Silicon gel sheeting for preventing and treating hypertrophic and keloid scars (Review)

O’Brien L, Pandit A

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Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

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ABSTRACT

Background

Keloid and hypertrophic scars are common and are caused by a proliferation of dermal tissue following skin injury. They cause functional and psychological problems for patients, and their management can be difficult. The use of silicon gel sheeting to prevent and treat hypertrophic scarring is still relatively new, and started in 1981 with treatment of burn scars.

Objectives

To determine the effectiveness of silicon gel sheeting for:

(1) prevention of hypertrophic or keloid scarring in people with newly healed wounds (e.g. post surgery);

(2) treatment of established scarring in people with existing keloid or hypertrophic scars.

Search strategy

Trials were identified from searches of the Cochrane Wounds Group Specialised Register (searched November 2007), the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 4, 2007); MEDLINE (2005 to November 2007); EMBASE (2005 to Week 46, 2007); CINAHL (2005 to November 2007) and reference lists of articles and relevant reviews. The major supplier of silicon gel sheeting (Smith and Nephew) was approached for details of unpublished, ongoing and recently published trials.

Selection criteria

Any randomised or quasi-randomised controlled trials, or controlled clinical trials comparing silicon gel sheeting for prevention or treatment of hypertrophic or keloid scars with any other non surgical treatment, no treatment or placebo.

Data collection and analysis

All relevant trials were assessed for methodological quality. Data were extracted independently by both review authors using a standardized form, and the results cross-checked. All trials, meeting the selection criteria were assessed for methodological quality.
Main results

Fifteen trials, involving 615 people, ranging in age from 2 to 81 years, were included in the review. The trials compared adhesive silicon gel sheeting with control; non-silicon gel sheeting; silicon gel plates with added Vitamin E; laser therapy; triamcinolone acetonide injection, and non-adhesive silicon gel sheeting. In the prevention studies, when compared with a no treatment option; whilst silicon gel sheeting reduced the incidence of hypertrophic scarring in people prone to scarring, (RR 0.46, 95% CI 0.21 to 0.98) these studies were highly susceptible to bias. Silicon gel sheeting produced a statistically significant reduction scar thickness (RR -1.99, 95% CI -2.13 to -1.85) and colour amelioration (RR 3.05, 95% CI 1.57 to 5.96) but again these studies were highly susceptible to bias.

Authors’ conclusions

Trials evaluating silicon gel sheeting as a treatment for hypertrophic and keloid scarring are of poor quality and highly susceptible to bias. There is weak evidence of a benefit of silicon gel sheeting as a prevention for abnormal scarring in high risk individuals but the poor quality of research means a great deal of uncertainty prevails.

Plain Language Summary

Silicon gel sheeting for preventing the development of hypertrophic and keloid scars and for treating existing scars.

Hypertrophic and keloid scars are types of abnormal and pronounced scarring that can cause psychological and functional problems for people and can be difficult to treat. Hypertrophic scarring is more common in fair skin and tends to follow surgery and burn injuries, whereas keloid scarring is more common in darker skin and occurs after trivial injuries such as insect bites, ear piercing and vaccination. Scars occurring on some sites of the body, such as the lower face, neck and upper arms are more likely to develop abnormally. Silicon gel sheeting is a soft, self-adhesive sheeting designed to be used on intact skin for preventing and treating both new and old hypertrophic and keloid scars. The review considered evidence on whether silicon gel sheeting prevents the development of hypertrophic or keloid scarring in people with newly healed wounds, and whether it is effective in treating established scars. Trials were identified that looked at prevention and treatment strategies. Most studies were of poor quality and it is unclear whether silicon gel sheeting helps prevent scarring or is effective in treating existing hypertrophic and keloid scars.

Background

Wounds, such as burns, surgical incisions and ulcers, are repaired through the deposition of components that form new skin. These components include blood vessels, nerves, elastin fibres (which give the skin some elasticity), and collagen fibres (for tensile strength), as well as glycosaminoglycans (GAGS) which form the gel-like ground substance (or matrix) in which the structural fibres, nerves and blood vessels are embedded. In the early stages of healing, a cicatrix is formed. The cicatrix consists of a thin layer of skin (the pellicle) that covers the wound and subsequently contracts and becomes paler in colour, forming the scar.

Some scars develop abnormally, giving rise to keloid and hypertrophic scars. The scars arise from an excessive proliferation of dermal tissue following skin injury, with keloid scars developing in five to 15% of wounds (Wittenberg 1999). This proliferation of dermal tissue is due to both the production of fibrous tissue (fibroplasias), and the accumulation of abundant and randomly organised new collagen bundles.

O’Sullivan 1996 observed that although the terms ‘keloid’ and ‘hypertrophic’ have often been used synonymously, the two sorts of scarring are, in fact, significantly different. The principle clinical feature that distinguishes them is that in keloid scars the scar tissue progressively encroaches upon the normal skin surrounding it, producing a scar that appears irregular and pendulous in areas. Conversely, the hypertrophic scar is confined to the tissue damaged by the original injury. This type of scar increases in dimension by pushing out its margins, rather than invading surrounding tissue. Clinicians usually base diagnosis of keloid scarring on the overgrown boundaries and delayed onset of the scar (hypertrophic scars develop soon after injury) (Shaffer 2002).
Keloid scarring is reported to be more common in darker skin (Beers 1999; Niessen 1998), while hypertrophic scarring is more common in fair skin (Beers 1999). Examination of scars with an electron microscope shows keloid collagen to be thin and irregular with cross-striations, suggesting immaturity, while keloid scars are deficient in lymphatics and their associated elastic fibres, and have a higher content of both water and soluble collagen than normal skin. Although hypertrophic scars have similar qualities in the early stages, after seven months the two become distinct as the water and collagen content of hypertrophic scars normalises (Raney 1993).

Hypertrophic scars tend to follow surgery and thermal injuries such as severe burns (Carney 1993; Eisenbeiss 1998; Shakespeare 1993), whereas keloid scars often originate after trivial injury such as ear piercing, insect bites and vaccination. The amount of scar tissue in a keloid scar exhibits little relation to the extent of the injury that caused it (O’Sullivan 1996).

Both types of scarring can cause functional and psychological problems for people, and their management can be difficult. Treatment options have included surgery, radiation therapy, steroid injections, pressure therapy, cryotherapy (treatment with liquid nitrogen), and laser therapy (Shafer 2002). Many surgical techniques have been applied to remove keloids, either alone, or in combination with other treatments. Surgery alone has shown a high recurrence rate (Raney 1993).

Scars in specific sites of the body, including the lower face, preternum, pectoral area of the chest, upper back, ears, neck, outer (deltoid) area of the upper arms are more likely to develop abnormally (O’Sullivan 1996). People with scars in these high-risk anatomical areas, or with a history of forming keloid scars, aim to prevent further scarring by observing certain principles that include: avoiding nonessential cosmetic surgery, closing all wounds with minimal tension, and using pressure garments for four to six months after injury or surgery (O’Sullivan 1996).

The use of topical silicon for prevention and treatment of hypertrophic scarring is still relatively new. Silicon was first used, in gel form, for the treatment of burn scars at Australia’s Adelaide Children’s Hospital in 1981 (Perkins 1982). Silicon has since been produced in various forms, including: silicon cream compounds (Sawada 1992); silicon oil or gel with additives such as Vitamin E (Palmieri 1995); in combination with other dressing media (Davey 1991); and as custom-made silicon applications. This particular review is solely concerned with commercially-produced adhesive silicon gel sheeting.

Silicon gel sheeting is a soft, self-adhesive and semi-occlusive sheet used for the treatment and prevention of both old and new hypertrophic and keloid scars. It is made from medical-grade silicon (cross linked polydimethylsiloxane polymer) and reinforced with a silicon membrane backing (Katz 1992; Thomas 1997) thought to give it increased durability and make handling easier (Williams 1996).

Silicon gel sheeting is designed to be used on intact skin. It should not be used on open wounds and, according to the product information sheet supplied by the manufacturers (Smith & Nephew 2000), is contraindicated in people with dermatological conditions that disrupt the integrity of the skin (for example severe acne or psoriasis).

The mode of action of silicon-based products on scar tissue is unknown. Some researchers suggested that silicon may penetrate the skin, but studies by Ahn 1989 and Swanson 1974 found no evidence of silicon in the scar or stratum corneum. Quinn 1985 found that there was no significant difference in pressures obtained at the scar surface beneath the gel, and also concluded that there was no difference in scar surface temperature and oxygen tension, or water vapour transmissivity of the gel.

The cost of silicon gel sheeting ($139 AUD (Australian Dollars) recommended retail price for a 12 x 15 cm sheet, $74 AUD for 12 x 6 cm sheet), may be moderated by the fact that, after rinsing, it can be reused by the patient or their carer. However, the fact remains that clinicians and funders of care will require clear evidence of its clinical effectiveness before recommending its use.

**OBJECTIVES**

The aim of this systematic review was to determine the effects of silicon gel sheeting in:

1. prevention of hypertrophic or keloid scarring in people with newly healed wounds (e.g. post surgery);
2. treatment of established scarring in people with keloid or hypertrophic scars after any type of wound.

**METHODS**

**Criteria for considering studies for this review**

Any randomised controlled trials (RCTs) or quasi-randomised controlled trials (QRCTs) (method for allocating participants to a treatment that is not strictly random e.g. by date of birth, hospital record number, alternation) or controlled clinical trials (CCCTs) (where an intervention group is compared to a comparison or control group) of interventions, were considered.
**Types of participants**

People with healed full-thickness wounding (from any cause) where the skin was intact, with or without scarring at baseline.

**Types of interventions**

All comparisons of silicon gel sheeting with other conservative techniques (e.g. hydrocolloid dressings, non-silicon gel sheeting, laser therapy, or no intervention) were eligible. Comparisons of silicon gel sheeting with surgery were excluded. Trials that reported only the absorption of silicon by the skin, but did not measure the effect on scar appearance were excluded.

**Types of outcome measures**

**Primary outcomes**

PREVENTION STUDIES:
The primary outcome measure was the number of people who developed keloid or hypertrophic scarring as determined by blood flow, hyperpigmentation, erythema (redness), scar thickness and regularity of scar.

TREATMENT STUDIES:
The primary measure was change in scar size (measured by area, length, volume, height, or width - usually by ruler, taking an impression, or ultrasound).

**Secondary outcomes**

PREVENTION STUDIES:
Other measures of clinical outcome including:
- scar size (measured by area, length, volume, height, or width - usually by ruler, taking an impression, or ultrasound);
- scar colour (measured against standard colour charts), blood flow (measured using laser-Doppler flowmetry) and scar appearance (measured on a three or five point scale with appropriate definitions);
- skin elasticity (measured serially with the use of an elastometer);
- development of complications (e.g. rashes, skin breakdown, measured on a numbered scale);
- cosmesis as defined by patient opinion (using assessment scales) and physician observations;
- patient tolerance, measured by reported side effects and adverse reactions;
- preference for different modes of treatment measured by patient choice after receiving at least two different types of treatment;
- compliance, measured by physician and patient report.

TREATMENT STUDIES:
Other measures of clinical outcome including:
- scar colour (measured against standard colour charts) blood flow (measured using laser-Doppler flowmetry), and scar appearance (measured on a 3 or 5 point scale with appropriate definitions);
- skin elasticity (measured serially with the use of an elastometer);
- development of complications (e.g. rashes, skin breakdown, measured on a numbered scale);
- cosmesis as defined by patient opinion (using assessment scales) and physician observations;
- patient tolerance, measured by reported side effects and adverse reactions;
- preference for different modes of treatment measured by patient choice after receiving at least two different types of treatment;
- compliance, measured by physician and patient report.

