# Practice Guidelines for the Application of Nonsilicone or Silicone Gels and Gel Sheets After Burn Injury

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**The objective of this review was to systematically evaluate available clinical evidence for the application of nonsilicone or silicone gels and gel sheets on hypertrophic scars and keloids after a burn injury so that practice guidelines could be proposed. This review provides evidence based recommendations, specifically for the rehabilitation interventions required for the treatment of aberrant wound healing after burn injury with gels or gel sheets. These guidelines are designed to assist all healthcare providers who are responsible for initiating and supporting scar management interventions prescribed for burn survivors. Summary recommendations were made after the literature, retrieved by systematic review, was critically appraised and the level of evidence determined according to Oxford Centre for Evidence-based Medicine criteria.[1] (J Burn Care Res 2015;36:345–374)**

## RECOMMENDATIONS

### Standards

The data generated from studies that only include participants with burn injuries are inconclusive and methodologically limited. Thus, the following guidelines have been based on literature generated from participants with scars originating from any dermal injury or disease. It is recommended that further randomized controlled trials (RCTs) that are adequately powered, use objective instrumentation to evaluate scars, and are methodologically rigorous be conducted with burn survivors.

### Practice guidelines

- Gels or gel sheets should be applied to burn scars that have a high probability of forming hypertrophic scars (HTS) (ie, wounds that require ≥21 days to heal, personal factors, etc.) as soon as the wound has re-epithelialized.
- Only immature scars should be treated with gels or gel sheets, as mature burn scars have not been shown to respond.
- There are no clear benefits to using gels versus gel sheets or nonsilicone versus silicone products with respect to the treatment effect, but there appear to be fewer adverse reactions when using silicone gels compared to gel sheets.

### Options

- Keloids may benefit from treatment with gels or gel sheets.

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## OVERVIEW

### Purpose

The purpose of these guidelines was to review evidence evaluating the application of nonsilicone or silicone gels and gel sheets after a burn injury. Since literature specific to burn survivors was limited, the search was expanded to include participants who developed scars as a result of other injuries and disorders. Rehabilitation specific information was extracted from the literature to provide further guidance for clinicians.

### Users

These guidelines are designed to aid burn care team members (nurses, occupational therapists, physical therapists, physicians, etc.) who are responsible for initiating and supporting the treatment of HTS or keloids after a burn injury. Additionally, the recommended guidelines can be implemented by healthcare professionals who do not routinely treat burn patients at their facilities, such as ambulatory care centers, outpatient clinics, etc.

### Clinical Problem

Deep burn wounds frequently heal with the formation of HTS or keloids,[2,3] which may profoundly affect a patient's functional and psychosocial recovery and quality of life.[4–6] Although a precise definition and method for differentiating HTS from keloids has not been agreed upon in the literature, keloids proliferate or originate beyond the confines of the original injury and are recognized as having important pathological differences.[7] International clinical recommendations published in 2002[8] supported the use of silicone gel sheets for the treatment of scar after a burn injury, but limited burn injury specific literature and literature addressing the use of nonsilicone gel sheets and gels available at that time. The objective of this review was to systematically evaluate the available evidence for the application of nonsilicone or silicone gels and gel sheets on HTS and keloids after burn injury so that practice guidelines could be proposed that specifically outline required rehabilitation interventions.

## PROCESS

The steps taken to develop the practice guidelines reported here are those outlined by Bowker and colleagues.[9] These steps included setting up a guideline development group, forging links with stakeholder groups, agreeing on the scope of the guidelines, formulating clinically relevant PICO (population, intervention, condition, outcome) questions, searching the literature for evidence, systematically appraising the evidence found, and making recommendations. The guideline development group consisted of an international assembly of occupational therapists, physicians and physiotherapists who were members of the American Burn Association Rehabilitation Committee, clinicians recruited from the American Burn Association, and clinicians who had previous experience with practice guideline development.[10] The scope of the guidelines is limited to the PICO question: "Do gels or gel sheets reduce the thickness and vascularity or increase the pliability of postburn hypertrophic scar or keloids?"

### Search Strategy

A broad computerized search was conducted in the following databases: Ovid MEDLINE, the Cumulative Index of Nursing & Allied Health Literature (CINAHL), Ovid EMBASE and the Cochrane Library, from the earliest available date until December 2, 2011. The search strategy was developed for MEDLINE by a medical librarian (J.B.) as described in Appendix 1, then adapted for the other databases. A total of 697 results were retrieved from all sources; 254 duplicates were removed, yielding 443 records for eligibility screening. Additional publications were retrieved by scanning reference lists in the articles reviewed.

### Selection for Inclusion

Since studies focusing on this clinical question were expected to be sparse, all study designs that provided original data on patients were selected. Examples of the cause of wounds included trauma, mammoplasty, surgery (ie. cancer excision), burn injuries, immunization sites, and acne. The title and abstract of each article were assessed. Only full length articles, in English or French, were selected for review, with review articles being excluded to allow the critical appraisal of original publications. Ultimately, 55 articles were deemed appropriate for the full review process. An additional six articles were added after scanning the reference lists of these articles (Figure 1).

### Data Extraction and Analysis

All studies were systematically critiqued and scored by at least two independent reviewers, drawing on the critical appraisal form designed by Law and colleagues.[11] Fourteen items comprised in the scoring of this form relate to study purpose, literature review,

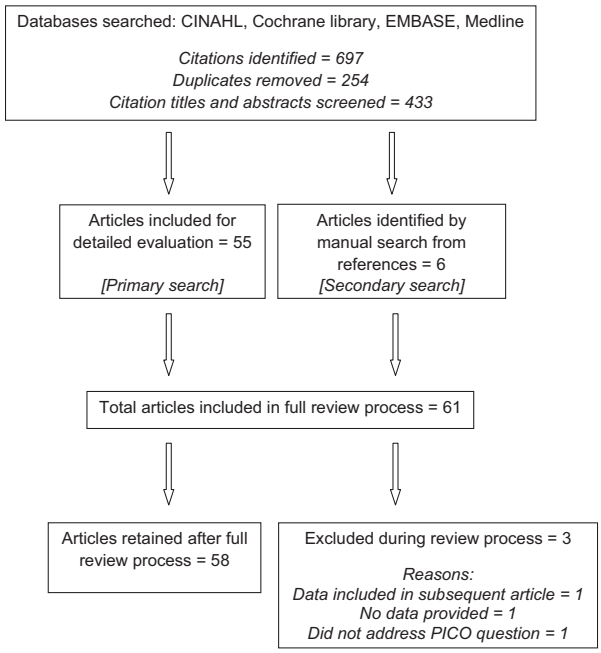


**Figure 1.** Flow chart for search strategy.

study sample, outcomes, interventions, results, conclusions, and clinical implications. The two reviewers independently extracted details required to complete the critical appraisal form. Each item was rated numerically as (1) for Yes and (0) for No or Not applicable. A total score was then calculated and compared to the second reviewer's results. If there were minor differences (±2 points), the discrepancies were discussed by both reviewers until a consensus was reached. When larger differences occurred, a third reviewer was called upon to critique the article and consensus was achieved among all three reviewers. After this process, one article was removed[12] because the data were also included in a subsequent article,[13] one because there were no data provided[14] and one because the authors' clinical question was not addressed.[15]

## RESULTS

### Study Characteristics

Table 1 summarizes the critique results for the 58 citations retained. Citations are presented in three categories, based on the population of patients included: 1) Burn scars only (denoted with double asterisk); 2) Combined burn and nonburn scar etiology (denoted by a single asterisk); and 3) nonburn or unspecified scars. As can be seen in the final column of this table, 16 of the 58 citations (28%) received a score of <5 out of a possible total score of 14, but were maintained for the sake of completeness. Of the remaining citations, 28 (48%) received a score of 5 to 9 and 14 (24%) received a score ≥10. The 11 studies that included burn scars only were more likely to score <5 compared to the total group, where six (55%) received a score of <5, two (18%) received a score of 5 to 9 and three (27%) received a score of ≥10 out of a possible total score of 14.

Table 2 presents the study characteristics of the 58 citations in detail. Twenty- seven were RCTs,[16–42] six were cohort studies,[13,43–47] 24 case series,[48–71] and one an expert opinion.[72] The sample size of all the studies ranged from 5 to 276 and those that included burn scars only ranged from 30 to 94 participants. Sample size of the RCTs ranged from 11 to 155 and for burn scar only studies, from 32 to 104 subjects. The level of evidence was assigned according to the updated Oxford Centre for Evidence-based Medicine Levels of Evidence.[1]

Eleven of the citations study samples contained combined burn and nonburn scar etiology: four RCTs,[17,25,26,30] two cohort studies,[13,43] and five case series.[52,57,59,60,63] Eleven studies included burn scar subjects only: five were RCTs,[22,23,28,38,39] five were case series,[48,58,66,68,69] and one was an expert opinion.[72]

### Scientific Foundation

The initial description of the use of silicone gel sheets (SGSs) was published by Perkins and colleagues,[72] who treated 42 patients with scars resulting from burn injuries. All of the patients were children, and approximately half were also wearing pressure garments. Their scar age ranged from newly closed wounds to 12 years post injury. No scar outcome data were provided, but the authors concluded that all of the patients showed "significant improvement." This early report was followed by a number of reports by Quinn and colleagues,[68,69] who reported on a series of patients and also explored some plausible mechanisms of action by which SGS were having an effect. The first report included 40 patients and the second report 125. It appears that all patients included in these two reports were burn survivors and completely different populations, but this was never clearly articulated. In both the reports, outcome measures included color and elevation, as well as "texture", which were quantified with an extensometer in the second report. In the first report, all patients improved within the first 2 months with respect to at least one of the skin characteristics that was evaluated, and in the second report 75 out of 125 improved. In the second report, 37 were lost

