviews and editorials
- Studies examining the efficacy of topical silicone gel in combination with various other treatment modalities
- Studies published in languages other than English or for which the full text article was unavailable

### Data Extraction

Two distinct authors collected the data using a predesigned data extraction sheet to obtain information from the included studies. To ensure accuracy, a third author independently checked and validated the extracted data to identify any discrepancies or omissions by cross-matching all data points with the original source materials. The extracted data from the included studies encompassed the study characteristics (author name, study region, study period, study design and sample size), patient demographics (age, gender and type of scar), interventional characteristics (type of intervention, control group, treatment duration and follow-up duration), efficacy outcomes (measurement tools utilized and baseline scores for the corresponding measurement tools) and safety outcomes (adverse events).

### Risk of Bias Assessment

The risk of bias in the included randomized clinical trials was evaluated using the Cochrane Collaboration's tool, which evaluates seven key areas: Random sequence generation, allocation concealment (to prevent selection bias), blinding of participants and staff (performance bias), blinding of

outcome assessment (detection bias), management of incomplete outcome data (attrition bias), selective reporting (reporting bias) and any other potential bias sources [14].

### Data Analysis

Standardized Mean Difference (SMD) was used to analyse the continuous variables. Data reported as median with range, mean with range or mean with 95% Confidence Intervals (CI) were converted into mean and Standard Deviation (SD) following the equations outlined by Hozo *et al.* [15]. Risk Ratios (RR) or Odds Ratios (OR) with 95% CI were utilized to analyze dichotomous variables. A fixed-effect model was adopted when assuming a single underlying population effect size, whereas a random-effects model was utilized when between-study variability was anticipated. Statistical heterogeneity was assessed using the Higgins  $I^2$  statistic, with a value of  $>50\%$  and the Cochrane Q (Chi-squared test), with a p-value of  $<0.10$  [16]. Data analysis was performed using Review Manager version 5.4 and Comprehensive Meta-Analysis v3 software. A difference was deemed statistically significant at  $p < 0.05$ . The Scar Assessment Scales were extracted from the work of Cadet *et al.* [17], with the help of WebPlotDigitizer software. Formal assessment of publication bias and sensitivity analyses were not performed due to the small number of included studies.

## RESULTS

### Search Process

A search conducted in PubMed, Web of Science and ProQuest yielded 123 articles. After removing 64 duplicates, 59 articles were screened by title and abstract. Following this, 46 articles were excluded as irrelevant, leading to a refined selection. Thirteen articles were then reviewed in full text, with five excluded due to reasons including non-randomized design, use of combination therapies or lack of relevant outcome data. Eight articles met the inclusion criteria and were selected for data extraction and meta-analysis. Figure 1 displays the PRISMA flow diagram summarizing this process.

### Demographic Characteristics of the Included Studies

This review encompassed eight studies involving 464 participants [7-14]. Out of these, 235 patients were treated with silicone gel, while 229 were placed in the control group. Four studies examined the application of silicone gel for post-burn scars and four for post-operative scars. The participants' ages ranged from 18 to 85 years, with treatment periods varying between two and six months. The baseline scores ranged from 1.33 to 10.26 in the silicone gel group and from 0.90 to 10.46 in the control group. Specific details regarding the characteristics of the included studies are presented in Table 1.