**Search methods for identification of studies**

For the search strategy for the original review see Appendix 1

**Electronic searches**

For this first update the following databases were searched:
- The Cochrane Wounds Group Specialised Register (searched 21/11/07);
- The Cochrane Central Register of Controlled Trials (CENTRAL) - The Cochrane Library Issue 4, 2007
- Ovid MEDLINE (2005 to November Week 1 2007)
- Ovid EMBASE (2005 to 2007 Week 46)
- Ovid CINAHL (2005 to November Week 3 2007)

The following search strategy was used to search CENTRAL:

1 MeSH descriptor Keloid explode all trees
2 MeSH descriptor Cicatrix, Hypertrophic explode all trees
3 Keloid* or hypertrophic or cicatrix
4 scar or scars or scarring
5 (#1 OR #2 OR #3 OR #4 OR #5)
6 MeSH descriptor Silicone Gels explode all trees
7 silicone NEXT gel*
8 silicone NEXT sheet*
9 silicone NEXT dressing*
10 (#7 OR #8 OR #9 OR #10)
11 (#6 AND #11)

The following search strategy was used in MEDLINE and was modified as necessary for EMBASE and CINAHL (available upon request).
1 exp Keloid/
2 exp Cicatrix, Hypertrophic/
Searching other resources

The reference lists of relevant review articles and all included studies were examined to identify further studies. The major supplier of silicon gel sheeting (Smith and Nephew) was approached for details of unpublished, ongoing and recently published trials. The search was not limited by language or publication status.

Data collection and analysis

Selection of studies

Two review authors (LOB, AP) assessed the title and abstracts of potentially eligible trials independently. The review authors obtained papers that were potentially relevant and, using eligibility criteria, assessed their full text for inclusion independently. Disagreements were resolved by discussion.

Data extraction and management

Data were extracted by one review author and checked for accuracy by a second review author. A standard data form was used to capture the following information:

1. characteristics of the study (design, method of randomisation, withdrawals/dropouts, funding source);
2. study participants (age, wound location, wound characteristics, scar type);
3. intervention (silicon gel, non silicon gel);
4. comparison intervention (e.g. laser therapy, compression, occlusive dressing);
5. duration of treatment;
6. outcome measures (type of scoring, timing of assessment, complications);
7. duration of follow up; and
8. results.

Additional unpublished data were requested from primary authors and included when available.

Assessment of risk of bias in included studies

Two review authors assessed the methodological quality of the included studies. Only RCTs, QRCTs, or CCTs were included in this review because of the increased risk of bias with other types of study. The Cochrane Skin Group's quality assessment narrative (including an evaluation of the following dimensions for each included study) was used to evaluate the quality of the research:

1. Was the randomisation schedule adequately protected (allocation concealment: adequate protection schemes include central randomisation; central dispensation of intervention at a pharmacy; numbered or coded containers; sequentially numbered, opaque, sealed envelopes)?
2. Was there a clear description of how the randomisation sequence was generated (e.g. table of random numbers, computer generation)?
3. Was the assessor of primary outcome masked to treatment allocation?
4. Was there masking of participants?
5. Were data from all randomised participants (including those who withdrew from the study) included in the analysis ('intention to treat')?
6. Was there a valid assessment of comparability of the study groups at baseline (e.g. for age, sex, duration and severity of complaint)?
7. Was there an acceptable description or definition of the type of scar - either hypertrophic or keloid?

Assessment of heterogeneity

Clinical heterogeneity was explored by examining potentially influential factors such as age of people, cause of scar (e.g. if from recent surgery), and age of scar before treatment commenced. When statistical pooling was done, statistical heterogeneity was tested for by chi-squared. If clinical heterogeneity was suspected, the studies were combined by narrative summary only. In the presence of statistical heterogeneity (i.e. when chi-squared was greater than degrees of freedom) but where other factors suggest pooling was appropriate, a random-effects model was used. Otherwise a fixed-effect model was used.

Data synthesis

The comparisons are:
1. Silicon gel sheeting compared with no treatment.
2. Silicon gel sheeting compared with non-silicon gel.
3. Silicon gel sheeting compared with silicon gel plates with added vitamin E.
4. Silicon gel sheeting compared with laser therapy.
5. Silicon gel sheeting compared with triamcinolone acetonide injection treatment.
6. Silicon gel sheeting compared with silicon gel sheeting (non adhesive).

Data for prevention (i.e. for newly healed scars) and treatment (i.e. for existing keloid or hypertrophic scars) have been dealt with separately.

The analysis tables contain quantitative data from individual trial reports for prespecified outcomes and subgroups (e.g. those with a high risk of abnormal scarring versus normal population) for both dichotomous and continuous outcomes.

A narrative summary of results is presented. Results of dichotomous variables are presented as relative risk (RR) with 95% confidence intervals (CI). Relative risk has been used rather than odds ratio, as event rates are high in these trials and odds ratios would give an inflated impression of the magnitude of effect. In addition, statistical pooling has been carried out on groups of studies which were considered to be sufficiently similar.

**RESULTS**

**Description of studies**

See: Characteristics of included studies; Characteristics of excluded studies.

Searches for this first update identified 11 potentially relevant articles. Independent scrutiny of the titles and abstracts by both review authors identified 2 new studies that met the inclusion criteria, bringing the total number of included studies to 15. Reasons for excluding the other studies can be found in the Characteristics of excluded studies.

Eleven authors were contacted by LOB for additional trial data, and three (de Oliveira 2001; Niessen 1998; Li-Tsang 2006) kindly supplied these. The manufacturers of silicon gel sheeting (Smith & Nephew) were contacted and supplied a categorised table of clinical trials conducted for key scar therapies. This was checked against the studies already sourced through the search strategy, and any papers not already considered were ordered, then subjected to the same eligibility criteria as the other trials to determine whether they should be included. No further trials were identified from this source.

All 15 included trials compared silicon gel sheeting with either a control or another treatment. The studies were mainly single centre studies, although one included data from four hospitals (Niessen 1998). The studies were conducted in eight countries, with most being conducted in either the USA (6 studies) or in Europe (4 studies).

The 15 included studies involved a total of 615 people aged between two to 81 years. The 'Characteristics of included studies' table provides details of individual studies. No age limits were explicitly applied however, where information was provided, most participants were adult.

In three studies (de Oliveira 2001; Gold 1994; Niessen 1998) a distinction was made between keloid and hypertrophic scarring, and the results were discussed separately.

The trials made the following comparisons based on the objectives (i.e. to determine the effectiveness of silicon gel sheeting in preventing and treating hypertrophic and keloid scars):

1. **Silicon gel sheeting compared with no treatment**

   **Prevention:**
   There were three prevention studies (Cruz-Korchin 1996; Gold 2001; Niessen 1998) involving 245 people.

   **Treatment:**
   There were seven treatment studies (Ahn 1989; Carney 1994; Colom Majan 2006; de Oliveira 2001; Li-Tsang 2006; Tan 1999; Wittenberg 1999) involving 174 people.

   **Prevention and treatment:**
   There were two studies that evaluated both prevention and treatment (Ahn 1991; Gold 1994) involving 82 people.

2. **Silicon gel sheeting compared with non-silicon gel**

   **Treatment:**
   There was one treatment study (de Oliveira 2001) involving 26 people.

3. **Silicon gel sheeting compared with silicon plates with added Vitamin E**

   **Treatment:**
   There was one treatment study (Palmieri 1995) involving 80 people.

4. **Silicon gel sheeting compared with laser therapy**

   **Treatment:**
   There were two treatment studies (Pacquet 2001; Wittenberg 1999) involving 40 people.
(5) Silicon gel sheeting compared with triamcinolone acetonide injection treatment

**Treatment:**
There were two treatment studies (Sproat 1992; Tan 1999) involving 34 people.

(6) Silicon gel sheeting compared with non adhesive silicon gel sheeting

**Prevention**
There was one prevention study (Niessen 1998) involving 129 people.

**Treatment**
There was one treatment study (Carney 1994) involving 42 people.
There were many different measurement techniques and tools used, which made pooling of results difficult.

**Risk of bias in included studies**
The quality of trial methodology varied widely. The results for individual trials are presented in Table 1 'Methodological quality of included studies'.

Table 1. Methodological qualities of included studies

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<td>Y</td>
<td>Y</td>
<td>N</td>
<td>drop-outs counted in final analysis</td>
<td>Y</td>
</tr>
<tr>
<td>Colom Majan 2002</td>
<td>not stated</td>
<td>Y</td>
<td>N</td>
<td>not stated</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

Overall, the quality of the trial methodology in the included studies was poor. Only two studies (Sproat 1992; Wittenberg 1999) met four or more of the seven quality criteria.

Three studies explicitly reported their method of generating the randomisation sequence. Colom Majan 2006 and Wittenberg 1999 used a computer-generated randomisation list; Sproat 1992 used a prescribed randomised sequence. The remainder did not describe their methods. The method of allocation concealment was not stated for any of the studies.

Blinding of outcome assessors (item 3) was only reported for three studies (Sproat 1992; Li-Tang 2006; Wittenberg 1999) and for one of the measures in one other study (de Oliveira 2001). Only one study, which compared silicon gel sheeting with silicon gel plates with added Vitamin E, masked participants to treatment (Palmieri 1995), and none provided a placebo treatment, despite such treatments being possible (Shaffer 2002). For example, a non-silicon gel-pad could have been applied as a placebo.

Clear statements of evidence of intention to treat analysis (item 5) were rarely presented in trial reports, and only one study (Wittenberg 1999) performed an ITT analysis. Six studies lost more than 10% of people to follow up.

The comparability of people at baseline (item 6) was generally good, although one study (Pacquet 2001) provided no information on the control group, making it impossible to judge whether those groups were comparable. Most studies were also explicit about their inclusion and exclusion criteria, which allowed a clearer definition of the study population.

In most trials silicon gel sheeting was applied for at least 12 hours per day, with three studies (de Oliveira 2001; Li-Tang 2006; Niessen 1998) specifying 24 hours per day; another (Carney 1994) stating “as many hours per day as possible”, and a third (Palmieri 1995) specifying 10 hours per day. However, one (Pacquet 2001) did not indicate the number of hours that the silicon gel sheeting was worn by participants. One study (Niessen 1998) changed the type of silicon gel sheeting used (from SIL-K to EPIDERM which is more adhesive) when the initial results from the first group of people (n = 80) were described by the authors as “disappointing”. Another study (Carney 1994) also used two different types of gel (SILASTIC Gel Sheet and CICA-CARE) and analysed the treatment subgroups separately.

Descriptions and definitions of the type of scar (hypertrophic ver-
sus keloid) were adequate in eight out of the 13 studies. Despite not giving a full description of the distinction between hypertrophic and keloid scars, de Oliveira 2001 classified their participants’ scars as either one or the other, and separated the scar types in their analysis. Gold 2001 compared high risk (i.e. those with a history of abnormal scarring) and low risk participant groups in their results. Most other studies combined hypertrophic and keloid scars in their analyses, raising questions about the appropriateness of the study design (Shaffer 2002).

Given the long-term process of remodeling and scarring, it is recommended that follow-up continues for at least one year (Shaffer 2002). Only three studies (Carney 1994; Colom Majan 2006; Niessen 1998) had follow up of 12 months. Five studies (Ahn 1989; Gold 1994; Palmieri 1995; Sproat 1992; Tan 1999) followed people for three months or less, which is clearly inadequate.

Effects of interventions
Where available quantitative data are presented in the analysis tables.