**Table 1.** Evidentiary table: evaluation of the quality of intervention studies

| Citation | Study Purpose | Literature Review | Design | Sample | | | Outcomes | |
|---|---|---|---|---|---|---|---|---|
| | | | | Size | Details | Justified | Reliable | Valid |
| Ahn et al 1991 | 1 | 1 | CO | 48† | 1 | 0 | 1 | 1 |
| Argirova et al 2006 | 0 | 0 | CS | 276* | 0 | 0 | 0 | 0 |
| Baum and Busuito 1998 | 0 | 1 | CS | 34 | 1 | 0 | 0 | 0 |
| Berman and Flores 1999 | 0 | 1 | RCT | 22 | 1 | 0 | 0 | 0 |
| Boutli-Kasapidou et al 2005 | 1 | 0 | CO | 30† | 1 | 0 | 0 | 0 |
| Carney et al 1994 | 1 | 1 | RCT | 42† | 1 | 0 | 0 | 0 |
| Cassuto et al 2010 | 0 | 1 | CS | 37 | 1 | 0 | 0 | 0 |
| Chan et al 2005 | 1 | 1 | RCT | 100 | 1 | 1 | 0 | 0 |
| Chernoff et al 2007 | 1 | 1 | CO | 30 | 1 | 0 | 0 | 0 |
| Chuangsuw anich et al 2000 | 1 | 0 | CS | 18 | 0 | 0 | 0 | 0 |
| Cruz-Korchin 1996 | 1 | 1 | CO | 20 | 1 | 0 | 0 | 0 |
| de Giorgi et al 2009 | 1 | 1 | RCT | 110 | 1 | 0 | 0 | 0 |
| de Oliveira et al 2001 | 1 | 1 | RCT | 26 | 1 | 0 | 0 | 0 |
| Dockery and Nilson 1994 | 1 | 1 | CS | 94† | 1 | 0 | 0 | 0 |
| Eishi et al 2003 | 1 | 1 | CS | 6 | 1 | 0 | 0 | 0 |
| Fulton 1995 | 1 | 0 | CS | 20 | 1 | 0 | 0 | 0 |
| Gibbons et al 1994 | 0 | 1 | CS | 5 | 0 | 0 | 0 | 0 |
| Gold 1993 | 0 | 1 | CS | 10 | 0 | 0 | 0 | 0 |
| Gold 1994 | 0 | 1 | CS | 34† | 0 | 0 | 0 | 0 |
| Gold et al 2001 | 1 | 1 | RCT | 96 | 1 | 0 | 0 | 0 |
| Hamanova and Broz 2002 | 1 | 0 | CS | 60* | 0 | 0 | 0 | 0 |
| Harte et al 2009 | 1 | 1 | RCT | 22* | 1 | 1 | 1 | 0 |
| Hirshowitz et al 1993 | 1 | 1 | CS | 32† | 0 | 0 | 0 | 0 |
| Hirshowitz et al 1998 | 1 | 1 | CS | 30† | 0 | 0 | 0 | 0 |
| Hosnuter et al 2007 | 1 | 1 | CO | 60 | 1 | 0 | 0 | 0 |
| Karagoz et al 2009 | 1 | 1 | RCT | 32* | 1 | 0 | 0 | 0 |
| Katz 1995 | 1 | 1 | CS | 48 | 0 | 0 | 0 | 0 |
| Klopp et al 2000 | 1 | 1 | RCT | 12 | 0 | 0 | 0 | 0 |
| Lacarrubba et al 2008 | 1 | 1 | CS | 8 | 1 | 1 | 0 | 0 |
| Lee et al 1996 | 1 | 1 | CS | 26† | 1 | 0 | 0 | 0 |
| Li-Tsang et al 2006 | 0 | 1 | RCT | 45† | 1 | 0 | 1 | 1 |
| Li-Tsang et al 2010 | 1 | 1 | RCT | 104† | 1 | 0 | 1 | 1 |
| Majan 2006 | 1 | 1 | RCT | 11 | 1 | 0 | 0 | 0 |
| Mercer 1989 | 0 | 0 | CS | 18 | 0 | 0 | 0 | 0 |
| Momeni et al 2009 | 1 | 1 | RCT | 38* | 1 | 0 | 0 | 0 |
| Murison and James 2005 | 1 | 0 | CS | 6 | 1 | 0 | 0 | 0 |
| Niessen et al 1998 | 1 | 1 | RCT | 155 | 1 | 0 | 1 | 1 |
| Ohmori 1988 | 0 | 0 | CS | 46* | 0 | 0 | 0 | 0 |
| Palmieri et al 1995 | 1 | 1 | RCT | 80† | 0 | 0 | 0 | 0 |
| Perez et al 2010 | 1 | 0 | RCT | 30 | 1 | 0 | 0 | 0 |
| Perkins et al 1983 | 1 | 0 | EO | 42* | 1 | 0 | 0 | 0 |
| Phillips et al 1996 | 1 | 1 | RCT | 20 | 1 | 0 | 1 | 1 |
| Puri and Talwar 2009 | 0 | 1 | CS | 30 | 0 | 0 | 0 | 0 |
| Quinn et al 1985 | 0 | 0 | CS | 40* | 1 | 0 | 0 | 0 |
| Quinn 1987 | 1 | 0 | CS | 125* | 0 | 0 | 0 | 0 |
| Rhee et al 2010 | 1 | 1 | RCT | 40 | 1 | 0 | 0 | 0 |
| Sakuraba et al 2011 | 1 | 0 | CS | 9 | 0 | 0 | 0 | 0 |
| Scuderi et al 2010 | 1 | 1 | RCT | 150 | 1 | 0 | 0 | 0 |
| Scuderi et al 2011 | 1 | 1 | RCT | 85 | 1 | 0 | 0 | 0 |
| Signori and Clementonit 2007 | 1 | 1 | RCT | 148 | 1 | 0 | 0 | 0 |
| Spencer 2010 | 1 | 0 | CS | 7 | 0 | 0 | 0 | 1 |
| Sprout et al 1992 | 1 | 1 | RCT | 14 | 0 | 1 | 1 | 1 |
| Steinstraesser et al 2011 | 1 | 1 | RCT | 38* | 1 | 0 | 1 | 1 |
| Tan et al 1999 | 1 | 1 | CO | 17 | 1 | 0 | 0 | 0 |
| van der Wal et al 2010 | 1 | 1 | RCT | 23* | 1 | 0 | 1 | 1 |
| Widgerow et al 2008 | 0 | 1 | RCT | 120 | 0 | 0 | 1 | 1 |
| Wigger-Alberti et al 2009 | 1 | 1 | RCT | 60 | 1 | 1 | 1 | 1 |
| Wittenberg et al 1999 | 1 | 1 | RCT | 19 | 1 | 1 | 0 | 0 |

*CS*, case series; *CO*, cohort; *EO*, expert opinion; RCT, randomized controlled trial.
*Only burn survivors.
†Burn survivors included; YES = 1; NO or N/A = 0.

| Intervention | | | Results | | | | | |
|---|---|---|---|---|---|---|---|---|
| Detailed Description | Contamination | Cointervention | Statistical Signif icance | Analysis Appropriate | Clinical Importance | Drop Outs Reported | Conclusions Appropriate | Total Score |
| 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 11 |
| 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 3 |
| 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 6 |
| 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 7 |
| 0 | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 8 |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 9 |
| 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 5 |
| 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 4 |
| 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 10 |
| 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 10 |
| 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 10 |
| 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 7 |
| 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 9 |
| 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 4 |
| 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 3 |
| 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 5 |
| 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 3 |
| 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 6 |
| 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 3 |
| 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 11 |
| 1 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 7 |
| 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 6 |
| 1 | 0 | 0 | 1 | 1 | 1 | 0 | 1 | 8 |
| 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 9 |
| 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 4 |
| 0 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 7 |
| 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 6 |
| 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 5 |
| 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 8 |
| 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 12 |
| 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 7 |
| 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 2 |
| 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 9 |
| 1 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 5 |
| 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 12 |
| 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 2 |
| 0 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 5 |
| 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 9 |
| 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 3 |
| 1 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 9 |
| 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 |
| 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 4 |
| 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 10 |
| 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 3 |
| 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 9 |
| 1 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 8 |
| 1 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 8 |
| 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 6 |
| 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 11 |
| 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 10 |
| 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 10 |
| 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 12 |
| 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 6 |
| 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 13 |
| 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 10 |