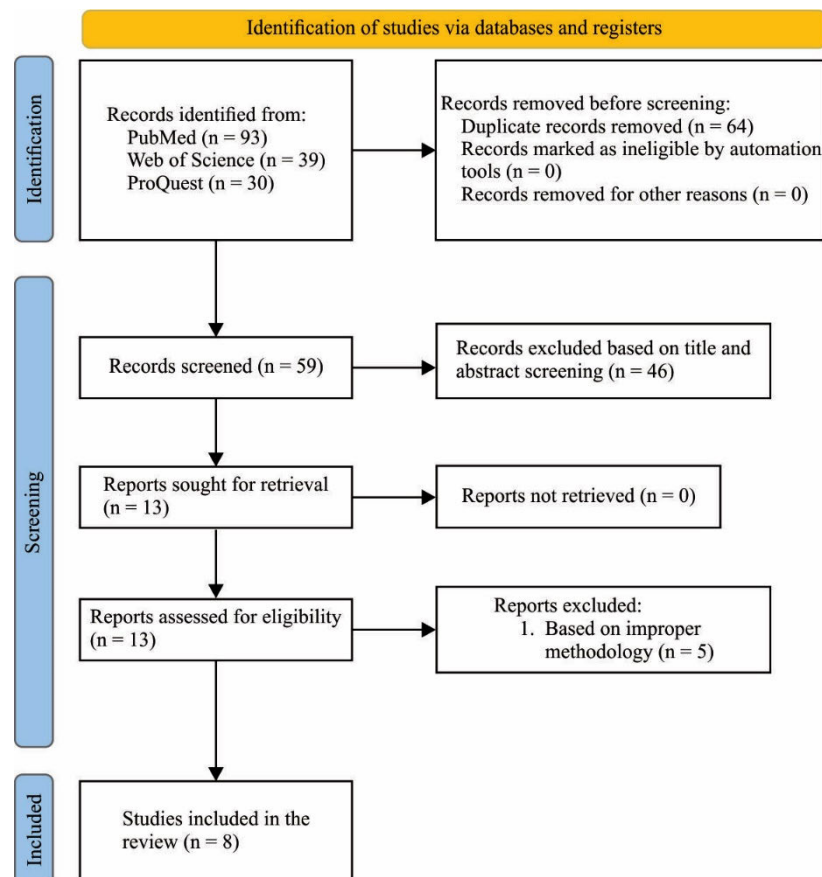


Figure 1: PRISMA Flow Diagram Illustrating a Summary of the Search Strategy

Table 1: Characteristics of Included Studies

Study ID	Study Design	Study period	Intervention	Control	Type of scar	Sample Size		Age		gender		Treatment Duration	Follow-up	Measurement Tools	Baseline Score	
						Intervention	Control	Intervention	Control	Males	Females				Intervention	Control
						Number	Number	Mean±SD	Mean±SD	Number	Number			Mean±SD	Mean±SD	
1 Caddet <i>et al.</i> [17]	Randomized double-blind clinical trial	January to November 2012	Silicone gel	Placebo Gel	Brow lift scars	12	12	58 to 85		10	2	2 months	6 months	POSAS	NR	NR
2 Karagoz <i>et al.</i> [19]	Randomized prospective comparative study	NR	Silicone gel	Topical onion extract	Postburn hypertrophic scars	15	15	24 years (range 3-55 years)		12	20	6 months	6 months	VSS	9.5±0	4.4±1.4
3 Meseci <i>et al.</i> [18]	Randomized controlled trial	January 2014–December 2014	Silicone gel	No Treatment	Pfannenstiel scar	21	18	44.05±4.57	43.44±5.99	0	39	3 months	6 months	mVSS	4.29±2.97	6.00±0.95
4 Nair <i>et al.</i> [22]	Randomised Control Clinical Trial	1 Jul 2018 to 30 Jun 2019	Silicone gel	Natural scar maturation	Pfannenstiel scar	27	25	(19, 33)		0	52	NR	12 weeks	VSS	NR	NR
5 Poeldrow <i>et al.</i> [20]	Single-blinded, prospective, randomised controlled trial	December 2018 and December 2020	Silicone gel	Standard of care emollient	Postburn hypertrophic scars	26	29	36 (25, 47)		34	21	3 months	3 months	mVSS, POSAS,	1.33±2.22	NR
6 Scuderi <i>et al.</i> [24]	Prospective phase 2 cross-over multicenter trial	April 2007 to May 2009	Silicone gel	Topical Cyanocerylates	Post Burn Surgery Scar	80	80	32 (18,52)		0	80	6 months	6 months	VSS	1.33±0.95	0.90±0.91
7 Wahba <i>et al.</i> [23]	A single-blind randomized controlled trial	June 2017 and January 2018	Silicone gel	Topical onion extract	Postburn hypertrophic scars	15	15	32.66±6.83	31.53±5.56	16	14	24 weeks	24 weeks	mVSS	10.26±1.22	10.46±0.99
8 Wiseman <i>et al.</i> [21]	Randomised Control Clinical Trial	August 2016 and November 2018	Silicone gel	Pressure garment	Postburn hypertrophic scars	51	49	3.54 (1.52, 8.78)	8.86 (1.82, 10.87)	57	43	NR	6 months	VSS	NR	NR