HOW THE RESULTS ARE PRESENTED AND WHAT THE TERMS MEAN
Results of dichotomous variables are presented as relative risk (RR) with 95% confidence intervals (CI). Relative risk has been used rather than odds ratio as event rates are high in these trials and odd ratios would give an inflated impression of the magnitude of effect. Where statistically significant heterogeneity existed (i.e. chi-square was greater than degrees of freedom) a random effects model was used.

The types of outcomes measured in the studies are listed in the Characteristics of Included Studies table. The primary outcome measure for prevention studies was the proportion of people who developed abnormal scarring in post-operative cases (measured in terms of blood flow, hyperpigmentation, erythema, thickness and regularity of scar). There were many different measurement techniques and tools used, making pooling of results difficult. Eight authors were contacted by LOB for additional trial data, and three (de Oliveira 2001; Li-Tsang 2006; Niessen 1998) kindly supplied these. Results are presented according to the comparisons given in the “Description of Studies” section. The manufacturers (Smith & Nephew) were contacted and supplied a categorised table of clinical trials conducted for key scar therapies. This was checked against the studies already sourced through the search strategy and any papers not already considered were ordered and subjected to the same criteria for inclusion.

A. SILICON GEL COMPARED WITH NO TREATMENT
There were twelve studies (Ahn 1989; Ahn 1991; Carney 1994; Colom Majan 2006; Cruz-Korchin 1996; de Oliveira 2001; Gold 1994; Gold 2001; Li-Tsang 2006; Niessen 1998; Tan 1999) in this category. Three of the studies (Cruz-Korchin 1996; Niessen 1998; Gold 2001) studied the prevention of scars for people undergoing surgery, seven studied the effect of silicon gel sheeting on existing hypertrophic or keloid scars (Ahn 1989; Carney 1994; Colom Majan 2006; de Oliveira 2001; Li-Tsang 2006; Wittenberg 1999; Tan 1999) and two studies (Ahn 1991; Gold 1994) included both prevention and treatment.

I: Prevention studies
Of the five trials that compared silicon gel sheet with no treatment for prevention of scarring, four (Ahn 1991; Cruz-Korchin 1996; Gold 2001; Niessen 1998) included people with healed surgical wounds, and one (Gold 1994) included people who had had keloid scars removed with CO2 laser. Two of the trials described people according to their risk of developing abnormal scarring - Gold 1994 only recruited “high risk” people, while Gold 2001 recruited “low” and “high” risk people and presented the results of these two groups separately.

Primary outcome: development of keloid or hypertrophic scarring
Cruz-Korchin 1996 reported that fewer incisions treated with silicon gel sheeting became hypertrophic, though this difference was not significant; relative risk (RR) 0.45 (95% confidence interval (CI) 0.19 to 1.07). Individually, two small trials (Gold 1994; Gold 2001) found no significant difference between the silicon gel sheeting and the control groups in terms of abnormal scarring in high risk individuals only (people who were prone to scarring), but when pooled (random effects) found that silicon gel sheeting was associated with significantly fewer abnormal scars; RR 0.46 (95% CI 0.21 to 0.98). Ahn 1991 found significantly fewer abnormal scars in people treated with silicon gel sheeting; RR 0.05 (95% CI 0 to 0.76), whilst Niessen 1998 found a significant difference in favour of the control group; RR 2.71 (95% CI 1.19 to 6.22). When all five trials were pooled (random effects, I² = 69%) there was no significant difference in the number of people developing abnormal scars; RR 0.55 (95% CI 0.21 to 1.45) (Analysis 1, Outcome 1). All these trials are susceptible to bias as they did not describe allocation concealment, blinding of outcome assessors or an ITT analysis.

Secondary outcomes:
Cruz-Korchin 1996 reported transient rash and minor skin maceration as complications, but there was no statistically significant difference between the groups. Niessen 1998 reported transient rash, which resolved on removal of the silicon gel sheeting. Pooling these studies (fixed effect, I² = 0%) demonstrated a statistically significant difference in favour of the control groups, this means
that more complications developed in the groups treated with silicon gel (RR 8.00, 95% CI 1.02 to 62.83)(Analysis 1, Outcome 2).

II: Treatment studies

Nine trials compared silicon gel sheeting with control for treating abnormal scarring (Ahn 1989; Ahn 1991; Carney 1994; Colom Majan 2006; de Oliveira 2001; Gold 1994; Li-Tsiang 2006; Tan 1999; Wittenberg 1999). The majority of control groups were untreated, one group received lanolin and massage. Five included people with hypertrophic scars resulting from thermal burns (Carney 1994; Gold 1994; Li-Tsiang 2006) or surgery (Colom Majan 2006; Wittenberg 1999). Three (Ahn 1991; Ahn 1989; de Oliveira 2001) included people with hypertrophic and keloid scarring, and one (Tan 1999) included people with only keloid scarring.

Primary outcome

As the studies used different outcome measures it was impossible to pool results. We examined outcomes of reduction of scar length and width (de Oliveira 2001) scar thickness (Li-Tsiang 2006) and reduction in scar size by 50% (Tan 1999). The studies found no significant difference between silicon gel sheeting and control for reduction in scar length, width, and reduction of size by 50% (Analysis 1, Outcomes 3, 4 and 6) but significant results for scar thickness favouring silicon gel (RR -1.99, 95% CI -2.13 to -1.85) (Analysis 1, Outcome 5) although this was only one study (Li-Tsiang 2006) with relatively small numbers (N=34).

Secondary outcomes:

All studies except Wittenberg reported secondary outcomes. There were no statistically significant differences between the treatment or control groups for improvements in scar appearance, scar colour and the relief of itching and pain.

Four studies (Colom Majan 2006; Li-Tsiang 2006; Tan 1999; de Oliveira 2001) showed a statistically significant amelioration of scar colour (defined as a significant improvement in erythema) with silicon gel (pooled RR 3.05, 95% CI 1.57 to 5.96, fixed effect, I² = 53.9%)(Analysis 1, Outcome 7). When a random effect model is applied this result is not statistically significant. It should be noted that this is a subjective outcome and only de Oliveira 2001 masked the outcome assessor, neither trial reported either the method of randomisation or that allocation was concealed.

Four studies (Ahn 1989; Ahn 1991; Carney 1994; Li-Tsiang 2006) reported a statistically significant improvement in scar elasticity in those people treated with silicon gel sheeting. Data were presented graphically (mean percentage of stretch and standard error of mean in Ahn 1989 and Ahn 1991; percentage of extensibility of scar in Carney 1994; mean only in Li-Tsiang 2006) and p values but actual measurement data were not reported. Further information was requested from trial authors by LOB with one reply Li-Tsiang 2006 resulting in new data. Reported data were treated as dichotomous (i.e. improvement in elasticity compared with no improvement) and due to the high heterogeneity likely caused by the different measurement methods (I² = 84.7%), pooled using a random effects model resulting in no statistically significant improvement in scar elasticity (RR 3.39 95% CI 0.77 to 14.18)(Analysis 1, Outcome 8).

Results for relief of pain and itch (Li-Tsiang 2006; Tan 1999) showed no statistically significant difference between the groups (Analysis 1, Outcome 9).

Three studies (Ahn 1989; Carney 1994; Colom Majan 2006) reported complications such as transient skin rashes, pruritis, itching or superficial maceration. Authors reported that these resolved promptly when the silicon gel sheeting was withdrawn, or when correct hygiene was practiced. Combining results from Ahn 1989 and Colom Majan 2006 we found statistically significantly more complications reported for silicon gel sheeting than in the control group (RR 14.83, 95% CI 1.80 to 121.93, fixed effects I² = 18%)(Analysis 1 Outcome 10). No raw data were reported by Carney, and email communication with the author did not produce further data.

B. SILICON GEL COMPARED WITH NON-SILICON GEL

I: Prevention studies

No prevention studies were identified.

II: Treatment studies

One study (de Oliveira 2001) of 26 people compared silicon gel sheeting with non silicon gel sheeting. This study classified scars as either hypertrophic or keloid.

Primary outcome:

There was no statistically significant difference between the two groups for reduction of scar width, or scar length, (Analysis 2, Outcomes 1 and 2).

Secondary outcomes:

There was no statistically significant difference between the two groups for amelioration of scar colour (RR 1.09, 95%CI 0.85 to 1.40)(Analysis 2, Outcome 3). Complications including irritative contact dermatitis were reported; this was resolved by washing the skin and removing the silicon gel sheeting for five hours.
C. SILICON GEL SHEETING COMPARED WITH SILICON GEL PLATES WITH ADDED VITAMIN E

I: Prevention studies
No prevention studies were identified.

II: Treatment studies
One study (Palmieri 1995) of 80 people with established hypertrophic and keloid scars resulting from either surgery or thermal burns was included.

Primary outcome:
Although photographs of scar size, colour, and cosmesis were objectively scored on a scale of zero to five, these results appear to have been combined with patient self-ratings of itching and pain on a Scott-Husskinson scale. The authors were contacted for clarification by LOB, but did not reply, therefore, these data could not be used and it was impossible to draw conclusions about the effectiveness of either treatment for change in scar size, or whether the assessors were blinded to treatment allocation.

Secondary outcomes:
A combined subjective and objective score showed that 75% of people treated with silicon gel sheeting had improvements in cosmesis, pain and itching of at least 50%, compared with 90% of those treated with silicon gel plates with added vitamin E. There was a statistically significant improvement in favour of silicon gel sheet with added vitamin E (RR 0.79, 95% CI 0.65 to 0.96) (Analysis 3 Outcome 1). No complications were reported.

E. SILICON GEL SHEETING COMPARED WITH TRIAMCINOLONE ACETONIDE INJECTION TREATMENT

I: Prevention studies
No prevention studies were identified.

II: Treatment studies
Two studies involving 34 people were identified (Sproat 1992; Tan 1999). Triamcinolone acetonide injections are an existing treatment for hypertrophic scars but can be painful.

Primary outcome:
Tan 1999 reported that two out of the 17 people (12%) treated with silicon gel sheeting had a statistically significant reduction (defined as at least 50%) in the size of keloid scars, in contrast to the 16 out of 17 people (94%) who had a significant reduction when treated with intralesional injections of triamcinolone acetonide (40 mg/ml); the RR was 0.13 (95% CI 0.03 to 0.46) (Analysis 4, Outcome 1). Sproat 1992 reported changes in scar height and width graphically. The researcher was contacted by LOB, but had not kept specific numerical data, so no analyses tables or graphs are available in this review for these measures. Sproat 1992 reported that scar height decreased for both treatment groups, but that scar width increased in both (more so with triamcinolone acetonide injection), this trial report was not supported by any data analysis and therefore must be viewed with caution.
Secondary outcomes:
Tan 1999 reported that people treated with the injections showed a statistically significant improvement in erythema compared to those treated with silicon gel sheeting; the RR was 0.10 (95% CI 0.01 to 0.70) (Analysis 4, Outcome 2). There was no statistically significant difference for symptomatic relief of itching and pain (Analysis 4, Outcome 3). Sproat 1992 reported a statistically significant difference in mean time to symptomatic improvement (weighted mean difference -2.90 days; 95% CI -3.93 to -1.87) (Analysis 4, Outcome 4) and patient preference in favour of the silicon gel sheeting; RR 5.50 (95% CI 1.48 to 20.42) (Analysis 4, Outcome 5).
Sproat 1992 reported one instance of superficial rash in the silicon gel sheeting group (which resolved on discontinuation of the sheeting for two days) compared with the severe pain (71% of people), skin atrophy, pigmentary changes, and white bead-like skin deposits (64% of people) experienced by participants in the triamcinolone injection group (OR 0.03, 95% CI 0.00 to 0.32)(Analysis 4, Outcome 6).
Tan 1999 reported that no adverse reactions occurred with either treatment.