**Table 2.** Characteristics of included studies

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Ahn et al 1991 | Intra individual cohort | • n = 48<br>• Group 1 = 29 Sx scars, all but two <40 yr, n = 10 were lost to follow-up<br>• Group 2 = 19 HTS, age range 3–78 yr, burns, Sx scars, spider bite | • Baseline, 1 and 2/12<br>• Scar volume<br>• Photograph<br>• Elastometer<br>• Homemade global scar assessment | • Tx = SGS secured with adhesive tape and worn >12 hrs/d<br>• Control = no treatment<br>• Group 1—half of the surgical excision assigned to Tx or control<br>• Group 2—half of the surface area of HTS assigned to Tx or control | • Increased scar volume of surgical scars at control sites (1/12 $P = .03$; 2/12 $P = .003$)<br>• No statistically significant reduction in scar volume of HTS<br>• Increased scar elasticity in Tx'd HTS compared to baseline at 1/12 ($P = .019$) and 2/12 ($P = .0001$) and compared to the control (1/12, $P = .005$; 2/12, $P = .0001$)<br>• HTS elasticity treatment effect plateaued at 2/12 | 3 |
| Argirova et al 2006 | Case series | • n = 276 children<br>• Burns | • Baseline, 4, 8, 12, 24/52<br>• VSS<br>• Photograph | • Group 1—(n = 232) – compression (24 hrs/d) + intralesional TCA (10–40 mg/ml) + SGS (8–24 hrs/d)<br>• Group 2— (n = 44) – compression (24 hrs/d) + SGS (8–24 hrs/d) | • No statistical comparisons provided<br>• Graphic outcomes presented for pigmentation, height, vascularity, itch, and pliability<br>• 17 patients developed skin reaction | 4 |
| Baum and Busuito 1998 | Case series | • n = 34<br>• Sx excisions | • Homemade evaluation (effective vs not effective) | • NSGS (>12 hrs/d × 8–12 wks) applied postsurgically + compression (n = 3) | • No statistical comparisons provided<br>• Stated that 31/34 scars were effectively treated | 4 |
| Berman and Flores 1999 | RCT | • N = 22 (10 HTS; 22 keloids)<br>• n = 9 lost to follow-up<br>• Age range 25–70 yrs<br>• Mean 7 mos postinjury<br>• Etiology not specified | • Scar volume<br>• Homemade evaluation (color, tenderness, itching, induration, patient satisfaction) | • Group 1—silicone gel filled cushion<br>• Group 2—SGS<br>• Group 1 and 2—>10 hrs/d | • No statistically significant difference between the groups<br>• 61% of the patients reported a satisfaction level of >9/10<br>• one patient developed skin reaction | 2 |
| Boutli-Kasapidou et al 2005 | CO | • n = 30<br>• Group 1 = 11F, 9M<br>• Group 2 = 6F, 4M<br>• Mean age 24 yrs<br>• Keloids and HTS<br>• Sx, acne, immunization, burns, spontaneous keloids | • Rating scale<br>• Patient assessment: pruritus, burning, tension<br>• Dr assessment: flattening, functionality, softness | • Group 1—polytherapy (cryotherapy, intralesional cortisone, SG [3x/d × 12 mos])<br>• Group 2—SGS (20 hrs/d × 12 mos) | • Patient satisfaction: Group 1 increase 6.05 ± 0.66 vs group 2 increase 1.8 ± 0.25 ($P < .0001$)<br>• Dr assessment: group 1 increase 6.4 ± 0.06 vs group 2 increase 1.7 ± 0.21 ($P < .0001$)<br>• Younger (2.9 ± 1.51-yr-old) keloids were more likely to respond than older (5.36 ± 1-yr-old) ($P < .001$) | 3 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Carney et al 1994 | Intraindividual RCT | • n = 42<br>• Mean 23.2 (2–60 yrs )<br>• 92% burns | • Extensometer<br>• Homemade evaluation (color, texture, general condition, patients' opinion) | • Group 1—SGS and control (intraindividual)<br>• Group 2—Cica care and control (intraindividual)<br>• Group 1 and 2—worn as much as possible | • Group 1—improvement was significantly greater in Tx'd vs control at 2/12 (extensibility $P < .0001$; color $P = 0.005$; texture $P$ .001) and 6/12 (extensibility $P < .03$; texture $P = .012$)<br>• Group 2—improvement was significantly greater in Tx'd vs control at 1/12 (extensibility $P < .03$), 2/12 (extensibility $P < .001$; color $P = .008$; texture $P$ .001) and 6/12 (extensibility $P < .04$; color $P = .007$; texture $P = .002$)<br>• Adverse reactions: pruritus, skin irritation<br>• No statistical difference between the groups | 2 |
| Cassuto et al 2010 | Case series | • n = 37 (31F, 6M) (n = 48 scars; 34 HTS + 14 keloids)<br>• Mean 34 (8–67 yrs)<br>• Mean scar age 9 (3–35 mos)<br>• Etiology not specified | • Baseline and 4 wks after every Tx (maximum Tx 21)<br>• VSS<br>• Photograph | • Laser (532 nm millisecond) + SGS (16–24 hrs/d) | • No statistical comparisons provided<br>• VSS improved from 12.6 (baseline) to 3.3 (final) | 4 |
| Chan et al 2005 | Intraindividual RCT | • n = 50<br>• Median age 61 (26–77 yrs)<br>• Sternal scar postcardiac surgery | • 2/52, 6/52, 3/12 postoperative<br>• VSS<br>• Pain (3 point scale)<br>• Itch (3 point scale)<br>• Digital image (rater blinded to group allocation)<br>• compliance | • Upper and lower portion of the scar randomly assigned to Tx and the control group<br>• Tx group—SG (semi-liquid stick)<br>• Control—NSGS<br>• Applied 2x/d<br>• Subjects blinded to group allocation<br>• 3/12 Tx | • Tx group significantly better on all outcome measures (pigmentation $P = .02$; vascularity $P = .001$; pliability $P = .001$; height $P = .001$; pain $P = .001$; itch $P = 0.02$)<br>• Tx group gradually improved between 6/52 and 3/12<br>• Control group gradually worsened over time<br>• 74% perfect compliance, 24% forgot sometimes, 2% forgot most of the time | 2 |
| Chernoff et al 2007 | Intraindividual cohort | • n = 30 bilateral active scars<br>• HTS, keloids or postlaser exfoliation erythema<br>• Etiology of HTS and keloids not specified | • Optical profilometry (surface topology, elevation)<br>• Homemade evaluation (erythema, scar symptoms [irritation, skin maceration] and difficulty using) | • Group 1 (n = 10)—SG (2x/d)<br>• Group 2 (n = 10)—SGS (morning and night)<br>• Group 3 (n = 10)—SG (morning) and SGS (night)<br>• Bilateral scar—no treatment control<br>• Tx time for all groups = 90 d | • Group 1, 2, and 3 were significantly less elevated ($P < .001$) and groups 1 and 2 were significantly less red ($P < .001$), less symptomatic ($P < .001$) compared to untreated control scar<br>• SG was easier to use that SGS ($P < .001$)<br>• Group 3 participants rated improvement most favorably | 3 |

(*Continued*)

**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Chuangsuwanich et al 2000 | Case series | • n = 18<br>• Mean age 21 (6–33 yr)<br>• Mean scar age 5.7 yrs (3 mos–20 yrs)<br>• HTS and keloids<br>• Etiology not specified | • Baseline, 1, 2, 4, 6 mos<br>• Height, weight, and color<br>• Photographs<br>• Scar volume<br>• Patient rating (poor, fair, good) | • Tx group: SGS, 12 hrs/d, 8/52 Tx | • Height of scar after Tx 66.67% better ($P = .058$)<br>• Weight of the scar after Tx 55.55% improved ($P = .09$)<br>• Color of the scar after Tx 36.84% improved<br>• Patient rating: 66.67% good | 4 |
| Cruz-Korchin 1996 | Intraindividual cohort | • n = 20<br>• Bilateral mammoplasty 14 d postoperatively | • Baseline, 1, 2, and 6 mos<br>• Appearance (raised vs flat)<br>• Photography<br>• Observation | • Bilateral breasts: one control, one Tx<br>• SGS postoperative day 14, 12 hrs/d × 2/12 | • At 2/12—25% of treated breasts were hypertrophic, 60% of nontreated were hypertrophic ($P < .05$)<br>• At 6/12—25% of treated breasts were hypertrophic, 55% of nontreated were hypertrophic ($P < .05$)<br>• Skin irritation in two patients | 3 |
| De Georgi et al 2009 | RCT | • n = 110 (55F, 55M)<br>• Group A = 65 (32F, 33M) (mean age 52 yrs range 26–81)<br>• Group B = 45 (23F, 22M) (mean age 48 yrs. range 23–76)<br>• Fresh Sx scars | • 1, 2, 3, 4, 6, 8 mos post Sx<br>• Scar alterations (keloids, HTS, diastasic scar, strophic scar)<br>• Pain and itch VAS | • Group A = SG + zinc oxide 2x/d × 60 d<br>• Group B = zinc oxide cream | • Abnormal scar formation: group A 27% vs group B 55% ($P = .038$)<br>–Keloids: group A 0% vs group B 11%<br>–HTS: group A 9% vs group B 22%<br>–Pain: group A 20% vs group B 47%<br>–Itch: group A 9% vs group B 35% | 2 |
| De Oliveira et al 2001 | Intraindividual RCT | • n = 26 (41 HTS and keloids)<br>• 15–53 yrs<br>• Scars >3 mos old<br>• Acne, Sx, spontaneous, trauma, ear ring, infected wound, herpes | • Baseline, 30, 60, 90, 120, 135 d<br>• Pain, itch (relief vs no relief)<br>• Induration<br>• Linear measure<br>• Color<br>• Intracicatricial pressure (only measured at 135 d) | • 2 scars Tx'd same patient: 1 SGS, 1 NSGS<br>• Untreated control scar if more than two scars<br>• Wear 24 hrs/d × 4.5 mos | • No difference in linear measures SG and non-SG (length $P = .5247$; width $P = .3354$)<br>• No difference SG vs NSG for color, itch, pain, induration, and intracicatricial pressure<br>• Significant when compared to control (length $P = .0139$; width $P = .0011$; color $P < .001$; induration $P < .0001$; intracicatricial pressure = .0152) | 2 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Dockery and Nilson 1994 | Case series | • n = 94<br>• 11–73 yrs<br>• 24M (23–73 yrs)<br>• 70F (11–66 yrs)<br>• L/E fresh, old scars, HTS, Sx, trauma, burns | • Baseline, 1, 2, 4, 6 mos<br>• Photograph<br>• Dr and Patient scar assessment at the end of Tx (width, elevation, color, sensation) | • SGS Tx 2/52—2/12<br>• Group 1—known scar formers (eight patients)<br>• Group—fresh HTS (<3 mos) (54 patients)<br>• Group 3—fresh keloids (<6 mos) (seven patients)<br>• Group 4—Long standing scar (>3 mos) or keloid (>6 mos) (15 patients)<br>• Group 5—non-Sx traumatic or burn scar (10 patients) | • No statistical comparisons provided<br>• Group 1—none developed HTS or keloids<br>• Group 2—49 greatly improved, 4 somewhat improved, 1 no improvement<br>• Group 3—3 greatly improved, 2 somewhat improved, 2 no improvement<br>• Group 4—11 greatly improved, 4 somewhat improved<br>• Group 5—8 greatly improved, 1 noncompliant, 1 had skin breakdown | 4 |
| Eishi et al 2003 | Case series | • n = 6 (3F, 3M)<br>• Mean 50.2 ± 24.9 (19–76 yrs)<br>• Mean scar age 82.0 ± 59.5 (10–180 mos)<br>• Keloids<br>• Etiology not specified | • Baseline, 1, 2, 3, 4, 5, 6 mos<br>• Evaluation Dr and patient (pain, itch, redness, elevation; 0 = no symptoms and 4 = severe symptoms)<br>• Biopsy before and after of one patient (Fas antigen expression and Mast cell count) | • SGS 12–24 hrs/d × 6 mos | • Pain: ↓ 4/52 ($P$ = .04), disappeared at 12/52<br>• Pruritus: ↓ 4/52 ($P$ = .02), disappeared at 12/52<br>• Redness: ↓ 8/52 ($P$ = .025), continued to ↓ 24/52 ($P$ = .033)<br>• Elevation: ↓ 8/52 ($P$ = .03)<br>• Mast cell no: ↓ ($P$ = .04)<br>• Fas expression: ↑ decreased in intensity of staining post Tx | 4 |
| Fulton 1995 | Case series | • n = 20<br>• HTS or keloids after skin trauma or fresh Sx scars | • Baseline, 1, 2, 4, 6 mos<br>• Evaluated by patient and Dr. (texture, color, thickness, and pruritus)<br>• Photographs<br>• Punch biopsy for silica content | • SGS 12–24 hrs/d × 8–12 wks<br>• Tx and control scars<br>• Intralesional TCA injection in persistent cases (7/20) | • No statistical comparisons provided<br>• 85 % softened or resolved HTS (17/20)<br>• no silica content difference in SGS and control | 4 |
| Gibbon et al 1994 | Case series | • n = 5 (3F, 2M)<br>• Mean age = 9 (2–12 yrs)<br>• Mean scar age = 9.2 (2–16 mos)<br>• HTS,[4] keloid[1]<br>• Etiology not specified | • Size, height, pliability, vascularity, pigmentation from VSS but no numeric values | • SGS 12–24 hrs/d × 0.25–8 mos | • No statistical comparisons provided<br>• 3/5 positive results: Reduction in scar size and thickness.<br>• Softening of scar-related<br>• Decrease vascularity<br>• 3/5 developed skin breakdown and rash | 4 |