Abbreviations: VSS= Vancouver Scar Scale; POSS= The Patient and Observer Scar Assessment Scale; NR=Non-reported

**Qualitative Assessment and Risk of Bias**

All of the included studies demonstrated a low risk of bias regarding random sequence generation, except for the study by Meseci *et al.* [18]. Four studies showed a low risk of allocation concealment bias, while Karagoz *et al.* [19], had an unclear risk of performance bias. Two studies exhibited a high risk of attribution bias [20,21] and all studies indicated a low risk of reporting bias. The results of the qualitative assessment and the risk of bias summary are presented in Figure 2a-b.

**Outcomes of Silicone Gel**

**Surgeon Scar Assessment Scales:** Seven studies [17-23] assessed the effect of silicone gel on scar outcomes using the surgeon scar assessment scales, categorized by scar type. The random-effects model ( $I^2 = 87.5, p < 0.001$ ) showed no significant difference between the silicone gel and control groups in both post-burn scars (SMD; -0.545, 95% CI; -1.743, 0.653,  $p = 0.372$ ) and post-operative scars (SMD; -0.260, 95% CI; -1.102, 0.581,  $p = 0.545$ ), yielding a pooled SMD of -0.354 (95% CI; -1.043, 0.334,  $p = 0.313$ ) (Figure 3a).

Subgroup analysis by control type revealed significant differences between silicone gel and natural scar maturation

(SMD: -0.703, 95% CI: -1.127, -0.279,  $p = 0.001$ ), as well as topical ointment extract (SMD; -1.674, 95% CI; -2.630, -0.719,  $p = 0.001$ ) (Figure 3b).

**Patient Scar Assessment Scale**

Three articles evaluated the difference in patient scar assessment scales between silicone gel and control groups [17,20,21]. There was no statistically significant difference between silicone gel and control groups (SMD; -0.203, 95% CI; -0.880, 0.474,  $p = 0.557$ ) in the random-effects model ( $I^2 = 60.8, p = 0.078$ ) (Figure 4).

**Response to Treatment**

Two articles included 69 patients and evaluated the odds of excellent response after silicone gel treatment for scars [18,19]. In the random-effects model ( $I^2 = 0\%, p = 0.57$ ), the likelihood of excellent response was 2.79 times higher among patients treated with silicone gel (95% CI; 0.84, 9.23,  $p = 0.09$ ), relative to the control group (Figure 5a). In this regard, the random-effects model ( $I^2 = 0\%, p = 0.62$ ) indicated that there was no statistically significant difference in the likelihood of a