F. SILICON GEL SHEETING COMPARED WITH SILICON GEL SHEETING (NON ADHESIVE)

I: Prevention studies
One study (Niessen 1998) involving 155 women undergoing bilateral breast reduction, this trial had three arms and scars were either treated with adhesive silicon gel sheeting (Epiderm adhesive), non adhesive silicon gel sheeting (SIL-K) or covered with Micropore alone.

Primary outcome:
The authors reported that 12 months after surgery no difference in hypertrophic scar development was found between the adhesive and non adhesive silicon gel sheets. However, they did not present separate data for the two intervention groups, but reported combined data for the silicon gel sheeting groups (adhesive plus non adhesive) compared with the control group. This trial was poorly reported, the method of allocating treatment to scar site was unclear. There was no blinded outcome assessment and no ITT analysis.

Secondary outcomes:
Results obtained from the trial author (Niessen) by email on 238 scars (114 adhesive silicon gel group, 124 non adhesive silicon gel group), showed no statistically significant difference in results for scar width, height, colour, and perfusion at 12 months post surgery (Analysis 5, Outcomes 1, 2, 3, and 4).

II: Treatment studies
One study (Carney 1994) involving 42 people with 47 scars was included, which compared adhesive (Cica Care) with non adhesive (Silastic) silicon gel sheeting.

Primary outcome:
Size of scar was not measured as part of this study.

Secondary outcomes:
Carney 1994 did not provide a statistical analysis of the comparison between the two silicon gel sheets, but stated that after six months of treatment, 88.9% of scars in the non-adhesive gel group, and 100% of the scars in the adhesive group were improved for colour, and 100% of both groups were improved for scar softness. The lead author was contacted by LOB and asked for data, however the author replied that the actual data had not been retained.

DISCUSSION
The introduction of silicon gel sheeting as both a prevention and treatment intervention in the early 1980s has led to many research trials of varied quality.
Whilst there is some weak evidence from 2 small trials (total 51 participants) that silicon gel treated incisions are less likely to become hypertrophic in high risk people, these trials had a high potential for selection and detection bias (method of randomisation unclear; no blinding of outcome assessors) and therefore must be viewed with a great deal of caution.
Similarly the findings that silicon gel sheeting improves the elasticity and colour of keloid scars came from low quality studies. Whilst triamcinolone appeared more effective at improving keloid scarring than silicon gel sheeting this finding too was from a single study with high susceptibility to bias (unclear randomisation; lack of blinding of outcome assessors).
In this review, only RCTs, QRCTs and CCTs were considered, leading to a relatively small number of studies (15) and people (615) for evaluation. Few studies compared similar interventions or measured similar criteria. Several trials had methodological problems, and reported inadequately on their randomisation protocols and/or allocation concealment, or failed to undertake an intention to treat analysis. Blinding of outcome assessors, which would not have been difficult to achieve, was poorly reported.
None of the included trials addressed health related quality of life, or the cost of treatments.
There was also some inconsistency in instruments of measurement, for example, different patient rating scales for pain/irritation were
used in each study, making it difficult to compare results. Only one of the patient scales was standardised and validated (the Scott-Husskinson Scale in Palmieri 1995), however, the full data set was not reported in this paper.

All but three of the studies had short duration of follow up (i.e. less than 12 months), which is inadequate given that scar remodeling and collagen synthesis continues for over a year.

It is interesting to note the difference between the results from Niessen 1998 and Cruz-Korchin 1996 trials when their clinical experiments were so similar (both treated women who had recently undergone breast reductions). Both researchers defined the difference in their trials, via letters published in Annals of Plastic Surgery (1997), in an attempt to explain their results. Niessen stated that the most important difference was the application of Micropore (3M) which provided support around the control (untreated) scars, thus demonstrating that "it is not the silicon material itself that prevents the development of hypertrophic scar tissue". In her response, Cruz-Korchin 1997 agreed that support would tend to reduce scar width, but silicon sheets would reduce width and flatten the hypertrophic scar. She also observed that her study population was composed mainly of Hispanics who are more prone to forming hypertrophic scars, and compared this to Neissen's study population of "fair-skinned Caucasians, in whom hypertrophic scarring seldom occurs". At present this trial is the only one to have compared Micropore against silicon gel sheeting and, therefore, more research is needed to investigate whether the physical support of the scar is as effective as silicon gel sheeting.

In summary the effects of silicon gel sheeting on hypertrophic and keloid scarring are unclear and warrant rigorous evaluation.

**AUTHORS' CONCLUSIONS**

**Implications for practice**

The main aims for practitioners dealing with wound healing and scar minimisation are good skin closure, elasticity, maintenance of functioning of underlying structures and good cosmetic appearance. There are many treatments available to prevent or minimise scarring (including, but not limited to, pressure therapy, topical moisturisers, surgical excision, intralesional corticosteroids, laser therapy, cryotherapy, silicon or non-silicon gel sheeting) but these vary in how well they are tolerated, as some people find them painful, uncomfortable, and/or expensive. Practitioners need to match treatments to the needs and wishes of their patients.

In this review, the evidence for the effects of silicon gel sheeting on scarring are obscured by the poor quality of the research. Thus whilst there appeared to be fewer abnormal scars in people at high risk of developing hypertrophic or keloid scars associated with use of silicon gel sheeting, these findings are highly susceptible to bias.

**Implications for research**

Given the functional and psychological impact of hypertrophic and keloid scarring, it is surprising that there are so few high quality research trials investigating the preventative and treating qualities of silicon gel sheeting. Such information would be welcomed by practitioners, together with estimates of benefit and complication rates.

Robust research to clarify the issues discussed in this review would consist of a trial that incorporated the following criteria:

1. blinded outcome assessment;
2. standardised, objective, validated, and repeatable outcome measurement;
3. adequate duration of follow up (at least 12 months, but preferably 18 months);
4. collection and reporting of recurrence data;
5. distinction between type of scar (hypertrophic versus keloid) and separation of results by scar type in the analysis.

A detailed list of suggestions for future research in keloid scar treatment is included in Shaffer 2002.

**ACKNOWLEDGEMENTS**

The authors would like to thank Anita Kainth, Michael Bigby and the Cochrane Wounds Group Editors (Nicky Cullum, David Margolis, and Andrea Nelson) who refereed the protocol and review, and June Poston who initiated the review. In addition, the authors would like to thank the staff at the Australasian Cochrane Centre who have been of enormous assistance, Dr Bess Fowler (formerly of Curtin University, School of Occupational Therapy) for support, encouragement and guidance and the staff of the Cochrane Wounds Group.
Silicon gel sheeting for preventing and treating hypertrophic and keloid scars (Review)

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**References to studies included in this review**

Ahn 1989  *(published data only)*

Ahn 1991  *(published data only)*

Carney 1994  *(published data only)*

Colom Majan 2006  *(published data only)*


Cruz-Korchin 1996  *(published data only)*

de Oliveira 2001  *(published data only)*

Gold 1994  *(published data only)*


Gold 2001  *(published data only)*
Gold M. The prevention of hypertrophic scars and keloids by the prophylactic use of topical silicone gel sheets following a surgical procedure. 20th World Congress of Dermatology; 2002, 1-5 July; Paris. 2002:IC1743.


Li-Tang 2006  *(published and unpublished data)*

Niessen 1998  *(published and unpublished data)*

Pacquet 2001  *(published data only)*

Palmieri 1995  *(published data only)*

Sproat 1992  *(published data only)*

Tan 1999  *(published data only)*

Wittenberg 1999  *(published data only)*

**References to studies excluded from this review**

Al-Mandeel 1998  *(published data only)*

Berman 1999  *(published data only)*

Chan 2005  *(published data only)*

Chuangsuwanich 2000  *(published data only)*

Clagston 1995  *(published data only)*
D’Andrea 2002. [published data only]

Dockery 1994 [published data only]

Donati 1991 [published data only]

Fulton 1995 [published data only]

Gold 1993 [published data only]

Hirshowitz 1993 [published data only]

Hosnutter 2001 [published data only]

Katz 1995 [published data only]

Klopp 2000 [published data only]

Lee 1996 [published data only]

Mercer 1989 [published data only]

Musgrave 2002 [published data only]

Muti E 1994 [published data only]

Nikkonen 2001 [published data only]

Ricketts 1996 [published data only]

Sawada 1999 [published data only]

Shigeki 1999 [published data only]

Signorini 2007 [published data only]

So 2003 [published data only]

Suetake 2000 [published data only]

Van den Kerchove 2001 [published data only]

Widgerow 2000 [published data only]

References to studies awaiting assessment

Chernoff 2007 [published data only]

Silicon gel sheeting for preventing and treating hypertrophic and keloid scars (Review)

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Loeding 1993  (published data only)

Terrill 2002  (published data only)
Terrill P. The effect of scar management products on the "normal" scar. Fourth Australian Wound Management Association Conference. 2002:40RT.

Additional references

Beers 1999

Carney 1993

Cruz-Korchin 1997

Davey 1991

Eisenbeiss 1998

Higgins 2006

Katz 1992
Katz B. Silastic gel sheeting is found to be effective in scar therapy. Cosmetic Dermatology 1992;6:1–3.

O’Sullivan 1996

Perkins 1982

Quinn 1985

Raney 1993

Sawada 1992

Shaffer 2002

Shakespeare 1993

SIGN 2007

Smith & Nephew 2000

Swanson 1974

Thomas 1997

Williams 1996

* Indicates the major publication for the study
CHARACTERISTICS OF STUDIES

Characteristics of included studies  [ordered by study ID]

Ahn 1989

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<td>Inclusion criteria: hypertrophic scars</td>
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<td>sex: not stated</td>
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| Interventions | Silicon gel sheeting applied to 14 scars for at least 12 hours per day over 8 weeks (untreated adjacent or mirror image scars on same patients used as control) |

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<th>Outcomes</th>
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<td>Clinical: scar elasticity, scar appearance, foreign body reaction</td>
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<td></td>
<td>Complications: occasional transient rashes or superficial maceration, both of which resolved promptly when treatment withdrawn</td>
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<th>Notes</th>
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Risk of bias

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Ahn 1991

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<tr>
<td></td>
<td>Blinding: not reported</td>
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<td></td>
<td>Intention to treat: data from those that withdrew not included</td>
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<td>48 patients</td>
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<td></td>
<td>Inclusion criteria: 29 patients with fresh surgical incisions (32 pairs of scars); 19 patients with established hypertrophic scars (23 scars)</td>
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### Ahn 1991

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<tr>
<td>Outcomes</td>
<td>Length of follow-up: measurements at one, two and six months Clinical: scar elasticity, scar volume Complications: rash (5), ulcer (3), pruritus (1), discomfort (1).</td>
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<td>Risk of bias</td>
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### Carney 1994

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<tr>
<td>Methods</td>
<td>Design: CCT Method of randomisation: not stated Blinding: not reported Intention to treat: unclear Lost to follow-up: 26</td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>Teaching Hospital, UK 42 patients Inclusion criteria: hypertrophic scars Exclusion criteria: no other scar reducing treatment in previous month sex: not stated age: 2 to 65</td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td>Half assigned to receive Silastic Gel Sheeting and half Cica-Care (untreated scar on same patient used as control)</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>Length of follow-up: measurements made at monthly intervals for 6 months, then follow up at 3 and 6 months after ceasing treatment Clinical: scar elasticity, appearance, colour Complications: mild irritation, pruritus</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td>Extensometric measurements made. Irritation rated by patient on scale of 0 to 5</td>
<td></td>
</tr>
<tr>
<td>Risk of bias</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>
### Colom Majan 2006

**Methods**
- Design: RCT
- Method of randomisation: randomised sequence
- Blinding: nil
- Intention to treat: unclear
- Lost to follow-up: 1