(*Continued*)

**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Gold 1993 | Case series | • n = 10 (16 scars)<br>• Sx and traumatic | • Baseline, 1, 2, 3 mos<br>• Evaluated by Dr. and patient (thickness, color, overall effectiveness; 0 no change and 3 complete resolution) | • SGS >12 hrs/d × 12 wks | • No statistical comparisons provided<br>• Patients reported moderate improvement in thickness, color, overall effectiveness (81.25%, 75%, 100%)<br>• Drs reported complete resolution (6.25%, 6.25%, 6.25%) or moderate change (50%, 68.75%, 93.75%) in thickness, color, overall effectiveness | 4 |
| Gold 1994 | Case series | • n = 34 (n = 21 group 1; n = 8 group 2; n = 5 group 3)<br>• Sx and burn | • Baseline, 1, 2 3 mos<br>• Evaluated by Dr. and patient (thickness, color, overall effectiveness; 0 no change and 3 complete resolution) | • SGS >12 hrs/d × 12 wks<br>• Group 1—17 HTS, 4 keloids where half of the scar was Tx'd, half of the scar was control<br>• Group 2—Sx site was treated after removal of keloid<br>• Group 3—HTS from burn | • No statistical comparisons provided<br>• Group 1—scar thickness moderate reduction: Patient = 33.3%, physician = 47.6%; Color change moderate: Patient = 19.1%, Dr = 42.9%; Overall moderate effectiveness: Patient = 23.8%, Dr = 52.3%<br>• Group 2—1 treated site resulted in recurrent keloid<br>• Group 3—4 of 5 minimal change; one moderate | 4 |
| Gold et al 2001 | RCT | • N = 96<br>• Stratified into low risk (n = 50) and high risk (n = 46)<br>• Mean 38.5 yrs (low risk); 34.8 yrs (high risk)<br>• Removal of skin lesions (benign and malignant tumors, sebaceous cysts, HTS, keloids) | • 2, 4, 8, 12, 16, 20, 24/52 post-Sx<br>• Physician observation<br>• Patient's opinion (discomfort, embarrassment, color height, texture, function)<br>• Photographic assessment<br>• No details provided about any of the scales | • Tx group—SGS (12–24 hrs/d applied 48 hrs/post surgery, sutures/staples removed 7–14 d)<br>• Control group—routine postoperative care<br>• 6/12 Tx | • Low risk group—no difference between the treatment and control<br>• High risk group—reduction in percentage who developed HTS or keloid ($P = .072$) but not statistically significant<br>• Individuals undergoing scar revision surgery—Increased rate of prevention ($P = .035$) (n = 4 Tx group vs n = 10 control) | 2 |

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|---|---|---|---|---|---|---|
| Hamanova and Broz 2002 | Case series | • n = 60 (80 sites) (24F, 36M)<br>• 18 Adults, 42 children<br>• Mean age 28.5 (5–55 yrs)<br>• 10 Patients with old, mature HTS, 50 patients with immature scar<br>• Burns | • Baseline 1, 2, 4, 6 mos<br>• Height, weight, color of scar<br>• Patient subjective report | • SGS Tx up to 2 yrs<br>• >20 hrs/d winter, >12 hrs/d summer<br>• Minimum size of scar: 10×40 mm, 3 mm height | • No statistical comparisons provided<br>• Positive effect in reduction immature HTS but not in mature scar (10 patients)<br>• 40% of the patients reported improvement in all the tested characteristics<br>• 10% of the subjects developed a skin reaction | 4 |
| Harte et al 2009 | RCT | • n = 22 (9F, 13M)<br>• Mean age = 36.8 (16–64 yrs)<br>• Mean TBSA 15 (1–55%)<br>• 14 U/E, 8 L/E<br><6 mos postinjury<br>• HTS postburn injury | • Baseline, 12 and 24 wks<br>• VSS<br>• Patient diary | • Group A—pressure therapy<br>• Group B—pressure therapy + SGS<br>• 23 hrs/d, replace every 7 d | • Overall reduction of VSS scores for both groups at 24 wks<br>• No difference between group A and B at 12 or 24 wks<br>• Power analysis determined 192 participants per group would be required, therefore results are under powered | 2 |
| Hirshowitz et al 1993 | Case series | • N = 32<br>• Mean age = 27.3 (5–51 yrs)<br>• Mean scar age 23 (10–60 mos)<br>• Post-Sx,[21] postburn,[13] post trauma[6] | • 1 m, every 2–3 mos for 12 mos.<br>• Scar appearance: hardness, elevation, color<br>• Pain, itch, discomfort subjective<br>• Digital photographs | • SGS | • No statistical comparisons provided<br>• 12.5% No improvement<br>• 15.6 % Slight improvement<br>• 37.5% Moderate improvement<br>• 34.4% Excellent improvement | 4 |
| Hirshowitz et al 1998 | Case series | • n = 30<br>• Scar age > 4 mos<br>• Sx scars and burn | • Hardness, elevation, color, pain, itch, discomfort | • 0.75 mm thick silicone cushion filled with silicone oil<br>• 12 mos Tx<br>• 33.3% had intralesional corticosteroid injections | • No statistical comparisons provided<br>• 63.3% Alleviation of symptoms at 6 mos<br>• 33.3% had recalcitrant scars | 4 |

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**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Hosnuter et al 2007 | Nonrandomized controlled cohort | • n = 60 (36F, 24M)<br>• HTS[39] and keloids[21] different<br>• Etiology not specified<br>• Mean age 40.3 ± 9.6 (22–61 yrs)<br>• Scar age range 1–6 mos | • Monthly for 6 mos<br>• Color, height, itch, pain (0 = none, 1 = mild, 2 = pronounced)<br>• Hardness (0 = normal, 1 = mild, 2 = moderate, 3 = pronounced)<br>• Therapeutic index (complete healing, clear improvement, moderate, poor) | • Group 1—topical onion extract (n = 21), 4x/d<br>• Group 2—SGS (n = 19), 24 hr/d<br>• Group 3—SGS (24 hrs/d) + onion extract (2x/d) (n = 20)<br>• 6 mos Tx | • Improvement with time: Group 1—color, hardness $P < .001$, pain $P < .05$; Group 2—color, hardness, itch $P < .01$, height $P < .001$; Group 3—color, height, hardness $P < .001$, itch $P < .01$<br>• More color reduction in group 1 vs group 2 ($P < .01$)<br>• More height reduction in group 3 vs group 1 ($P < .05$)<br>• No significant difference in improvements in hardness, itch, pain between the groups<br>• Five withdrawals due to itching | 3 |
| Karagoz et al 2009 | RCT | • n = 32 (45 scars) (20F, 12M)<br>• Mean age 24 (3–55 yrs)<br>• Scar age <6 mos<br>• HTS postburn injury | • Baseline and 6 mos<br>• VSS<br>• Photograph | • Group 1—silicone gel, 2x/d<br>• Group 2—SGS 24 hrs/d<br>• Group 3—onion extract, 2x/d<br>• 6 mos Tx | • Before and after Tx differences for each group ($P < .05$)<br>• Significantly better improvement in group 1 vs 3 and 2 vs 3 ($P < .05$)<br>• No difference between group 1 and 2<br>• Skin maceration: two patients in group 2 | 2 |
| Katz 1995 | Case series | • n = 34 (36 chronic scars >3 mos)<br>• n = 14 (14 fresh scars <3 mos) | • Baseline, 2, 6 mos<br>• Dr and patient assessed redness, elevation based on photographs | • SGS >12 hrs/d × 2 mos | • No statistical comparisons provided<br>• 20/36 Chronic scars improved after Tx<br>• 11/14 Fresh scar—no HTS developed after 6 mos<br>• Dermatitis occurred with three patients | 4 |
| Klopp et al 2000 | Intraindividual RCT | • n = 12<br>• L/E scars after removal of veins for cardiac surgery<br>• Scars 2.5–4 yrs<br>• Sites randomly assigned | • Venular flow rate<br>• Microvessel length<br>• No. of blood cell-perfused nodal points in a defined tissue volume<br>• Skin temperature<br>• Surface quality | • Group 1—NSGS (polyurethane) alone<br>• Group 2—NSGS (polyurethane) + pressure<br>• Group 3—pressure alone<br>• Group 4—SGS + pressure<br>• Pressure administered using stretch bandages<br>• 15 mm between Tx sites<br>• 8 wks Tx | • Reported significant changes for all measurement listed for all groups but no *P* values were provided ( decrease in vessel length and venular flow rate; decrease in the no. of aggregated erythrocytes; increase in the skin temperature; decrease in surface roughness) | 2 |