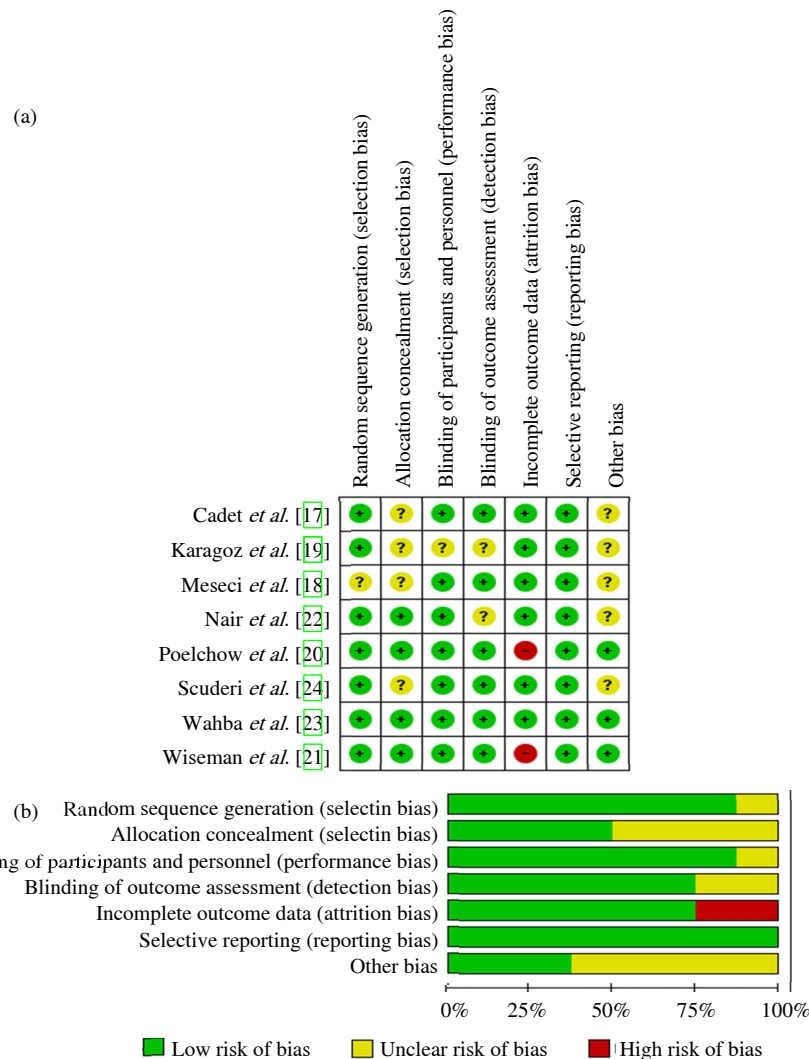


Figure 2(a-b): (a) Qualitative Assessment and (b) Risk of Bias Summary

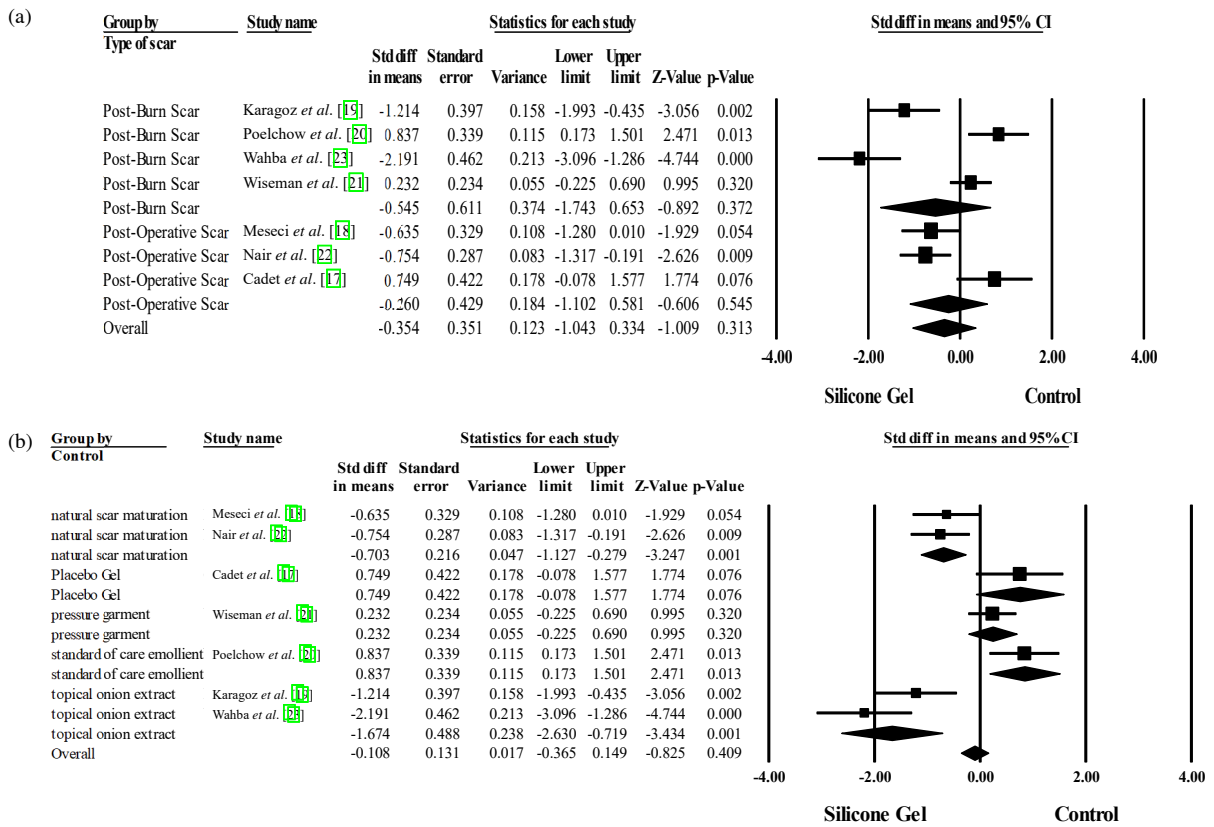


Figure 3(a-b): Forest Plot of Summary Analysis and Subgroup Analysis of the Surgeon Scar Assessment Scales Between Silicone Gel and Control Groups Among Patients with Scars Based on (a) Type of Scar and (b) Type of Control

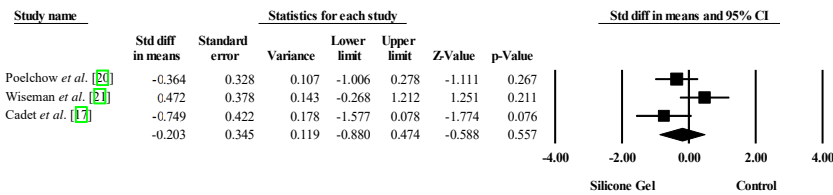