**Participants**
- Special Sciences Institute, Spain
- 11 patients
- Inclusion criteria: adults >18 years with post-op scars
- Exclusion criteria: underlying relevant disease, known hypersensitivity to product used; inability to comply/attend follow up; keloid scar
- Sex: all female
- Age: 20 to 43

**Interventions**
- Silicon gel sheeting applied to 6 scars for 23 hours per day for a maximum of 1 week. 5 controls had no treatment

**Outcomes**
- Length of follow-up: measurements made at monthly intervals for 6 months, then at 12 months
- Clinical: Vancouver scale for appearance; patient’s rating of pain and itch
- Complications: local skin reaction

**Notes**

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

### Cruz-Korchin 1996

**Methods**
- Design: CCT
- Method of randomisation: 50% applied Silicone to breast on dominant-hand side, 50% on breast on non-dominant hand side
- Blinding: not reported
- Intention to treat: unclear
- Lost to follow-up: 0

**Participants**
- Teaching Hospital, USA
- 20 patients (40 scars)
- Inclusion criteria: bilateral McKissock reduction mammoplasties
- Exclusion criteria: not stated
- Sex: all female
- Age: not stated
**Cruz-Korchin 1996**  
(Continued)

<table>
<thead>
<tr>
<th>Interventions</th>
<th>pre-cut silicon elastomer sheet worn for 12 hours/day for 2 months (untreated adjacent scar on opposite breast of same patient used as control)</th>
</tr>
</thead>
</table>
| Outcomes      | Length of follow-up: measurements made at 2 months; follow-up at 6 months  
Clinical: scar hypertrophy  
Complications: transient rash in 1 patient, minor skin maceration in 1 patient |

**Notes**

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

**de Oliveira 2001**

**Methods**

- Design: RCT  
- Method of randomisation: not stated  
- Blinding: only for intracuticular pressure measurement  
- Intention to treat: unknown (baseline data not given)  
- Lost to follow-up: not reported

**Participants**

- Teaching Hospital, Brazil  
- 26 patients (41 scars - classified as either hypertrophic or keloid)  
- Inclusion criteria: hypertrophic or keloid scars  
- Exclusion criteria: radiation or corticosteroid therapy in last 12 months  
- sex: 5 male, 21 female  
- age: 15 - 53 years

**Interventions**

- Patients with 2 scars: one scar received silicon gel sheet, the other non-silicon gel sheet (both worn 24 hrs/day).  
- Patients with 3 scars: as above with one “control” scar with no treatment.

**Outcomes**

- Length of follow-up: measurements made at 0, 30, 60, 90, 120 and 135 days  
- Clinical: symptomatic relief of pain and itching, induration (hardness), length, width, colour of scar  
- Intracuticular pressure  
- Complications: irritative contact dermatitis, which resolved with skin washing and removal of the gel for 5 hours.

**Notes**

- Intracuticular pressure defined as “the necessary pressure to inject a 0.5 ml of triamcinolone solution into the scar tissue”  
- Colour measured by 1000 colour paint-chart

**Risk of bias**

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
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<td>Authors' judgement</td>
<td>Description</td>
</tr>
</tbody>
</table>
## Allocation concealment?

<table>
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<tr>
<th>Item</th>
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<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

### Gold 1994

#### Methods
- **Design**: CCT
- **Method of randomisation**: not stated
- **Blinding**: not reported
- **Intention to treat**: unclear
- **Lost to follow-up**: 0

#### Participants
- **Gold Skin Care Centre, USA**
- **34 patients**
- **Inclusion criteria**: Phase 1: hypertrophic or keloid scar
  Phase 2: 2 distinct keloids on same body part removed by CO2 laser
  Phase 3: scars from thermal burns
- **Exclusion criteria**: not stated
- **sex**: not stated
- **age**: not stated

#### Interventions
- **Phase 1 & 3**: Scar divided in half - random allocation for each half to receive either silicon gel sheeting (minimum of 12 hrs/day for 12 weeks); other half no treatment (control)
- **Phase 2**: one scar covered with SGS (as above) other scar untreated

#### Outcomes
- **Length of follow up**: 12 weeks
- **Clinical**: Phase 1: Patient & physician evaluation of overall improvement and colour
  Phase 2: recurrence of keloid
  Phase 3: scar thickness and colour
- **Complications**: none reported

#### Notes
- Change rated on a 4 point scale

### Risk of bias

#### Item

<table>
<thead>
<tr>
<th>Item</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

### Gold 2001

#### Methods
- **Design**: RCT
- **Method of randomisation**: not stated
- **Blinding**: not reported
- **Intention to treat**: data from patients who withdrew not included in analysis
- **Lost to follow-up**: 19 from low-risk group; 11 from high-risk group
Gold 2001  (Continued)

| Participants | Gold Skin Care Centre, USA  
96 patients  
Inclusion criteria: Dermatologic surgery patients, 2 groups:  
Low Risk (no history of abnormal scarring); High Risk (significant history of abnormal scarring)  
Exclusion criteria: not stated  
sex: low risk gp 30 male, 20 female; high risk gp 9 male 37 female  
age: 36.7 years (mean) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions</td>
<td>Random allocation to receive either silicon gel sheeting (minimum of 12 hrs/day for 6 months) applied at 48 hrs post surgery, or routine post-operative care (control group)</td>
</tr>
</tbody>
</table>
| Outcomes | Length of follow-up: measurements made at 2, 4, 8, 12, 16, 20, and 24 weeks  
Clinical: patient’s opinion, physician observations, scaled photographic analysis  
Complications: none reported |
| Notes | Patient’s opinion of the site was assessed in terms of discomfort, embarrassment, colour, height, texture and function and was recorded on a 4 point scale |

| Risk of bias |
| --- | --- | --- |
| Item | Authors’ judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Li-Tsang 2006

| Methods | Design: RCT  
Method of randomisation: not stated  
Blinding: assessor blinded  
Intention to treat: data from subjects who withdrew included in analysis  
Lost to follow-up: 3 |
| --- | --- |
| Participants | 45 Chinese patients  
Inclusion criteria: history of burns, scald or severe skin trauma resulting in hypertrophic scar  
Exclusion criteria: age > 50 years, scar > 20 cm² or <3 mm thickness  
sex: 29 male, 16 female  
age: 29.65 years (mean) |
| Interventions | Random allocation to receive either silicon gel sheeting (24 hrs/day for 6 months) +15 min lanolin deep massage twice a day vs lanolin massage only |
| Outcomes | Length of follow-up: measurements made at 1, 2, 4, and 6 months  
Clinical: scar pigmentation, thickness, Vancouver scale for appearance; patient’s rating of pain and itch |
| Notes | Colour & thickness measured with spectrocolorimeter & tissue ultrasound palpation system. |

| Risk of bias |
| --- | --- | --- |
| Item | Authors’ judgement | Description |
| | | |
Niessen 1998

Methods
- Design: CCT
- Method of Randomisation: not stated
- Blinding: not reported
- Intention to treat: data from subjects who withdrew not included in analysis
- Lost to follow-up: 36

Participants
- 4 University Hospitals, Netherlands
- 155 patients
- Inclusion criteria: bilateral breast reduction surgery
- Exclusion criteria: not stated
- sex: all female
- age: 14 - 69 years

Interventions
- Scars covered with silicon sheet held in place with Micropore tape, either:
  - Left lateral and right medial sides, or
  - Right lateral and left medial side of scars
- Untreated “control” part of scar supported with Micropore tape
- Silicon was worn for 24 hours/day for 3 months

Outcomes
- Length of follow-up: measurements made at 2 weeks, 3 months, 6 months and 12 months
- Clinical: width, height, blood flow and colour of scar, patient complaints about itching and pain
- Complications: skin irritation

Notes
- Width measured by ruler; height judged as either 1 normal, 2 hypertrophic, 3 keloid
- Patient complaints assessed on a 10 point scale (1=no complaints
10=very severe itching or pain)

Risk of bias

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<tbody>
<tr>
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</tbody>
</table>

Pacquet 2001

Methods
- Design: CCT
- Method of randomisation: not stated
- Blinding: not reported
- Intention to treat: unclear
- Lost to follow-up: 0
Pacquet 2001 (Continued)

| Participants | University Medical Centre, Belgium  
20 patients  
Inclusion criteria: Adults with post-surgical or post-traumatic keloid scars  
Exclusion criteria: no previous scar treatment  
sex: 2 male, 9 female in laser group; not stated for silicon gel group  
age: 17 - 63 years for treatment group (no info available on controls) |
| Interventions | 11 patients treated with 585 nm pulsed dye laser  
(1-3 treatments at 6-8 week intervals)  
9 patients (controls) with application of silicon gel sheeting |
| Outcomes | Length of follow-up: measurements made on 5 occasions at 3 week intervals  
Clinical: erythema and melanin of scar  
Complications: none reported |
| Notes | Size measured by ruler  
Erythema and Melanin measured by spectrophotometer |

Risk of bias

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Allocation concealment?</td>
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</tbody>
</table>

Palmieri 1995

| Methods | Design: RCT  
Method of randomisation: not stated  
Blinding: patients were blinded to treatment  
Intention to treat: unclear  
Lost to follow-up: 0 |
| Participants | University trial, Italy  
80 patients  
Inclusion criteria: adults with hypertrophic and keloid scars  
Exclusion criteria: psychological disturbance  
sex: both; numbers not stated  
age: 18 - 63 years |
| Interventions | Random allocation to 2 groups:  
Scars covered with silicon plates with added Vitamin E (5g)  
Or  
Scars covered with silicon gel sheet  
Both worn for 10 hours/day (overnight)and fixed with tape |
| Outcomes | Length of follow-up: measurements made at 4 and 8 weeks  
Clinical: Scott-Husskinson Scale (for pain and itching) |
Photography of front and side of scar - evaluated on colour, size, cosmetic appearance
Complications: none reported

Notes
Scoring of scar appearance on a scale of 0 - 5; Itching and pain recorded by patients on Scott-Husskinson scale

Risk of bias

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</tbody>
</table>

Sproat 1992

Methods
Design: RCT
Method of randomisation: randomised sequence
Blinding: Assessors were blinded
Intention to treat: unknown (baseline data not given)
Lost to follow-up: 0

Participants
Teaching Hospital, Canada
14 patients
Inclusion criteria: adults with symptomatic hypertrophic sternal scars after cardiac surgery
Exclusion criteria: not stated
sex: 7 females, 7 males
age: 33 - 81 years

Interventions
Matched design - scar divided into halves (upper and lower) each receiving a different treatment:
Half injected with Kenalog.
Silicone gel sheet applied to other half for 12 hours/day for 12 weeks

Outcomes
Length of follow-up: measurements made weekly for 12 weeks
Clinical: scar length, width, height measured by a blinded observer.
Photographs taken before and after.
Patient symptoms and rating of pain of injection.
Patient treatment preference
Complications: Kenalog: skin atrophy, white bead-like skin deposits, pigmentary changes
Silicone: rash

Notes
Patient treatment preference elicited at the end of the trial.
Photographs evaluated by five independent observers

Risk of bias

<table>
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<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
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</tr>
</tbody>
</table>
### Tan 1999

| Methods | Design: CCT  
Method of randomisation: not stated  
Blinding: not stated  
Intention to treat: unclear  
Lost to follow-up: 3 |
|----------|------------------|
| Participants | National Skin Centre, Singapore  
20 patients (60 keloid scars)  
Inclusion criteria: adults with multiple keloid scars (acquired at least 2 years ago) located on the same anatomic site  
Exclusion criteria: not stated  
sex: 18 male, 2 female  
age: 19 - 40 |
| Interventions | 3 scars on each subject: 1 scar as control (no treatment), 1 received silicone gel sheet, 1 injected with triamcinolone acetonide (40 mg/ml) at intervals of 4 weeks |
| Outcomes | Length of follow-up: measurements made at 4, 8 and 12 weeks  
Clinical: scar length, width, height; change in colour and texture; improvement in the symptoms of pain and/or pruritis  
Complications: none |
| Notes | Clinical photographs were taken at baseline and at week 12.  
Patients rated pain/pruritis using a 5-point scale.  
2 Physicians recorded changes at each visit. |
| **Risk of bias** | **Item** | **Authors' judgement** | **Description** |
| | Allocation concealment? | Unclear | B - Unclear |

### Wittenberg 1999

| Methods | Design: RCT  
Method of Randomisation: computer-generated randomisation list  
Blinding: assessor masked when taking measurements  
Intention to treat: results from patient who withdrew were counted  
Lost to follow-up: 1 |
|----------|------------------|
| Participants | Teaching Hospital, USA  
20 patients  
Inclusion criteria: adults with uniform, linear hypertrophic scars secondary to surgical wounds  
Exclusion criteria: treatment of the scar within the preceding 2 months, keloidal scarring, scars less than 8 cm long  
sex: 5 male, 15 female  
age: 24 - 81 |
Interventions

Each scar was divided into 3 sections, and each section was randomly assigned to 1 of 2 treatments (585 nm pulsed laser or silicon gel sheet) or designated as a control.

