

Silicone gel sheeting for healing keloid scars: a WHAM evidence summary

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CLINICAL QUESTION

What is the best available evidence for silicone gel sheeting (SGS) for healing existing keloid scars?

SUMMARY

Silicone gel sheeting (SGS) (also referred to as silicone gel patch or silicone gel dressing) is a semi-occlusive, flexible dressing made of medical-grade, cross-linked silicone polymers that has been used widely as a non-invasive treatment to heal pathological scarring, including keloids. Silicone gel sheeting is described as having properties that maintain hydration, modulate fibroblast activity and reduce transepidermal water loss (TEWL).¹⁻⁵ Silicone gel sheeting is used as a standalone treatment, or as an adjunct to other treatments (e.g., pressure therapy or corticosteroid injections).⁶ *Level 1* evidence⁷ reported that there is very low certainty regarding the effectiveness of SGS alone for treating existing keloid scars, with no clear benefit for SGS compared to no treatment, non-silicone dressings or intralesional steroid injections.

CLINICAL PRACTICE RECOMMENDATIONS

All recommendations should be applied with consideration to the clinical presentation, the person, the health professional and the clinical context.

There is currently insufficient evidence to support the use of silicone gel sheeting as an effective standalone treatment for healing existing keloid scars.

SOURCES OF EVIDENCE

This summary was conducted using methods published by the Joanna Briggs Institute.⁸⁻¹⁰ The summary is based on a systematic literature search combining search terms related to 'keloid scar' and 'silicone dressing' and 'silicone gel sheeting'. First, a search was conducted in the Cochrane Database of Systematic Reviews for any relevant systematic reviews. Two systematic reviews^{6, 7} published in 2023 were identified, with the highest level of evidence arising from a Cochrane review.⁷ Next, a search was made in Medline (Ovid), PubMed and Scopus for studies published in English that met the inclusion criteria for the identified Cochrane review⁷ (i.e., randomised controlled trials [RCTs]), which failed to identify additional studies.

BACKGROUND

Keloid (also known as cheloid) scarring is a pathological response to skin injury, marked by excessive fibroblast proliferation and collagen deposition, resulting in raised, firm lesions that extend beyond the original wound margin and rarely regress spontaneously.^{6, 7, 11, 12} Keloid scars contrast to hypertrophic scarring that is confined to the initial wound margin. Keloids can cause significant physical discomfort, functional impairment, and psychological distress due to their appearance and symptoms such as pain and pruritus.^{6, 7, 11, 12} and do not regress spontaneously.⁶ The incidence of keloids varies widely, with higher rates in dark skinned populations and during puberty and pregnancy, and they often affect the chest, shoulders, upper arms, and earlobes.^{6, 7, 11, 12}

Table 1. Levels of evidence for intervention studies reporting on silicone gel sheeting

Level 1 evidence	Level 2 evidence	Level 3 evidence	Level 4 evidence	Level 5 evidence
Experimental designs	Quasi-experimental designs	Observational – analytic designs	Observational – descriptive studies	Expert Opinion/ bench research
1.a Systematic review of RCTs ⁷	None	None	None	None
1.b Systematic reviews of RCTs and other study designs ⁶				

Silicone gel sheeting (SGS) is a semi-occlusive, flexible dressing made of medical-grade silicone that are widely used for non-invasive management of abnormal scars, including keloids.^{6, 7, 11, 13} Although the precise mechanism of action is not fully understood, it is proposed that silicone occludes and hydrates the stratum corneum, reducing TEWL and modulating fibroblast activity and collagen synthesis, thereby promoting scar maturation.^{2-5, 14-17}

CLINICAL EVIDENCE

Clinical evidence on SGS for treating keloid scar comes from a Cochrane review⁷ at low risk of bias which included two RCTs of small size^{18, 19} (see Table 2). The two studies^{18, 19} were clinically heterogeneous, with differences in scar aetiology, location, and duration. Both trials had methodological limitations, small sample sizes, lack of validated scales to measure scar severity and suboptimal outcome reporting that led to uncertainty regarding the effectiveness of SGS for treating keloid scars⁷ (*Level 1*). A second systematic review⁶ reported several non-randomised trials exploring use of SGS; however, the available data was similarly limited in quality and content, and the SGS was often in combination with other treatments (e.g., pressure therapy or corticosteroid injection), confounding the findings (*Level 1*).