Figure 4: Forest Plot of Summary Analysis of the Standardized Mean Difference and 95% CI of the Patient Scar Assessment Scales Between Silicone Gel and Control Groups Among Patients with Scars

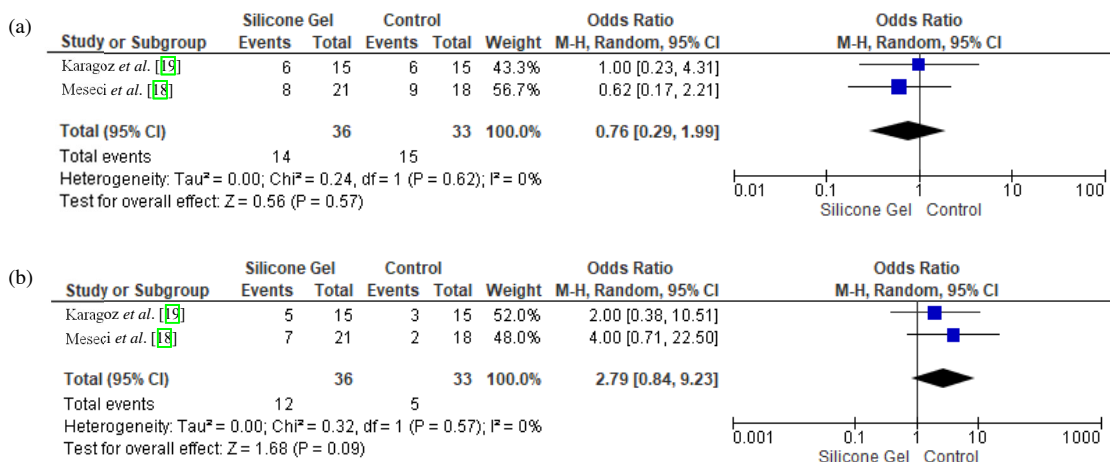


Figure 5(a-b): Forest Plot of Summary Analysis of the Event Rate of (a) Excellent Response and (b) Good Response Between Silicone Gel and Control Groups Among Patients with Scars