Outcomes

Length of follow-up: measurements at 0, 8, 16, 24, and 40 weeks
Clinical: hypertrophic scar blood flow, elasticity, and volume.
Histological assessment of fibrosis, number of telangiectasias, number of mast cells.
Patient’ subjective complaints of pruritis, pain and burning.
Consenting patients (n=5) underwent punch biopsies at 0 and 40 weeks
Complications: one patient unable to use silicone gel sheet due to skin irritation, one patient withdrew because of pain during laser treatment

Notes

Elasticity measured by elastometer
Blood flow measured with a laser Doppler
Patients rated pain and burning on a quartile scale (1 - no/minimal pain - 4-severe)

Risk of bias

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</tbody>
</table>

Characteristics of excluded studies  [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Mandeel 1998</td>
<td>No control group</td>
</tr>
<tr>
<td>Berman 1999</td>
<td>No control group</td>
</tr>
<tr>
<td>Chan 2005</td>
<td>Used paint-on silicon (not silicon gel sheet)</td>
</tr>
<tr>
<td>Chuangsuwanich 2000</td>
<td>No control group</td>
</tr>
<tr>
<td>Clugston 1995</td>
<td>Non-human subjects</td>
</tr>
<tr>
<td>D’Andrea 2002</td>
<td>Not a trial - 2 groups allocated according to position on waiting list, lesion size, and age</td>
</tr>
<tr>
<td>Dockery 1994</td>
<td>No control group</td>
</tr>
<tr>
<td>Donati 1991</td>
<td>No control group</td>
</tr>
<tr>
<td>Fulton 1995</td>
<td>No control group</td>
</tr>
<tr>
<td>Gold 1993</td>
<td>No control group</td>
</tr>
<tr>
<td>Study Year</td>
<td>Details</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hirshowitz 1993</td>
<td>No control group</td>
</tr>
<tr>
<td>Hollands 1999</td>
<td>Concentrates on local biochemical changes in skin (i.e. does not look at clinical outcomes such as scar size, colour, volume)</td>
</tr>
<tr>
<td>Hosnutter 2007</td>
<td>No control group</td>
</tr>
<tr>
<td>Katz 1995</td>
<td>No control group</td>
</tr>
<tr>
<td>Klopp 2000</td>
<td>SGS was applied in combination with pressure garment (not on own)</td>
</tr>
<tr>
<td>Lee 1996</td>
<td>No control group</td>
</tr>
<tr>
<td>Mercer 1989</td>
<td>No control group</td>
</tr>
<tr>
<td>Musgrave 2002</td>
<td>Outcome measured was effects on blood flow and perfusion</td>
</tr>
<tr>
<td>Muti E 1994</td>
<td>No control group</td>
</tr>
<tr>
<td>Nikkonen 2001</td>
<td>No control group</td>
</tr>
<tr>
<td>Ricketts 1996</td>
<td>Non-randomised pairs study that concentrates on local biochemical changes in skin (i.e. does not look at clinical outcomes such as scar size, colour, volume)</td>
</tr>
<tr>
<td>Sawada 1990</td>
<td>Used silicon cream (not gel sheet)</td>
</tr>
<tr>
<td>Shigeki 1999</td>
<td>Concentrates on local biochemical changes in skin (i.e. does not look at clinical outcomes such as scar size, colour, volume)</td>
</tr>
<tr>
<td>Signorini 2007</td>
<td>Used paint-on silicon (not silicon gel sheet)</td>
</tr>
<tr>
<td>So 2003</td>
<td>Intervention patient education, both groups received silicon gel</td>
</tr>
<tr>
<td>Suetake 2000</td>
<td>Concentrates on local biochemical changes in skin (i.e. does not look at clinical outcomes such as scar size, colour, volume)</td>
</tr>
<tr>
<td>Van den K 2001</td>
<td>SGS was applied in combination with pressure garment (not on own)</td>
</tr>
<tr>
<td>Widgerow 2000</td>
<td>No control group. Combines silicone gel sheet with surgery and steroids (injection and cream) - i.e. no subjects received silicone gel only</td>
</tr>
</tbody>
</table>
## DATA AND ANALYSES

Comparison 1. Silicon gel versus no treatment (control)

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of abnormal scarring - prevention</td>
<td>5</td>
<td>402</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.55 [0.21, 1.45]</td>
</tr>
<tr>
<td>1.1 High-risk of scarring</td>
<td>2</td>
<td>51</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.46 [0.21, 0.98]</td>
</tr>
<tr>
<td>1.2 Low risk of scarring</td>
<td>1</td>
<td>31</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.35 [0.02, 8.08]</td>
</tr>
<tr>
<td>1.3 Risk not stated</td>
<td>3</td>
<td>320</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.57 [0.10, 3.40]</td>
</tr>
<tr>
<td>Development of complications - prevention</td>
<td>2</td>
<td>350</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>8.0 [1.02, 62.83]</td>
</tr>
<tr>
<td>2.1 Prevention</td>
<td>2</td>
<td>350</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>8.0 [1.02, 62.83]</td>
</tr>
<tr>
<td>Reduction of scar length - treatment</td>
<td>1</td>
<td>27</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Reduction in scar width - treatment</td>
<td>1</td>
<td>27</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Scar thickness - treatment</td>
<td>1</td>
<td>34</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-1.99 [-2.13, -1.85]</td>
</tr>
<tr>
<td>Reduction of keloid scar size by 50% - treatment</td>
<td>1</td>
<td>34</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>5.65 [0.25, 126.87]</td>
</tr>
<tr>
<td>Scar colour amelioration - treatment</td>
<td>4</td>
<td>106</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.05 [1.57, 5.96]</td>
</tr>
<tr>
<td>Improvement in scar elasticity - treatment</td>
<td>4</td>
<td>109</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>3.39 [0.77, 14.85]</td>
</tr>
<tr>
<td>Symptomatic relief of itching &amp; pain - treatment</td>
<td>2</td>
<td>52</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.30 [0.98, 1.73]</td>
</tr>
<tr>
<td>Development of complications - treatment</td>
<td>2</td>
<td>39</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>14.83 [1.80, 121.93]</td>
</tr>
</tbody>
</table>

Comparison 2. Silicon gel versus non-silicon gel or dressing

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction of scar width</td>
<td>1</td>
<td>30</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-0.03 [-0.15, 0.09]</td>
</tr>
<tr>
<td>Reduction of scar length</td>
<td>1</td>
<td>30</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-0.02 [-0.07, 0.03]</td>
</tr>
<tr>
<td>Scar colour improvement</td>
<td>1</td>
<td>30</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.09 [0.85, 1.40]</td>
</tr>
</tbody>
</table>
### Comparison 3. Silicon gel versus silicon plates with added Vitamin E

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Improvement in cosmesis, itching, and pain &gt; 50%</td>
<td>1</td>
<td>80</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.79 [0.65, 0.96]</td>
</tr>
</tbody>
</table>

### Comparison 4. Silicon gel versus triamcinolone acetonide Injection treatment

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Reduction of keloid scar size by 50%</td>
<td>1</td>
<td>34</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.13 [0.03, 0.46]</td>
</tr>
<tr>
<td>2 Improvement in erythema</td>
<td>1</td>
<td>34</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.1 [0.01, 0.70]</td>
</tr>
<tr>
<td>3 Symptomatic relief of itching and pain</td>
<td>1</td>
<td>18</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.6 [0.20, 1.79]</td>
</tr>
<tr>
<td>4 Average time (in days) to improvement</td>
<td>1</td>
<td>28</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-2.9 [-3.93, -1.87]</td>
</tr>
<tr>
<td>5 Patient preference</td>
<td>1</td>
<td>28</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>5.5 [1.48, 20.42]</td>
</tr>
<tr>
<td>6 Development of complications</td>
<td>1</td>
<td>28</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>0.03 [0.00, 0.32]</td>
</tr>
</tbody>
</table>

### Comparison 5. Adhesive silicon gel versus non-adhesive silicon sheet

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Scar width</td>
<td>1</td>
<td>238</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>0.80 [-0.01, 1.61]</td>
</tr>
<tr>
<td>2 Scar height</td>
<td>1</td>
<td>238</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>3 Scar colour</td>
<td>1</td>
<td>233</td>
<td>Std. Mean Difference (IV, Fixed, 95% CI)</td>
<td>-0.09 [-0.35, 0.17]</td>
</tr>
<tr>
<td>4 Scar perfusion</td>
<td>1</td>
<td>235</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-1.40 [-4.25, 1.45]</td>
</tr>
</tbody>
</table>

Silicon gel sheeting for preventing and treating hypertrophic and keloid scars (Review)
**Analysis 1.1. Comparison 1 Silicon gel versus no treatment (control), Outcome 1 Development of abnormal scarring - prevention.**

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

**Comparison:** 1 Silicon gel versus no treatment (control)

**Outcome:** 1 Development of abnormal scarring - prevention

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Random,95% CI</td>
<td></td>
<td>M-H,Random,95% CI</td>
</tr>
<tr>
<td>1 High-risk of scarring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gold 1994</td>
<td>1/8</td>
<td>3/8</td>
<td></td>
<td>12.7 %</td>
<td>0.33 [ 0.04, 2.56 ]</td>
</tr>
<tr>
<td>Gold 2001</td>
<td>5/17</td>
<td>11/18</td>
<td></td>
<td>23.9 %</td>
<td>0.48 [ 0.21, 1.10 ]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>25</td>
<td>26</td>
<td></td>
<td>36.7 %</td>
<td>0.46 [ 0.21, 0.98 ]</td>
</tr>
<tr>
<td>Total events:</td>
<td>6 (Silicon gel sheet), 14 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td>Tau² = 0.0; Chi² = 0.11, df = 1 (P = 0.74); I² = 0.0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 2.01 (P = 0.045)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Low risk of scarring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gold 2001</td>
<td>0/15</td>
<td>1/16</td>
<td></td>
<td>7.2 %</td>
<td>0.35 [ 0.02, 8.08 ]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>15</td>
<td>16</td>
<td></td>
<td>7.2 %</td>
<td>0.35 [ 0.02, 8.08 ]</td>
</tr>
<tr>
<td>Total events:</td>
<td>0 (Silicon gel sheet), 1 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td>not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.65 (P = 0.52)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Risk not stated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ahn 1991</td>
<td>0/21</td>
<td>10/21</td>
<td></td>
<td>8.6 %</td>
<td>0.05 [ 0.00, 0.76 ]</td>
</tr>
<tr>
<td>Cruz-Korchin 1996</td>
<td>5/20</td>
<td>11/20</td>
<td></td>
<td>23.6 %</td>
<td>0.45 [ 0.19, 1.07 ]</td>
</tr>
<tr>
<td>Niessen 1998</td>
<td>19/119</td>
<td>7/119</td>
<td></td>
<td>23.9 %</td>
<td>2.71 [ 1.19, 6.22 ]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>160</td>
<td>160</td>
<td></td>
<td>56.1 %</td>
<td>0.57 [ 0.10, 3.40 ]</td>
</tr>
<tr>
<td>Total events:</td>
<td>24 (Silicon gel sheet), 28 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td>Tau² = 1.91; Chi² = 13.70, df = 2 (P = 0.001); I² = 85%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.61 (P = 0.54)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>200</td>
<td>202</td>
<td></td>
<td>100.0 %</td>
<td>0.55 [ 0.21, 1.45 ]</td>
</tr>
<tr>
<td>Total events:</td>
<td>30 (Silicon gel sheet), 43 (Control)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td>Tau² = 0.85; Chi² = 16.32, df = 5 (P = 0.01); I² = 69%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.21 (P = 0.23)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