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| Lacarrubba 2008 | Case series | • n = 8 (6F, 2M)<br>• Mean age 29 (12–49 yrs)<br>• <90 d posttrauma or surgery | • Baseline, 1, 2, 3 mos<br>• Scar thickness by ultrasound<br>• Clinical evaluation of size, redness and texture | • Silicone gel applied 2x/d<br>• 6 mos Tx<br>• Three patients with control scars | • No statistical comparisons provided<br>• Mean scar thickness reduced by 37% (4 mm before Tx [3.4–6.1]; 2.5 mm after [2.1–3.2])<br>• Two patients c/o itch | 4 |
| Lee et al 1996 | Case series | • n = 26 participants (15F, 11M) with 45 scars<br>• Mean age 26 (3–52 yrs)<br>• Scars <6/12 old<br>• Burns, operative scars, tattoo scars, keloids | • Baseline, monthly for 6 mos<br>• 3 point scale (0 = worse, 1 = remained the same, 2 = improved) for color, texture, thickness, and regularity | • Group 1—SGS (Sil-K)<br>• Group 2—SGS epiderm<br>• Held in place with adhesive strip, tubigrip or bandage<br>• 6/12 Tx | • No statistical comparisons provided<br>• Improvement reported in both the groups (90% improvement in color and texture, 80% improvement in regularity, 50% improvement in thickness)<br>• Some patients complained of itch and maceration | 4 |
| Li-Tsang et al 2006 | RCT | • n = 45<br>• Mean 29.65 ± 17.6 yrs<br>• Chinese subjects with scar >3 mm thick<br>• Burns, trauma | • Baseline, 1, 2, 4, 6 mos<br>• Spectrocolorimeter (color)<br>• Tissue ultrasound palpation system (thickness)<br>• VSS (pliability)<br>• Pain (VAS)<br>• Itch (VAS) | • Tx group—SGS (24 hrs/d) + 15 min massage 2x/d with lanolinControl group—15 min massage 2x/d with lanolin6 mos Tx | • Decreased thickness over 6/12 in Tx group relative to control ($P < 0.01$)<br>• Increased pliability over 6/12 in Tx group relative to control ($P < 0.01$)<br>• No statistically significant difference in itch, pain, or color | 2 |
| Li-Tsang et al 2010 | RCT | • n = 104 (84 completed all assessment)<br>• Mean age 21.8 ± 18.7<br>• Mean scar age 14.9 ± 30.8 mos<br>• Burns, trauma | • Baseline 2, 4, 6 mos<br>• Spectrocolorimeter (color)<br>• Tissue ultrasound palpation system (thickness)<br>• VSS (pliability)<br>• Pain (VAS)<br>• Itch (VAS)<br>• Patient satisfaction (interview) | • Group 1—pressure garments (24 hr/d except hygiene)<br>• Group 2—SGS<br>• Group 3—pressure garments + SGS<br>• Group 4—control<br>• 6 mos Tx<br>• Pressure garments and SGS worn 24 hrs/d except for hygiene | • Thickness: group 3 improved at 2/12, 4/12, and 6/12 and group 1 at 6/12 ($P < .001$) relative to control but no difference between Tx groups ($P = .066$)<br>• Pliability: at 6/12 all groups improved ($P < .001$); group 3 was significantly more pliable than control at 2/12 ($P = .002$) and 4/12 ($P < .0001$)<br>• Pigmentation: at 6/12 all groups were lighter and more yellow ($P < .001$)<br>• Pain: group 2 ($P = .001$) and group 3 ($P = .004$) reduced relative to control<br>• Itch: authors report reduced itch for all Tx groups but data indicates an increase for group 1 from baseline to 6/12 | 2 |

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**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Majan 2006 | RCT | • n = 11 (11F)<br>• Control group mean age 28.8 (20—43 yrs)<br>• Tx group mean age 29.4 (22–40 yrs)<br>• Post-Sx scars | • Baseline, monthly until 6 mos and 12 mos<br>• VSS<br>• Dr and patient overall assessment at baseline and 12 mos | • Tx group—SGS<br>• Control—no treatment<br>• Wear up to 23 hrs/d<br>• Tx initiated 2/52—2/12 post-Sx and continued for 12 mos | • No statistical comparisons provided<br>• All scars improved (VSS)<br>• Overall assessment: Dr rated 5/5 in Tx group as very good or good, patients rated 4/5 very good or good<br>• One patient experienced skin reaction | 2 |
| Mercer 1989 | Case series | • n = 18 (7F, 11M) (22 keloids)<br>• Mean age 19 (3–64 yrs)<br>• Mean scar age 35 (9–120 mos) | • Baseline, 1, 2–3, 6 mos<br>• Height, color, texture | • Progressively increased wear time of SGS to 24 hrs/d | • No statistical comparisons provided<br>• 86% Scars positively responded to SGS (texture 86%, color 84%, height 68%)<br>• 3 Scars (14%) showed no response to TX<br>• Three Patients experienced skin reaction | 4 |
| Momeni et al 2009 | Intraindividual RCT | • n = 38 (18F, 16M)<br>• Mean age 22 (1.5–60 yrs)<br>• HTS postburn injury | • VSS<br>• Baseline, 1, 4 mos<br>• Pigmentation, vascularity, pliability, pain, itch | • HTS divided into 2 sides—side 1 = SGS; side 2 = NSGS (propylene glycol and hydroxyethyl cellulose sheeting)(referred to as placebo control)<br>• Tx initiated 2–4 mo postinjury<br>• Worn 24 hrs/d | • Side 1—at 4/12 all scores except pain were significantly lower in the SGS group than the NSGS ($P < .05$)<br>• Side 2—No significant change at 1/12 or 4/12 | 2 |
| Murison and James 2006 | Case series | • n = 6<br>• Age range 30–58 yrs<br>• Scar age 3–6 mos to 4–5 yrs<br>• Etiology not specified | • Digital photographs<br>• Modified VSS: redness, elevation, hardness, itch, tenderness, pain<br>• Spectrophotometric intracutaneous scope (SIS) | • SG 2x/d x 8/12 | • No statistical comparisons provided<br>• Modified VSS Improved for all subjects<br>• SIS—7.2% decrease in collagen, 3% increase in blood flow | 4 |

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|---|---|---|---|---|---|---|
| Niessen et al 1998 | RCT | • n = 155 (all F women)<br>• Mean age 31 (14–69 yrs)<br>• Breast reduction Sx scars | • Baseline, 1, 2, 4, 6 mos<br>• Thickness (ultrasound)<br>• Blood flow (laser doppler)<br>• Color (chromameter)<br>• Pain (VAS)<br>• Itch (VAS)<br>• Punch biopsy, ruler | • Group 1—SGS (Sil-K) (n = 80)<br>• Group 2—SGS (epiderm) (n = 75)<br>• Group 1 and 2 were randomly assigned to left lateral and right medial or left medial and right lateral with the remainder as control<br>• Tx initiated 3 d postoperatively, 24 hrs/d × 3 mos<br>• SGS applied with stretch tension and fixed with micropore<br>• Control—micropore only | • 119 participants completed the study<br>• Developed HTS: 64.3% at 3 mos, 56.6% at 6 mos, 35.3% at 12 mos<br>• Occurrence of HTS increases with ease of tanning ($P < .02$)<br>• No difference between 2 silicone Tx'd sites<br>• increased HTS at Tx sites relative to control: at 6 mos ($P = .006$); at 12 mos ($P = .02$)<br>• Several patients developed skin irritation | 2 |
| Ohmori 1988 | Case series | • n = 46 (48 scars)<br>• Keloids<br>• Burns, acne, trauma | • Subjective scale<br>• Redness, elevation, subjective complaints (itch, pain) | • 1 mm SGS<br>• 8–12 hrs/d | • No statistical comparisons provided<br>• Excellent = 6; Good = 24; Fair = 12; Poor = 6 | 4 |
| Palmieri et al 1995 | RCT | • n = 80<br>• 18–63 yrs<br>• Scar age: 3 mos–2 yrs postinjury<br>• HTS or keloids posttrauma[70] or burns[10] | • Evaluation at 4 and 8 wks<br>• Photographs for color, size and cosmetic appearance<br>• Itch, pain | • Group A—SGS + vitamin E<br>• Group B—SGS<br>• Wore between 10 PM & 8 AM | • At 4/12 group A 85% improved by more than 50% and group B 55% ($P < .01$)<br>• At 8/12 group A 95% improvement by more than 50% and Group B 75% ($P < .05$) | 2 |