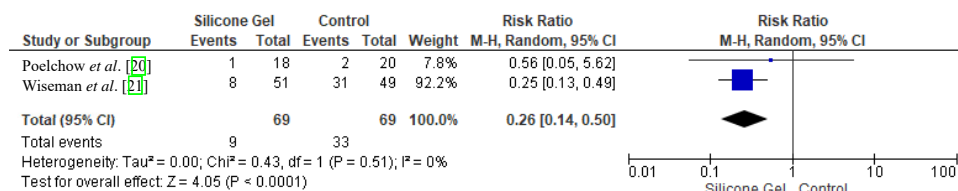


Figure 6: Forest Plot of Summary Analysis of the Risk Ratio and 95% CI of Adverse Events Between Silicone Gel and Control Groups Among Patients with Scars

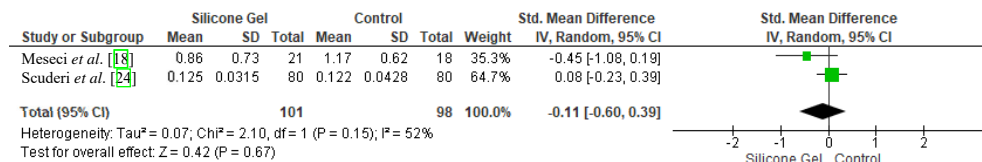


Figure 7: Forest Plot of Summary Analysis of the Standardized Mean Difference and 95% CI of the Mean Height Between Silicone Gel and Control Groups (e.g., Pressure Garments, Standard of Care, Topical Cyanoacrylate) Among Patients with Scars

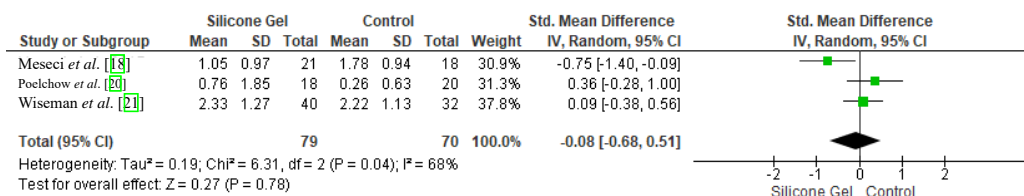


Figure 8: Forest Plot of Summary Analysis of the Standardized Mean Difference and 95% CI of the Mean Pigmentation Between Silicone Gel and Control Groups Among Patients with Scars

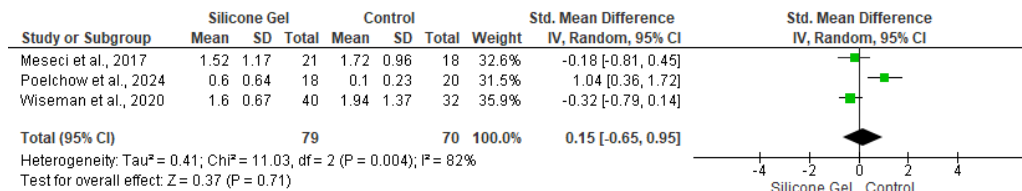


Figure 9: Forest Plot of Summary Analysis of the Standardized Mean Difference and 95% CI of the Mean Vascularity Between Silicone Gel and Control Groups Among Patients with Scars

good response between the silicone gel and control groups (OR: 0.76, 95% CI: 0.29, 1.99, p = 0.57) (Figure 5b).

**Adverse Events**

The risk of adverse events after silicone gel treatment for patients with scars was evaluated among 138 patients [20,21]. The risk of adverse events was significantly lower among patients treated with silicone gel, with an RR of 0.26 hovering between 0.14 and 0.050 (p<0.001) in the random-effects model (I<sup>2</sup> = 0%, p = 0.51), as shown in Figure 6.

**Vancouver Scar Scale Domains**

**Height:** Two studies including 199 patients [18,24], evaluated the difference in mean scar height between silicone gel and control groups. There was no statistically significant difference between both groups with an SMD of -0.11 (95% CI: -0.60, 0.39, p = 0.67) in the random-effects model (I<sup>2</sup> = 52%, p = 0.15) as described in Figure 7.