0.002 0.1 1 10 500
Favours silicon gel Favours control
### Analysis 1.2. Comparison 1 Silicon gel versus no treatment (control), Outcome 2 Development of complications - prevention.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 1 Silicon gel versus no treatment (control)

Outcome: 2 Development of complications - prevention

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Prevention</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cruz-Korchin 1996</td>
<td>2/20</td>
<td>0/20</td>
<td>50.0 %</td>
<td>5.00 [ 0.26, 98.00 ]</td>
<td></td>
</tr>
<tr>
<td>Niessen 1998</td>
<td>5/155</td>
<td>0/155</td>
<td>50.0 %</td>
<td>11.00 [ 0.61, 197.24 ]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>175</td>
<td>175</td>
<td>100.0 %</td>
<td>8.00 [ 1.02, 62.83 ]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 7 (Silicon gel sheet), 0 (Control)
Heterogeneity: Chi^2 = 0.14, df = 1 (P = 0.71); I^2 = 0.0%
Test for overall effect: Z = 1.98 (P = 0.048)

---

### Analysis 1.3. Comparison 1 Silicon gel versus no treatment (control), Outcome 3 Reduction of scar length - treatment.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 1 Silicon gel versus no treatment (control)

Outcome: 3 Reduction of scar length - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>IV,Fixed,95% CI</td>
<td>IV,Fixed,95% CI</td>
</tr>
<tr>
<td>de Oliveira 2001</td>
<td>16 0.07 (0.07)</td>
<td>11 0 (0)</td>
<td>0.0 [ 0.0, 0.0 ]</td>
<td>0.0 [ 0.0, 0.0 ]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>16</td>
<td>11</td>
<td>0.0 [ 0.0, 0.0 ]</td>
<td>0.0 [ 0.0, 0.0 ]</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable
Test for overall effect: Z = 0.0 (P < 0.00001)
### Analysis 1.4. Comparison 1 Silicon gel versus no treatment (control), Outcome 4 Reduction in scar width - treatment.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 1 Silicon gel versus no treatment (control)

Outcome: 4 Reduction in scar width - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
</tr>
<tr>
<td>de Oliveira 2001</td>
<td>16</td>
<td>0.17 (0.18)</td>
<td>11</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>16</td>
<td>11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

---

### Analysis 1.5. Comparison 1 Silicon gel versus no treatment (control), Outcome 5 Scar thickness - treatment.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 1 Silicon gel versus no treatment (control)

Outcome: 5 Scar thickness - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
</tr>
<tr>
<td>Li-Tsang 2006</td>
<td>12</td>
<td>4.17 (0.17)</td>
<td>22</td>
<td>6.16 (0.25)</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>12</td>
<td>22</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 27.47 (P < 0.00001)
Analysis 1.6. Comparison 1 Silicon gel versus no treatment (control), Outcome 6 Reduction of keloid scar size by 50% - treatment.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 1 Silicon gel versus no treatment (control)

Outcome: 6 Reduction of keloid scar size by 50% - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel</th>
<th>Control</th>
<th>Odds Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Odds Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tan 1999</td>
<td>2/17</td>
<td>0/17</td>
<td></td>
<td>100.0%</td>
<td>5.65 [0.25, 126.87]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>17</td>
<td>17</td>
<td></td>
<td>100.0%</td>
<td>5.65 [0.25, 126.87]</td>
</tr>
</tbody>
</table>

Total events: 2 (Silicon gel), 0 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.09 (P = 0.28)

Analysis 1.7. Comparison 1 Silicon gel versus no treatment (control), Outcome 7 Scar colour amelioration - treatment.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 1 Silicon gel versus no treatment (control)

Outcome: 7 Scar colour amelioration - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colom Majan 2006</td>
<td>6/6</td>
<td>3/5</td>
<td></td>
<td>43.1%</td>
<td>1.59 [0.79, 3.23]</td>
</tr>
<tr>
<td>de Oliveira 2001</td>
<td>15/16</td>
<td>0/11</td>
<td></td>
<td>6.7%</td>
<td>21.88 [1.45, 331.34]</td>
</tr>
<tr>
<td>Li-Tsang 2006</td>
<td>9/22</td>
<td>3/12</td>
<td></td>
<td>44.4%</td>
<td>1.64 [0.54, 4.92]</td>
</tr>
<tr>
<td>Tan 1999</td>
<td>1/17</td>
<td>0/17</td>
<td></td>
<td>5.7%</td>
<td>3.00 [0.13, 68.84]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>61</td>
<td>45</td>
<td></td>
<td>100.0%</td>
<td>3.05 [1.57, 5.96]</td>
</tr>
</tbody>
</table>

Total events: 31 (Silicon gel sheet), 6 (Control)

Heterogeneity: Chi² = 6.51, df = 3 (P = 0.09); I² = 54%

Test for overall effect: Z = 3.27 (P = 0.0011)
### Analysis 1.8. Comparison 1 Silicon gel versus no treatment (control), Outcome 8 Improvement in scar elasticity - treatment.

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

**Comparison:** 1 Silicon gel versus no treatment (control)

**Outcome:** 8 Improvement in scar elasticity - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
<th>Weight M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahn 1989</td>
<td>9/14</td>
<td>0/14</td>
<td>15.3% 19.00 [1.21, 297.89]</td>
<td></td>
</tr>
<tr>
<td>Ahn 1991</td>
<td>12/18</td>
<td>2/18</td>
<td>25.6% 6.00 [1.56, 23.07]</td>
<td></td>
</tr>
<tr>
<td>Colom Majan 2006</td>
<td>5/6</td>
<td>4/5</td>
<td>31.0% 1.04 [0.59, 1.83]</td>
<td></td>
</tr>
<tr>
<td>Li-Tsang 2006</td>
<td>16/22</td>
<td>3/12</td>
<td>28.2% 2.91 [1.06, 8.01]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td></td>
<td></td>
<td>100.0% 3.39 [0.77, 14.85]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 42 (Silicon gel), 9 (Control)

Heterogeneity: Tau^2 = 1.75; Chi^2 = 19.63, df = 3 (P = 0.0002); I^2 = 85%

Test for overall effect: Z = 1.62 (P = 0.11)

---

### Analysis 1.9. Comparison 1 Silicon gel versus no treatment (control), Outcome 9 Symptomatic relief of itching & pain - treatment.

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

**Comparison:** 1 Silicon gel versus no treatment (control)

**Outcome:** 9 Symptomatic relief of itching & pain - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel n/N</th>
<th>Control n/N</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
<th>Weight M-H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Li-Tsang 2006</td>
<td>22/22</td>
<td>11/12</td>
<td>96.7% 1.11 [0.90, 1.36]</td>
<td></td>
</tr>
<tr>
<td>Tan 1999</td>
<td>3/9</td>
<td>0/9</td>
<td>3.3% 7.00 [0.41, 118.69]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td></td>
<td></td>
<td>100.0% 1.30 [0.98, 1.73]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 25 (Silicon gel sheet), 11 (Control)

Heterogeneity: Chi^2 = 3.73, df = 1 (P = 0.05); I^2 = 73%

Test for overall effect: Z = 1.81 (P = 0.07)
### Analysis 1.10. Comparison 1 Silicon gel versus no treatment (control), Outcome 10 Development of complications - treatment.

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars  

**Comparison:** 1 Silicon gel versus no treatment (control)  

**Outcome:** 10 Development of complications - treatment

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Control</th>
<th>Odds Ratio M-H,Fixed 95% CI</th>
<th>Weight</th>
<th>Odds Ratio M-H,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahn 1989</td>
<td>8/14</td>
<td>0/14</td>
<td>33.9 %</td>
<td></td>
<td>37.92 [ 1.89, 760.53 ]</td>
</tr>
<tr>
<td>Colom Majan 2006</td>
<td>1/6</td>
<td>0/5</td>
<td>66.1 %</td>
<td></td>
<td>3.00 [ 0.10, 90.96 ]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>20</strong></td>
<td><strong>19</strong></td>
<td><strong>100.0 %</strong></td>
<td><strong>14.83</strong></td>
<td><strong>14.83 [ 1.80, 121.93 ]</strong></td>
</tr>
</tbody>
</table>

Total events: 9 (Silicon gel sheet), 0 (Control)  
Heterogeneity: Chi² = 1.22, df = 1 (P = 0.27); I² = 18%  
Test for overall effect: Z = 2.51 (P = 0.012)

### Analysis 2.1. Comparison 2 Silicon gel versus non-silicon gel or dressing, Outcome 1 Reduction of scar width.

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars  

**Comparison:** 2 Silicon gel versus non-silicon gel or dressing  

**Outcome:** 1 Reduction of scar width

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Non-silicon gel</th>
<th>Mean Difference IV,Fixed 95% CI</th>
<th>Weight</th>
<th>Mean Difference IV,Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>de Oliveira 2001</td>
<td>16 0.17 (0.18)</td>
<td>14 0.2 (0.15)</td>
<td>-0.03 [-0.15, 0.09]</td>
<td>100.0%</td>
<td>-0.03 [-0.15, 0.09]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>16</strong></td>
<td><strong>14</strong></td>
<td><strong>100.0 %</strong></td>
<td></td>
<td><strong>-0.03 [-0.15, 0.09]</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable  
Test for overall effect: Z = 0.50 (P = 0.62)
Analysis 2.2. Comparison 2 Silicon gel versus non-silicon gel or dressing. Outcome 2 Reduction of scar length.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 2 Silicon gel versus non-silicon gel or dressing

Outcome: 2 Reduction of scar length

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Non Silicon gel</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
<td>IV,Fixed,95% CI</td>
</tr>
<tr>
<td>de Oliveira 2001</td>
<td>16</td>
<td>0.07 (0.07)</td>
<td>14</td>
<td>0.09 (0.08)</td>
<td>-0.02 [-0.07, 0.03]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>16</td>
<td>14</td>
<td>100.0 %</td>
<td>-0.02 [-0.07, 0.03]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 0.72 (P = 0.47)

Analysis 2.3. Comparison 2 Silicon gel versus non-silicon gel or dressing. Outcome 3 Scar colour improvement.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 2 Silicon gel versus non-silicon gel or dressing