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**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Perez et al 2010 | RCT | • n = 30<br>• HTS or keloids<br>• Etiology not specified | • Baseline, 4, 8, 12, 16 wks scar volume<br>• Investigators evaluation of induration, erythema, pigmentation, pain, itch, cosmetic assessment<br>• Patient satisfaction<br>• Spectrometric intracutaneous scope | • Group 1—TCA + SGS + vitamin E (2x/d)<br>• Group 2—onion extract gel (3–4x/d)<br>• Group 3—placebo control (2x/d)<br>• Tx period 16/52 | • n = 15 patients completed study<br>• At 16/52 relative to baseline: group 1 improved on volume ($P = .01$), length ($P = .02$), induration ($P < .01$), erythema (< .01), pigmentation, ($P < .01$), investigator evaluation ($P < .01$), patient satisfaction ($P = .04$); group 2 volume ($P = .01$), length ($P = .02$), width ($P = .02$), induration ($P = .03$); group 3 volume ($P = .02$), patient satisfaction ($P = .01$)<br>• Significant improvement: group 1 vs 3—investigator cosmetic evaluation ($P < .01$), induration ($P < .001$), pigmentation ($P < .001$), erythema ($P = .01$); group 2 vs 3: investigator cosmetic evaluation ($P < .01$), induration ($P < .001$), pigmentation ($P < .001$), tenderness ($P < .05$)<br>• Overall satisfaction: group 1 and 2 >76/100 | 2 |
| Perkins et al 1983 | Case series | • n = 42<br>• Age range 4 mos–16 yrs<br>• Newly healed to mature (12 yrs) burn scars | • Scar improvement, pain | • SGS (spenco)<br>• 20/42 patients with pressure therapy | • No objective results or statistical comparisons provided<br>• Subjective claims of benefits | 5 |
| Phillips et al 1996 | RCT | • n = 20<br>• HTS and keloids<br>• Mean age = 33.3 yrs<br>• Mean scar age 8.5–9 yrs<br>• Etiology not specified | • Baseline, 2, 4, 8 wks, and 1 mo post Tx termination<br>• VSS<br>• Scar volume<br>• Photographs<br>• Transcutaneous oxygen measures | • Group 1—NSGS (hydrocolloid) for 7 d, replaced if it became dislodged<br>• Group 2—control moisturizer 1x/d<br>• 8 mos Tx | • No difference between Tx groups<br>• Significant reduction in itch ($P < .03$) in both the groups with time<br>• Adverse skin reactions in 4 patients | 2 |
| Puri and Talwar 2009 | Case series | • n = 30 (2:1 male:female ratio)<br>• Age range 5–60 yrs<br>• HTS and keloid<br>• Scar age range: <1/12–>6/12<br>• Etiology not specified | • Evaluation 1x/12×6 mos<br>• Graded: I = normal, II = mildly hypertrophic, III = hypertrophic, IV = keloid | • SG 2x/d x 0.25–8 mos | • No statistical comparisons provided<br>• Improvement after Tx: No. of cases increased from 0–60% (grade I) and decreased 26.6–20% (grade II), 50–10 (grade III), 23.3–10% (grade IV) | 4 |

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|---|---|---|---|---|---|---|
| Quinn et al 1985 | Case series | • n = 40<br>• 1–67 yrs<br>• Scar age:1–144 mos<br>• HTS and keloids<br>• Etiology not specified but presumed burn injury | • Evaluated scar qualities texture, color, elevation | • SGS with bandage, adhesive tape, silicone base adhesive + pressure garment | • No statistical comparisons provided<br>• 7/40 Improved on 3 scar qualities, 18/40 on 2 and 15/40 on 1 after 2 mos Tx<br>• Mode of action of SGS does not involve pressure, temperature, oxygen tension or occlusion | 4 |
| Quinn 1987 | Case series | • n = 125 (129 scars)<br>• Etiology not specified but presumed burn injury | • Evaluated scar qualities texture (extensometer), color, elevation | • SGS held in place by different methods<br>• 12–24 hrs/d x 2 mos | • 10/129 Improved on 3 scar qualities, 28/129 on 2 and 37/129 on 1 after 2 mos Tx<br>• 14 Developed a rash, 3 resulted in tissue breakdown, 37 were lost to follow up<br>• SGS has water vapor transmission rate lower than normal skin | 4 |
| Rhee et al 2010 | RCT | • n = 40<br>• Mean age = 31.7 (16–51 yrs)<br>• Asian participants after scar revision or mass excision | • Evaluation at 2/52, 1/12, and 3/12<br>• Pigmentation, vascularity, height using a photograph | • Group 1—SGS x 12 hrs/d x 3 mos<br>• Group 2—control | • No differences at 2/52<br>• 1/12 SGS showed decrease in height ($P < .0024$)<br>• 3/12, SGS showed decrease in pigmentation ($P < .0002$), vascularity ($P < .0002$) and height ($P < .00001$)<br>• 2 patients developed skin rash | 2 |
| Sakuraba et al 2011 | Case series | • n = 9 (5F, 4M)<br>• Mean age = 41.1 (18–67 yrs)<br>• Etiology not specified | • Protuberance, redness, rubbing, cramping, and itching rated on a scale of 0 = negligible–4 = severe | • SGS<br>• 24 hrs/d, 2 wks post-op for 24 wks | • Rubbing ($P = .035$), cramping ($P = .002$) and itching ($P = .021$) improved | 4 |
| Scuderi et al 2010 | RCT | • n = 150 (89F, 61M)<br>• Mean age = 32 (18–52 yrs)<br>• HTS age = 6–24 mos<br>• Sx and traumatic scar | • Baseline, 1, 3, 6, 12 mos<br>• Global scar assessment<br>• Color (photograph), overall softening, width (ruler), length (caliper), elevation (optical profilometry)<br>• VAS—itch, color, pliability, thickness, relief | • Group A— (n = 107) (asymmetrical): NSG (cyanoacrylates)<br>• Group B— (n = 40) (linear): half SG, 2x/d; half NSG (cyanoacrylates) (3 layers every 3–5 d)<br>• Tx 3 mos | • Group A—89.7% improved on global scar assessment<br>• Group B—Scar elevation reduced in both the groups at 1/12 (SG $P < .0001$) (NSG $P < .0001$) and 1 yr (SG $P < .0001$) (NSG $P < .0001$)<br>• One patient developed skin reaction | 2 |

(*Continued*)

**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Scuderi et al 2011 | Intra individual RCT | • n = 85<br>• Mean age 32 (18–52 yrs)<br>• Bilateral mammoplasty | • Baseline, 1, 3, 6, 12 mos<br>• Scar width (ruler), length (caliper), elevation (optical profilometry), texture<br>• VAS: itch, color, pliability, thickness, relief | • One breast Tx'd with NSG (cyanoacrylate) every 3–5 d for 3mos<br>• One breast Tx'd with SG, 2x/d x 3/12 | • Elevation: increased between baseline and 1/12 (NSG and SG $P < .0001$); decreased between baseline and 1 yr (NSG $P = .0182$; SG $P = .0174$)<br>• Scar width: increased between baseline and 1 yr (NSG and SG $P < .0001$); increased in width significantly less with NSG Tx ($P < .0001$)<br>• 3 patients experienced skin reaction to NSG | 2 |
| Signorini and Clementonit 2007 | RCT | • n = 148<br>• Mean age = 53.5 (5–82 yrs)<br>• Scar age: 10 d–3 wks<br>• Recent Sx scar | • Baseline, 1, 2, 3, 4, and 6 mos<br>• Overall evaluation (Grade 1 = normal, 2 = mildly hypertrophic, 3 = hypertrophic, 4 = keloid) | • Tx group: SG (2x/d x 4 mos)<br>• Control group | • Grade of Tx vs control scars at 6 mos: 1 = 67 vs 28%; 2 = 26 vs 46%; 3 = 6 vs 0%; 4 = 1 vs 26% which was significantly different ($P < .001$) | 2 |
| Spencer 2010 | Case series | • n = 7<br>• Sx excision—skin cancer | • Baseline, 1, 3 mos<br>• VSS and Dr's evaluations<br>• Mexameter for erythema and pigmentation | • Linear scar divided into two: half with SG, half control<br>• SG 2x/d for 3 mos | • No statistical comparisons provided<br>• No difference in erythema and pigmentation between the groups<br>• 5/7 SG group were better than control as assessed by physician<br>• 4/7 SG group were better than control on VSS | 4 |
| Sproat et al 1992 | Intra individual RCT | • n = 14<br>• Mean age = 41–81 yrs<br>• Scar age: 4 mos–3 yrs<br>• Post sternotomy scars | • Photographs, length, width, height, blinded assessment<br>• VAS for pain injection | • Scar divided into two: half Tx with SGS 12 hrs/d x 12/52, other half Tx with TCA injection 40 mg/ml | • 11/14 patients favored SGS ($P < .05$)<br>• 82% of the blinded observers preferred SGS results<br>• Pain with injection = 6.7 ± 3.0 VAS<br>• Symptomatic complaints improved with SGS 2.9 ± 1.44 d sooner than TCA ($P < .05$)<br>• Scar height decreases with both Tx<br>• Side effects: 64% with TCA, 1% with SGS | 2 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Steinstraesser et al 2011 | Intra individual RCT | • n = 38 (11F, 17M)<br>• Mean age = group 1—42.3 ± 13.3; group 2—43.1 ± 13.7<br>• Burns | • Baseline, 2/52, 2, 6, 12, 18 mos<br>• Clinical assessment, VSS, redness (chronometer), profilometry, photographs<br>• PRIMOS | • Randomly assigned to Tx groups: 1) SG + pressure vs pressure alone or 2) SGS + pressure vs pressure alone—no information provided about allocate to pressure alone<br>• 12 mos Tx | • Improved with time from baseline to 18 mos: VSS—SG and SGS + pressure (5.9 ± 1.5–1.9 ± 1.6) and pressure alone (5.8 ± 1.9–1.8 ± 1.3) ($P < .001$) but there was no difference between the groups; redness SG and SGS + pressure (15.4 ± 2.2–11.0 ± 2.1) ($P < .001$) and pressure alone (15.9 ± 2.2–11.3 ± 2.3) ($P = .003$) but there was no difference between the groups<br>• Profilometry improved between 2 and 18 mos for SG + pressure (323.1 ± 197.5–257.6 ± 178.3; $P = .047$) but not SGS + pressure or pressure alone<br>• Pain decreased with SG and SGS + pressure and pressure alone ($P = .005$) but there was no difference between the groups<br>• Itch decreased with SG and SGS + pressure ($P = .005$) and pressure alone ($P = .003$) but there was no difference between the groups<br>• 31.5% SGS developed a skin reaction<br>• Power analysis determined that 192 participants are required per group | |
| Tan et al 1999 | Intra individual cohort | • n = 17 (3 scars/subject)<br>• Age: 19–40 yrs<br>• Keloids<br>• Acne and spontaneous | • Baseline, 4, 8,12/52<br>• Length, width, height of keloids<br>• Color, texture<br>• Pain/itch<br>• Responsive or nonresponsive | • Group 1—control<br>• Group 2—SGS 12 hrs/d<br>• Group 3—TCA 0.1 ml/site every 4/52 | • No significant change for the control or SGS group<br>• 94% improved with TCA injections by 12/52 ($P < .05$)<br>• SGS group: 18% became softer, 6% became less red, 75% were less itchy<br>• TCA group: 70% became softer, 59% became less red, 50% were less itchy, and 60% less painful | 3 |
| Van der Wal et al 2010 | Intra individual blinded RCT | • n = 23 (13M, 10F)<br>• 46 scars postburn injury<br>• Mean age = 38 (18–69 yrs)<br>• Mean scar age = 123 (36–338 d) | • Baseline, 1, 3, 6, 12 mos<br>• POSAS, dermaspectrometer | • Group 1– SG<br>• Group 2—placebo control<br>• 2x/d<br>• mean time Tx = 263 (195–347d) | • Group 1: decreased itch at 3/12 ($P = .018$) at 6/12 ($P = .013$); decreased roughness at 3/12 ($P = .014$) relative to baseline<br>• Redness and pigmentation, no statistical difference<br>• Significant treatment effect: observer's relief scores ($P = .012$) were lower at 3/12 with SG Tx than the control | 2 |