**Pigmentation**

The difference in mean pigmentation scores between silicone gel and control groups was evaluated among 149 patients within three articles [18,20,21]. There was no statistically significant difference between silicone gel and control groups (SMD: -0.08, 95%CI: -0.68, 0.51, p = 0.78) in the random-effects model (I<sup>2</sup> = 68%, p = 0.04), which is illustrated in Figure 8.

**Vascularity**

Three articles included 149 patients and evaluated the mean vascularity score between silicone gel and control groups [18,20,21]. Meta-analyzing the data in the random-effects model (I<sup>2</sup> = 82%, p = 0.04) revealed no statistically significant difference between silicone gel and control groups (SMD: 0.15, 95% CI: -0.65, 0.95, p = 0.71) (Figure 9).

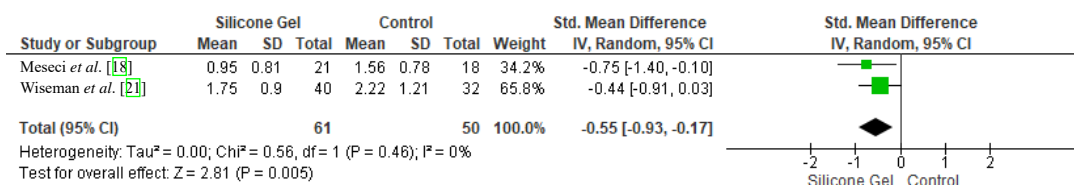


Figure 10: Forest Plot of Summary Analysis of the Standardized Mean Difference and 95% CI of the Mean Pliability Between Silicone Gel and Control Groups Among Patients with Scars

### Pliability

Two articles included 111 patients [18,21] and evaluated the mean pliability score between silicone gel and control groups. There was a statistically significant lower mean pliability score between both groups with an SMD of -0.55 (95% CI; -0.93, -0.17,  $p = 0.005$ ) in the random-effects model ( $I^2 = 0\%$ ,  $p = 0.46$ ), as illustrated in Figure 10.

### DISCUSSION

This updated systematic review and meta-analysis evaluates the safety and efficacy of topical silicone gel in the treatment of hypertrophic scars and keloids compared to control interventions, including placebo, no treatment and alternative topical therapies such as onion extract.

Among 464 patients participating in eight clinical trials, 235 received silicone gel and 229 were assigned to control groups. Subgroup analysis by scar type revealed no statistically significant difference between silicone gel and control groups in both surgeon- and patient-rated scar assessment scales but subgroup analysis based on the kind of control revealed a statistically significant difference between silicone gel and natural scar maturation (SMD; -0.703, 95% CI; -1.127, -0.279,  $p = 0.001$ ) and topical ointment extract (SMD; -1.674, 95% CI; -2.630, -0.719,  $p = 0.001$ ). Likewise, scar characteristics, including height, pigmentation and vascularity, showed no meaningful difference between groups. However, the mean pliability score was significantly lower in the silicone gel group (SMD = -0.55,  $p = 0.005$ ), with no heterogeneity ( $I^2 = 0\%$ ), indicating enhanced scar flexibility and consistency of this effect across studies. This study suggests a potential mechanical benefit of silicone gel, particularly for scars located in areas where function and mobility are critical.

These results partially align with the meta-analysis by Wang *et al.* [25], which also demonstrated a significant improvement in scar pliability following the use of silicone gel. However, unlike our findings, their analysis reported broader benefits, including reductions in pigmentation and height, particularly when treatment duration extended beyond six months. Specifically, they reported significant pooled effects for pigmentation (SMD = -0.55, 95% CI: -0.83 to -0.26;  $p = 0.0002$ ), height (SMD = -0.73, 95% CI: -1.02 to -0.44;  $p < 0.00001$ ) and pliability (SMD = -0.49, 95% CI: -0.95 to -0.03;  $p = 0.04$ ). The differences may be explained by the shorter follow-up periods in our included studies, as Wang *et al.* [25] noted that the effectiveness of silicone gel was not consistently observed in studies with only 3-month follow-up durations.