Outcome: 3 Scar colour improvement

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Non silicon gel</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>de Oliveira 2001</td>
<td>15/16</td>
<td>12/14</td>
<td>1.09 [0.85, 1.40]</td>
<td>100.0 %</td>
<td>1.09 [0.85, 1.40]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>16</td>
<td>14</td>
<td>100.0 %</td>
<td>1.09 [0.85, 1.40]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 15 (Silicon gel sheet), 12 (Non silicon gel)

Heterogeneity: not applicable

Test for overall effect: Z = 0.71 (P = 0.48)
Analysis 3.1. Comparison 3 Silicon gel versus silicon plates with added Vitamin E, Outcome 1 Improvement in cosmesis, itching, and pain > 50%.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 3 Silicon gel versus silicon plates with added Vitamin E

Outcome: 1 Improvement in cosmesis, itching, and pain > 50%

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Silicon gel + Vit E</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palmieri 1995</td>
<td>30/40</td>
<td>38/40</td>
<td><img src="image1.png" alt="Image" /></td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.79 [0.65, 0.96]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>40</strong></td>
<td><strong>40</strong></td>
<td><img src="image2.png" alt="Image" /></td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.79 [0.65, 0.96]</td>
</tr>
</tbody>
</table>

Total events: 30 (Silicon gel sheet), 38 (Silicon gel + Vit E)

Heterogeneity: not applicable

Test for overall effect: Z = 2.41 (P = 0.016)

Analysis 4.1. Comparison 4 Silicon gel versus triamcinolone acetonide Injection treatment, Outcome 1 Reduction of keloid scar size by 50%.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 4 Silicon gel versus triamcinolone acetonide Injection treatment

Outcome: 1 Reduction of keloid scar size by 50%

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Triamcinolone inj.</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tan 1999</td>
<td>2/17</td>
<td>16/17</td>
<td><img src="image3.png" alt="Image" /></td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.13 [0.03, 0.46]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>17</strong></td>
<td><strong>17</strong></td>
<td><img src="image4.png" alt="Image" /></td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.13 [0.03, 0.46]</td>
</tr>
</tbody>
</table>

Total events: 2 (Silicon gel sheet), 16 (Triamcinolone inj.)

Heterogeneity: not applicable

Test for overall effect: Z = 3.12 (P = 0.0018)
Analysis 4.2. Comparison 4 Silicon gel versus triamcinolone acetonide Injection treatment, Outcome 2 improvement in erythema.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 4 Silicon gel versus triamcinolone acetonide Injection treatment

Outcome: 2 improvement in erythema

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet n/N</th>
<th>Triamcinolone inj. n/N</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tan 1999</td>
<td>1/17</td>
<td>10/17</td>
<td></td>
<td>100.0%</td>
<td>0.10 [0.01, 0.70]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>17</td>
<td>17</td>
<td>100.0%</td>
<td>0.10 [0.01, 0.70]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 1 (Silicon gel sheet), 10 (Triamcinolone inj.)
Heterogeneity: not applicable
Test for overall effect: Z = 2.32 (P = 0.020)

Analysis 4.3. Comparison 4 Silicon gel versus triamcinolone acetonide Injection treatment, Outcome 3Symptomatic relief of itching and pain.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 4 Silicon gel versus triamcinolone acetonide Injection treatment

Outcome: 3 Symptomatic relief of itching and pain

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet n/N</th>
<th>Triamcinolone inj. n/N</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tan 1999</td>
<td>3/9</td>
<td>5/9</td>
<td></td>
<td>100.0%</td>
<td>0.60 [0.20, 1.79]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>9</td>
<td>9</td>
<td>100.0%</td>
<td>0.60 [0.20, 1.79]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 3 (Silicon gel sheet), 5 (Triamcinolone inj.)
Heterogeneity: not applicable
Test for overall effect: Z = 0.92 (P = 0.36)
### Analysis 4.4. Comparison 4 Silicon gel versus triamcinolone acetonide Injection treatment, Outcome 4

**Average time (in days) to improvement.**

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

**Comparison:** 4 Silicon gel versus triamcinolone acetonide Injection treatment

**Outcome:** 4 Average time (in days) to improvement

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel</th>
<th>Triamcinolone inj.</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sproat 1992</td>
<td>14 3.9 (0.62)</td>
<td>14 6.8 (1.86)</td>
<td>-2.90</td>
<td>100.0%</td>
<td>-3.93, -1.87</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>14</td>
<td>14</td>
<td>-2.90</td>
<td>100.0%</td>
<td>-3.93, -1.87</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 5.53 (P < 0.00001)

-10 -5 0 5 10
Favours silicon Favours triamcinolon

### Analysis 4.5. Comparison 4 Silicon gel versus triamcinolone acetonide Injection treatment, Outcome 5

**Patient preference.**

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

**Comparison:** 4 Silicon gel versus triamcinolone acetonide Injection treatment

**Outcome:** 5 Patient preference

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel</th>
<th>Triamcinolone inj.</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed 95% CI</td>
<td></td>
<td>M-H,Fixed 95% CI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sproat 1992</td>
<td>11/14</td>
<td>2/14</td>
<td>5.50 [1.48, 20.42]</td>
<td>100.0%</td>
<td>5.50 [1.48, 20.42]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>14</td>
<td>14</td>
<td>5.50 [1.48, 20.42]</td>
<td>100.0%</td>
<td>5.50 [1.48, 20.42]</td>
</tr>
</tbody>
</table>

Total events: 11 (Silicon gel), 2 (Triamcinolone inj.)

Heterogeneity: not applicable

Test for overall effect: Z = 2.55 (P = 0.011)

0.005 0.1 1 10 200
Favours triamcinol Favour silicon
Analysis 4.6. Comparison 4 Silicon gel versus triamcinolone acetonide Injection treatment, Outcome 6 Development of complications.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 4 Silicon gel versus triamcinolone acetonide Injection treatment

Outcome: 6 Development of complications

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Silicon gel sheet</th>
<th>Triamcinolone inj</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
<th>Weight</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sproat 1992</td>
<td>1/14</td>
<td>10/14</td>
<td>100.0 %</td>
<td>0.03</td>
<td>[ 0.00, 0.32 ]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>14</td>
<td>14</td>
<td>100.0 %</td>
<td>0.03</td>
<td>[ 0.00, 0.32 ]</td>
</tr>
</tbody>
</table>

Total events: 1 (Silicon gel sheet), 10 (Triamcinolone inj)
Heterogeneity: not applicable
Test for overall effect: Z = 2.91 (P = 0.0036)

Analysis 5.1. Comparison 5 Adhesive silicon gel versus non-adhesive silicon sheet, Outcome 1 Scar width.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 5 Adhesive silicon gel versus non-adhesive silicon sheet

Outcome: 1 Scar width

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Adhesive silicon gel</th>
<th>Non-adhesive</th>
<th>Mean Difference M-H,Fixed,95% CI</th>
<th>Weight</th>
<th>Mean Difference M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Niessen 1998</td>
<td>114</td>
<td>124</td>
<td>0.80 [-0.01, 1.61]</td>
<td>100.0 %</td>
<td>0.80 [-0.01, 1.61]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>114</td>
<td>124</td>
<td>100.0 %</td>
<td>0.80</td>
<td>[-0.01, 1.61]</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable
Test for overall effect: Z = 1.93 (P = 0.054)
### Analysis 5.2. Comparison 5 Adhesive silicon gel versus non-adhesive silicon sheet, Outcome 2 Scar height.

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars  
**Comparison:** 5 Adhesive silicon gel versus non-adhesive silicon sheet  
**Outcome:** 2 Scar height

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>adhesive silicon gel</th>
<th>non-adhesive silicon</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Niessen 1998</td>
<td>114 1.2 (0.4)</td>
<td>124 1.2 (0.4)</td>
<td></td>
<td>100.0 %</td>
<td>0.0 [-0.10, 0.10]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>114</td>
<td>124</td>
<td></td>
<td>100.0 %</td>
<td>0.0 [-0.10, 0.10]</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable  
Test for overall effect: $Z = 0.0$ ($P = 1.0$)

---

### Analysis 5.3. Comparison 5 Adhesive silicon gel versus non-adhesive silicon sheet, Outcome 3 Scar colour.

**Review:** Silicon gel sheeting for preventing and treating hypertrophic and keloid scars  
**Comparison:** 5 Adhesive silicon gel versus non-adhesive silicon sheet  
**Outcome:** 3 Scar colour

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>adhesive silicon gel</th>
<th>non-adhesive silicon</th>
<th>Std. Mean Difference</th>
<th>Weight</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Niessen 1998</td>
<td>114 4.3 (2.3)</td>
<td>119 4.5 (2.2)</td>
<td>-0.09 [-0.35, 0.17]</td>
<td>100.0 %</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>114</td>
<td>119</td>
<td>-0.09 [-0.35, 0.17]</td>
<td>100.0 %</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable  
Test for overall effect: $Z = 0.68$ ($P = 0.50$)
Analysis 5.4. Comparison 5 Adhesive silicon gel versus non-adhesive silicon sheet, Outcome 4 Scar perfusion.

Review: Silicon gel sheeting for preventing and treating hypertrophic and keloid scars

Comparison: 5 Adhesive silicon gel versus non-adhesive silicon sheet

Outcome: 4 Scar perfusion

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>adhesive silicon gel</th>
<th>non-adhesive silicon sheet</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
<td>IV,Fixed,95% CI</td>
</tr>
<tr>
<td>Niessen 1998</td>
<td>114</td>
<td>22.3(8.9)</td>
<td>121</td>
<td>23.7(13.1)</td>
<td>-1.40 [-4.25, 1.45]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>114</td>
<td>22.3(8.9)</td>
<td>121</td>
<td>23.7(13.1)</td>
<td>-1.40 [-4.25, 1.45]</td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 0.96 (P = 0.34)

APPENDICES

Appendix 1. Search strategy for the original review

For the original review we searched the Cochrane Wounds Group Specialised Register (September 2005); the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 3, 2005); MEDLINE (1989 to June 2002); EMBASE (1988 to May 2002); and CINAHL (1982 to May 2002).

The following search strategy was used to search CENTRAL:
1. KELOID explode all trees (MeSH)
2. HYPERTROPHY explode all trees (MeSH)
3. CICATRIX explode all trees (MeSH)
4. CICATRIX HYPERTROPHIC explode all trees (MeSH)
5. (keloid* or hypertrophic or scar* or cicatrix)
6. (#1 or #2 or #3 or #4 or #5)
7. SILICONES explode all trees (MeSH)
8. silicon*
9. (#7 or #8)
10. (#6 and #9)

WHAT'S NEW

Last assessed as up-to-date: 20 November 2007.

23 May 2008 Amended Converted to new review format.
HISTORY

Review first published: Issue 1, 2006

11 February 2008  New search has been performed  For this first update, new searches were carried out in January and 21st November 2007. 11 studies were identified of which two were included (Colom Majan 2002, Li-Tsang 2006). Seven studies were excluded, and additional data has been requested from a further two (this has not been received at the time of writing). The reviewers’ conclusions remain unchanged.

15 November 2005  New citation required and conclusions have changed  Substantive amendment

CONTRIBUTIONS OF AUTHORS

Lisa O’Brien developed and wrote the protocol. Data for the review were extracted by Lisa O’Brien and Abhay Pandit, the text of the review and this update was written by Lisa O’Brien.

DECLARATIONS OF INTEREST

None known

sources of support

Internal sources

• No sources of support supplied

External sources

• Australasian Cochrane Centre, Australia.
• School of Occupational Therapy, Curtin University, Australia.
INDEX TERMS

Medical Subject Headings (MeSH)
*Occlusive Dressings; Cicatrix, Hypertrophic [prevention & control; "therapy"]; Keloid [prevention & control; "therapy"]; Randomized Controlled Trials as Topic; Silicone Gels [*therapeutic use]

MeSH check words
Humans