(*Continued*)

**Table 2.** (*Continued*)

| Authors | Design | Sample | Outcome Measures | Intervention | Results | Level of Evidence |
|---|---|---|---|---|---|---|
| Widgerow et al 2009 | RCT | • n = 120 (170 scars)<br>• 18—82 yrs<br>• Group 1 (n = 60)—Sx excision assigned to Tx (n = 30) or control (n = 30)<br>• Group 2 (n = 20)—2 Sx excision sites/patients assigned to Tx or control<br>• Group 3 (n = 10)—bilateral breast Sx R & L assigned to Tx or control<br>• Group 4 (n = 30) cosmetic procedures compared to historical controls | • POSAS<br>• Homemade 4 point scar classification 1) normal, 2) mildly hypertrophic, 3) hypertrophic, 4) keloid | • Tx group—Microporous tape + NSGS<br>• Control group—Microporous tape (applied post surgically) | • Scar Classification<br>• Group 1—significantly more Tx'd scars were mild scars at 2/12 and 6/12 ($P < .0001$)<br>• Group 2—significantly more Tx'd scars were mild scars at 6/12 ($P = .006$)<br>• Group 3—significantly more Tx'd with mild scars at 2/12 ($P = .032$)<br>• Group 4—significant reduction in scar severity from 1/12–6/12<br>• POSA<br>• Group 1—stiffness ($P = .0003$) and thickness ($P < .0001$) were superior in Tx patients<br>• Group 2—stiffness ($P = .06$) and thickness ($P = .0022$) were superior in Tx patients<br>• Group 3—Tx'd scars showed significant improvement in itchiness<br>• OSAS<br>• Group 1—all parameters were significantly better in Tx group ($P < .005$)<br>• Group 2—all parameters except vascularity significantly improved in Tx group | 2 |
| Wigger-Albert et al 2009 | Intra individual RCT | n = 60 (44F, 16M)<br>Mean age = 38.2 (16–61 yrs)<br>Scar age = 49.6 (3–355 mos)<br>Etiology not specified | Baseline, 4, 8, and 12 wks<br>Primary outcome: Patient's questionnaire overall SI<br>Redness (chromameter)<br>Clinical scar assessment modified | Scar divided into two: half Tx with SGS and half Tx NSGS (polyurethane)<br>12 wks Tx<br>Remove SGS and NSGS up to 1 hr/d | SI: significantly improved at 4/52 ($P < 0.0001$) and 8/52 ($P = .012$); improvement was significantly more pronounced for polyurethane at 4/12 ($P < 0.0001$) and 8/12 ($P = .012$)<br>Redness: lower for polyurethane at 8/52 ($P = .0016$) | 2 |

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|---|---|---|---|---|---|---|
| Wittenberg et al 1999 | Intra individual RCT | n = 20 (19 scars) (15F, 5M)<br>Mean age = 49 yrs.<br>Mean scar age = 32 mos<br>Sx scars | Baseline, 8, 16, 24, 40 wks<br>Blood flow/volume (laser doppler), elasticity, punch biopsy<br>Self assessment of pain, itch, and burning<br>Scar volume | Same scar in 3 groups: SGS, laser, and control<br>SGS >12 hrs/d x 24 wks<br>Laser 4 Tx at 8 wk intervals | No difference between Tx and control groups<br>Itch ($P = .005$), burning ($P = .01$), and blood flow ($P = .001$) decreased with time<br>Scar volume: overall time effect ($P = .02$), only control showed a significant reduction from baseline to 40 wks ($P = .007$) | 2 |

*c/o*, complained of; *CO*, cohort; *Dr*, doctor; *F*, female; *HTS*, hypertrophic scars; *M*, male; *L*, left; *L/E*, lower extremity; *n*, sample size number; *NSGS*, nonsilicone gel sheets; *POSAS*, Patient and Observer Scar Assessment Scales; *R*, right; *RCT*, randomized controlled trials; *SG*, silicone gel; *SGS*, silicone gel sheets; *SI*, scar index; *Sx*, surgery; *TCA*, triamcinolone acetonide; *Tx*, treatment; *U/E*, upper extremity; *VAS*, visual analogue scale; *VSS*, Vancouver scar scale; *x/52*, number of weeks; *x/12*, number of months.

to followup, 14 developed a rash and three experienced skin breakdown. These articles received a critique rating of <5 (Table 1), but have been described due to their historic importance. The remainder of the detailed review will be restricted to reports that obtained a rating ≥5, as the validity of the conclusions of poorly rated reports is questionable.

## Burn Scar–Only Literature

There were no case series in the burn scar–only literature reviewed that received a rating ≥5. However, since 2009 there have been five RCTs that recruited exclusively burn survivors for their studies. Harte and colleagues[22] examined 22 adult burn survivors who were treated with either pressure or pressure and SGS. Using the Vancouver Scar Scale (VSS) to evaluate scar outcome, there was no difference between treatment groups at 12 or 24 weeks. A power analysis of their data revealed that 384 participants would be required before any conclusions could be drawn. Karagoz and colleagues[23] examined 32 burn survivors aged three to 44 years old. Participants were allocated to silicone gel (SG), SGS or onion extract. The VSS was used to evaluate outcome, and all groups showed significant improvements after treatment. The improvements were significantly better for the SG vs onion extract group and for the SGS vs onion extract group, but there was no difference between the SG and SGS groups. Momeni and colleagues[28] examined 38 burn survivors between the ages of 1.5 and 60 years. Participants had a HTS that was divided into two sides, one treated with SGS, the other with nonsilicone gel sheet (NSGS) (self adhesive propylene glycol and hydroxyethyl cellulose sheeting, which the authors refer to as a placebo control). The VSS was used to compare outcomes between the SGS and NSGS in terms of scar itch, pigmentation, pliability and vascularity. The VSS scores of the SGS-treated scars were significantly lower at 4 months compared to those of the NSGS-treated scars. Steinstraesser and colleagues[38] examined 38 burn survivors. Participants were randomly assigned to SG and pressure or SGS and pressure. Half of their scars also received only pressure therapy. Using the VSS as an outcome measure, the SG and pressure as well as SGS and pressure, and pressure alone improved from baseline to 18 months, but there was no difference between the groups. Using the chromameter to measure redness, an improvement was reported in SG and SGS and pressure, and pressure alone groups at 18 months, but again no difference was demonstrated between groups. Profilometry (scar surface

microtopography) was measured using the PRIMOS optical three dimensional measuring system (GFM, Berlin, Germany). Profilometry improved between two and 18 months for SG and pressure, but not for SGS and pressure or pressure alone. Pain and itch were also reduced in all groups, but there was no difference between the groups. A power analysis of their data revealed that 192 participants per group would be required before any conclusions could be drawn. Van der Wal and colleagues[39] examined 23 adult burn survivors using the Patient and Observer Scar Assessment Scale (POSAS) and a dermaspectrometer. The participants' scars were divided in half and treated with SG or a placebo control. There was a reduction in itch and roughness with time, but no change in redness and pigmentation. The observer's relief score of the POSAS did show a significantly lower score with SG treatment at 3 months, but the difference was no longer significant at 6 months.

All of the burn scar–only studies include different treatments and comparison groups; therefore, taken together it is difficult to develop confident conclusions. All of these studies used either the VSS or POSAS as their outcome measure but two also included profilometry and a colorimeter (chromameter or dermaspectrometer). Using the VSS as an outcome measure, two of the studies[23,28] reported better results with SG and SGS versus onion extract or SGS versus NSGS, but two reported no difference between the groups[22,38] when comparing pressure and pressure plus SGS or SG plus pressure and SGS plus pressure compared to pressure alone. Using profilometry, the later study did find a significant improvement with SG and pressure treatment compared to SGS and pressure or pressure alone. The final study[39] used the POSAS and dermaspectrometer and only reported significant differences on the observer's relief score at 3 months but not 6 months. Thus, the findings of these burn scar–only studies evaluating the use of gels and gel sheets are inconsistent and inconclusive.

Several issues should be taken into consideration, including the small number of participants, with 38 participants allocated to each treatment by Momeni and colleagues[28] being by far the largest number in any study (range 11–38). In fact, two of the studies performed a post hoc power analysis that determined that they were under-powered,[22,38] confirming that their results must be interpreted with caution. In addition, the VSS has been shown to be far less reliable than objective instrumentation that measures the same skin characteristics[73,74]; thus, the outcome measures used may not have been sensitive enough to detect change. These two methodological limitations both potentially contribute to the possibility of type 1 errors; therefore, it cannot be concluded that gels and gel sheets have no effect on scars. Another methodological issue that must be considered is that none of these studies had a "no-treatment control group" limiting comparison to the alternative treatment that was being investigated. Two of the studies stated that they had a placebo control,[28,39] but did not report on the occlusive properties of the products being used. Since one of the currently proposed mechanisms of action of gels and gel sheets is occlusion,[8,75] it cannot be concluded that these were true placebo controls unless the occlusive properties of these products has been objectively documented and investigated to determine whether they have a therapeutic benefit.