Scar severity (clinician-rated)

Silicone gel sheeting compared with no treatment

The Cochrane review⁷ reported very low certainty evidence from two studies comparing SGS to no treatment. In the first study, scar size, colour, and intracatrical pressure were significantly improved in keloid scars treated with SGS compared with no treatment.¹⁸ However, the second study showed no significant difference in reduction in scar size ($\geq 50\%$ reduction in size) between keloid scars treated with SGS compared with no treatment.¹⁹ Therefore, the evidence is very uncertain regarding the benefits of SGS for measures of keloid scar severity compared with no treatment⁷ (*Level 1*).

Silicone gel sheeting compared with other treatment options

The same review⁷ reported very low certainty evidence that there were no statistically significant differences between SGS and a non-SGS for the following outcome measures: scar size, hardness, colour and intracatrical pressure.¹⁸ Additionally, SGS was also shown to be less effective than intralesional corticosteroid injections, but the difference was not statistically significant¹ and the outcome measure (success rate) was poorly defined.¹⁹ Overall, the evidence is uncertain regarding benefits of SGS for measures of keloid scar severity compared with other treatment options⁷ (*Level 1*).

Pain

Both the studies reported in the Cochrane review¹ included patient-reported outcome measures (patient reported pain). In the first study, there was no improvement in pain (reported by patients on a five-point scale) reported for keloid scars after either 4 or 12 weeks of treatment with SGS.¹⁹ In the second study, there was no significant difference in number of participants who reported reduction in pain with SGS, non-silicone get sheeting or no treatment.¹⁸ Overall, the evidence is uncertain regarding impact of SGS on keloid scar pain compared with other treatment options⁷ (*Level 1*).

CONSIDERATIONS FOR USE

- Silicone gel sheeting might be most suitable for small, stable keloid scars and less feasible for large scars or anatomical areas that are more mobile.^{7, 13}
- Level of adherence to the treatment and duration of use may impact the effectiveness of treatment.⁷
- Silicone gel sheeting is generally well tolerated, with a low incidence of mild adverse effects,^{20, 21} including minor local skin irritation.^{20, 22} One of the studies reported in this evidence summary specifically noted that no adverse events occurred.¹⁹

Table 2. Silicone gel sheeting/patch regimens for treating keloid scars reported in the research

Study	Participants	Silicone gel sheeting regimen	Comparator treatments	Outcome measures	Level of evidence
De Oliveira et al., 2001 ¹⁸	Individuals with keloid scars arising from acne, surgery, earrings, wound infection, herpes and trauma (n=16 participants with 25 keloid scars)	Intervention: SGS 24h/day for 4.5 months (n=8)	Comparator 1: Non-silicone gel sheeting 24h/day (n=7) Comparator 2: No treatment (n=10)	<ul style="list-style-type: none"> • Scar size • Scar hardness • Scar colour • Intracatrical pressure • Pain 	Level 1.c
Tan et al., 1999 ¹⁹	Individuals with keloid scars of unreported aetiology (n= 17 participants with 51 scars completed treatment)	SGS 12h/day (n=20) for 12 week	Comparator 1: Triamcinolone acetonide (corticosteroid) injections (n=20) Comparator 2: No treatment (n=20)	<ul style="list-style-type: none"> • Reduction in scar size • Change in scar colour (erythema) • Pain 	Level 1.c

CONFLICT OF INTEREST

The authors declare no conflicts of interest in accordance with International Committee of Medical Journal Editors (ICMJE) standards.

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ABOUT WHAM EVIDENCE SUMMARIES

Wound Healing and Management Collaborative (WHAM) evidence summaries are consistent with methodology published in Munn Z, Lockwood C, Moola S. *The development and use of evidence summaries for point of care information systems: A streamlined rapid review approach*, *Worldviews Evid Based Nurs*. 2015;12(3):131-8. Methods are provided in detail in resources published by the Joanna Briggs Institute as cited in this evidence summary and on the WHAM website. WHAM evidence summaries undergo peer-review by an international multidisciplinary Expert Reference Group. More information: <https://www.whamwounds.com>

WHAM evidence summaries provide a summary of the best available evidence on specific topics and make suggestions that can be used to inform clinical practice. Evidence contained within this summary should be evaluated by appropriately trained professionals with expertise in wound prevention and management, and the evidence should be considered in the context of the individual, the professional, the clinical setting and other relevant clinical information.

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