Although the finding was not statistically significant (OR = 2.79, 95% CI: 0.84-9.23;  $p = 0.09$ ), the observed trend toward improved excellent response with silicone gel suggests a possible trend toward benefit, although this did not reach statistical significance, which should be explored in future high-powered trials and the risk of adverse events was significantly lower compared to control (RR = 0.26), indicating a favorable safety profile. Our results are in line with Goldberg *et al.* [26], who reported excellent safety in a 3-month pilot study using 100% silicone gel, with no adverse events observed. This result reinforces the notion that silicone gel remains a safe and well-tolerated treatment, particularly for early intervention and sensitive skin areas.

Multiple reviews have assessed the efficacy of silicone gel. A meta-analysis by De Decker *et al.* [27] concluded that silicone gel has both prophylactic and therapeutic benefits in hypertrophic and keloid scars; however, most of the included trials were of high risk of bias, making definitive efficacy conclusions cautious. In contrast, our review included randomized controlled trials; however, some studies demonstrated unclear or high risk of bias in specific domains, which should be considered when interpreting the findings.

Our findings align with long-term evidence showing improved pliability is a consistent benefit of silicone gel. No significant changes were observed in pigmentation, height or vascularity. Additionally, subgroup analysis showed no difference between post-burn and post-surgical scars, suggesting that etiology may not significantly affect treatment response. Uniquely, our meta-analysis is the first to establish that silicone gel yields consistent pliability benefits regardless of scar etiology—an insight that significantly expands current understanding of its therapeutic scope.

A 2017 review by Hsu *et al.* [28] similarly evaluated both silicone gel and silicone gel sheeting in the prevention and management of hypertrophic scars and keloids and reported modest benefits in scar outcomes. However, the authors highlighted that most of the included studies were small-scale, non-blinded or lacked standardized outcome assessments, which limited the strength of their conclusions [28]. This underscores the added value of our systematic review, which exclusively included low-bias randomized controlled trials with scar-type stratification.

A key strength of this review is the inclusion of RCTs only and the use of multiple validated scar assessment tools to provide a comprehensive and clinically relevant evaluation. Significantly, pliability and adverse event

outcomes exhibited no heterogeneity ( $I^2 = 0\%$ ), thereby reinforcing the reliability of these domains. However, limitations include small sample sizes, short follow-up durations and variation in outcome measurement methods across studies, which may limit generalizability.

Future studies should be adequately powered, randomized and designed with a low risk of bias to improve the reliability of outcomes. The use of standardized and objective outcome measures, such as blinded assessments, digital imaging or validated scar scales, is essential to reduce subjectivity and enhance comparability across studies. There is also a need for more randomized controlled trials comparing silicone gel with alternative treatments. Furthermore, long-term follow-up data are necessary to determine the durability of cosmetic improvements and functional benefits. High-quality RCTs will enable the generation of more robust and generalizable findings, thereby supporting future systematic reviews and evidence-based clinical guidelines.

Given its favorable safety profile and potential benefit in improving scar pliability, topical silicone gel may be considered a reasonable non-invasive option, particularly in early-stage or functionally sensitive scars. While aesthetic improvements may require adjunctive therapies, silicone gel remains an accessible and well-tolerated base therapy in scar management.

## CONCLUSIONS

This systematic review and meta-analysis suggest that topical silicone gel is a safe and well-tolerated treatment option that may improve scar pliability. However, evidence for broader efficacy across all scar outcomes remains limited and inconsistent. Further high-quality randomized controlled trials are required to clarify its overall clinical effectiveness. By exclusively including low-risk randomized controlled trials and employing detailed scar-type subgroup analysis, our study addresses key limitations of previous reviews and provides novel insight into the generalizability of silicone gel across various scar etiologies. Furthermore, the search strategy was restricted to selected databases and English-language publications, which may have introduced publication bias. Notably, consistent improvements in pliability and a strong safety profile were observed with zero heterogeneity, reinforcing the reliability and clinical applicability of the findings. These results position silicone gel as a well-tolerated, non-invasive and effective first-line therapy in scar management.

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