## Combined Burn and Nonburn Scar Etiology Literature

For the studies that included burn scars in addition to participants with scars resulting from other etiologies, there were five case series, all of which noted an improvement across time, and four out of the five received a rating of ≥5. Dockery and Nilson[52] examined 94 participants treated with SGS that were divided into five different groups (known scar formers, fresh HTS, fresh keloids, long standing scars and traumatic or burn scars). The participants were monitored for 6 months, based upon photographs and physician and participant scar assessments. Although no statistical comparison was provided, the author reported either a lack of development of scar when placed on newly healed wounds or improvement in most participants after treatment. In 1993, Hirshowitz and colleagues[59] examined a series of 32 participants treated with SGS who developed scars after surgery, trauma or burns. The authors reported that 71.9% of the participants showed moderate or excellent improvement over a 12-month period. Then in 1998, Hirshowitz and colleagues[60] examined 30 participants treated with thick silicone cushions filled with silicone oil who developed scars after surgery or burns. Alleviation of symptoms was noted after 6 months in 63.3% of the participants, with the remainder being reported as having recalcitrant scars. Lee and colleagues[63] reported on 26 participants who were treated with two different types of SGS, with improvements being reported in both groups for color and texture (90%), regularity (80%), and thickness (50%).

An intra individual cohort study reported by Ahn and colleagues in 1991 included participants who developed scars after burns, surgery and spider bites. There were two groups of participants

who had either a recent surgical excision or existing HTS. The sites were divided in half, with half being treated with SGS and half receiving no treatment. For the recent surgical excision group, the no treatment control site significantly increased in volume at months 1 and 2, but the treatment site did not. The HTS sites did not reduce in volume but elasticity did improve, both with time and compared to the no treatment control, as measured by the elastometer. Boutli-Kasapidou and colleagues[44] examined 30 participants in a cohort study that had either HTS or keloids, but the authors never indicated the proportion of each and throughout the article referred to all as keloids, who received either polytherapy (cryotherapy, intralesional cortisone, SG) or SGS. The results of both the participants' level of satisfaction and the physician's assessment saw significantly greater improvement in the polytherapy group. The authors also reported significantly better improvement in less mature keloids.

Of the four RCTs that combined burn and nonburn scar etiology, one was an intra individual study[17] and the others randomly assigned participants to different groups.[25,26,30] The intra individual study by Carney and colleagues included two groups that were treated with two different SGS and a randomly assigned control site that did not receive any treatment.[17] Using an extensometer and subjective evaluation, improvements in extensibility, color and texture were significantly greater in both groups compared to their no treatment control site, but there was no significant difference between the two different SGS. Li-Tsang and colleagues[25] conducted an RCT examining the effect of SGS plus massage compared to only massage in 45 participants who developed scars after traumatic or burn injuries. The SGS plus massage treatment group showed significantly greater reductions in thickness and increases in pliability after 6 months compared to the massage only group when assessed with the tissue ultrasound palpation system and VSS respectively. There was no significant difference in itch, pain, or color. In 2010, Li-Tsang and colleagues randomly assigned 104 participants to four different groups (pressure garments, SGS, pressure garments and SGS, and no treatment control). The evaluation results at 6 months included 84 participants and demonstrated a significant improvement in thickness with pressure garments alone or pressure garments and SGS, compared to no treatment control. The pressure garment and SGS group was significantly more pliable than the no-treatment control at 2 and 4 months, but by 6 months pliability had improved for all groups compared to baseline and there was no significant difference between the groups. Pain significantly improved in the SGS and pressure garments and SGS group compared to the no treatment control group. Pigmentation significantly improved with time for all the groups, but the improvement did not differ between the groups. Palmieri and colleagues[30] randomly assigned 80 participants to treatment with SGS plus vitamin E or SGS alone. Participants were evaluated at 4 and 8 weeks using photographs to assess color, size and cosmetic appearance that revealed a significantly greater percentage of participants rated as improved when treated with SGS plus vitamin E.

As a group, the RCTs that included combined burn and nonburn scar etiology were more likely to find a positive effect with SGS than the comparison treatment. Three of the four studies had a no treatment control group, with the fourth comparing SGS to SGS plus vitamin E, where the latter had significantly better results. Three of these studies used objective instrumentation (extensometer, tissue ultrasound palpation system and spectrometer) in addition to subjective outcome measures.

## Nonburn or Unspecified Scar Literature

Of the case series that did not include burn scars or did not specify the etiology of the condition that preceded the scar formation, five received a rating of ≥5.[53,56,62,65,71] Eishi and colleagues[53] treated six participants' scars with SGS for 6 months. Pain and itch were significantly reduced at 4 weeks and had disappeared by 12 weeks. Redness and elevation were significantly reduced by 8 weeks, with a further reduction in redness at 6 months. Gold[56] reported moderate improvement in thickness (81.25%), color (75%), and overall effectiveness (100%) when he evaluated 10 participants who were treated with SGS over a 3-month period. Physician's evaluation of outcome reported complete resolution in a small percentage (6.25%) or moderate change in thickness (50%), color (68.75%), and overall effectiveness (93.75%). Lacarrubba and colleagues[62] examined eight participants treated with SG and reported a 37% reduction in the mean thickness of scars, using high frequency ultrasound as an evaluation tool. Murison and James[65] evaluated six participants treated with SG, which they evaluated using a modified VSS and spectrophotometric intracutaneous scope (SIS). All participants improved on the VSS and showed a 7.2% reduction in collagen and 3% increase in blood flow with the SIS. Spencer[71] reported on seven participants who had SG applied to half of their post surgical excision while the other half received no treatment. After 3 months of treatment, the SG treated half was rated as better by the

physician in five of the seven excision scars and using the VSS, four out of seven were rated better.

There were four cohort studies, three of which were intra individual. Chernoff and colleagues[44] assigned participants with bilateral scars to one of the three treatment groups; 1) SG 2X/day; 2) SGS day and night; or 3) SG (day) and SGS (night) with their bilateral scar serving as an untreated control scar. After 90 treatment days, all the three treatment groups were significantly less elevated, red, itchy, and irritated in the SG and SGS group than the untreated control. Participants rated SG as easier to apply and combined SG and SGS as producing the most favorable outcome. Cruz-Korchin[45] examined 20 participants after bilateral mammoplasty where one side was treated with SGS and the other was an untreated control. Six months post surgery, HTS were found in 25% of the treated breasts and 55% of the untreated breasts. Hosnuter and colleagues[46] assigned 60 participants to three treatment groups: topical onion extract, SG, or SGS plus topical onion extract. Improvement was reported over time for all the groups, with significantly more color reduction reported with topical onion extract compared to SG and significantly greater height reduction with SGS plus topical onion extract compared to topical onion extract alone. Tan and colleagues[47] reported the outcome of 17 participants with three keloids each who were assigned to SGS treatment, triamcinolone acetonide (TCA) injections, or no treatment. Statistically significant improvements were seen after 12 weeks of TCA injections, but not in the SGS-treated keloids or the untreated keloids.

There were 18 RCTs reviewed that included nonburn and unspecified scar etiology, all of which received a rating of ≥5. Berman and Flores[17] reported on 22 participants treated with either a silicone gel-filled cushion or SGS. There was no significant difference between the groups. Chan and colleagues[18] reported an intra individual trial where the upper and lower portions of the scar of 50 participants were randomly allocated to SG or NSG. The SG group was significantly better for all subscales of the VSS after 3 months of treatment. De Giorgi and colleagues[19] reported on 110 participants who had recently undergone surgery and were assigned to apply either SG with zinc oxide or zinc oxide cream alone to their excision site after staple removal. There were significantly fewer participants who developed abnormal scar in the SG group (27% vs 55%) during the 8-month followup period. De Oliveira and colleagues[20] reported on 26 participants with 41 scars. One scar was treated with SGS and a second with NSGS. If the participant had more than two scars, then the third served as an untreated control scar. There was no significant difference between the SGS and NSGS treated scars with respect to length, width, color, itch, pain, induration, and intracicatricial pressure, but when compared to the untreated control there were significant differences for length, width, color, induration, and pressure. Gold and colleagues[21] reported on 96 participants who were stratified into low risk (n = 50) and high risk (n = 46) participants who were treated with SGS or routine postoperative care. There was no statistically significant difference for either low or high risk groups, although participants who were undergoing scar revision surgery had an increased rate of scar prevention. Klopp and colleagues[24] reported on an intra individual RCT where 12 participants' scars were treated with NSGS, NSGS plus pressure, pressure, and SGS plus pressure. Vessel length, venular flow rate, erythrocyte, and aggregate number were all evaluated using vital microscopic methods in addition to the skin temperature and surface roughness. The authors reported that all the measured characteristics significantly improved in all groups at $P < .05$. The improvement seen with SGS and NSGS plus pressure was substantially greater than that for NSGS or pressure alone. Majan[27] reported on 12 participants whose post surgical scars were randomly assigned to SGS or no treatment. Although the authors presented positive VSS results and physicians' overall impressions, no statistical comparisons were included. Niessen and colleagues[29] randomly assigned 155 women who had undergone breast reductions to two different types of SGS. Each group had one side treated with the SGS and the other side an untreated control. The authors reported the percentage of participants who developed HTS, but it was unclear whether this was on the treatment or control side, or both. There was no difference in the outcome between the two different SGS treated sites, but there were significantly more HTS that formed on the SGS treated side than on the untreated control side. Perez and colleagues[31] randomly assigned 30 participants to one of three treatments (TCA, SGS and vitamin E, onion extract gel, or placebo control). Fifteen of the participants completed the 16-week treatment period, five in each group. All the three groups significantly improved with time, as described in Table 2. When the treatment groups were compared to the placebo control, the investigator's cosmetic evaluation, induration and pigmentation showed significantly more improvement for both the groups, as well as erythema for group 1 and tenderness for group 2. Phillips and colleagues[32] randomly assigned 20 participants to NSGS treatment

or control moisturizer for 8 weeks. There was no significant difference between treatment groups, but both the groups reported a significant reduction with itching over time. Rhee and colleagues[33] randomly assigned 40 participants to SGS or untreated control groups after scar revision and mass excision surgeries. At 1 month, the SGS treated scars were significantly decreased in height compared to the untreated control scars. Pigmentation and vascularity were also reduced in the SGS treated participants at 3 months. Scuderi and colleagues[34] had two groups of participants. The first group received treatment with NSG, with improvement reported for 89.7% of the participants based on a global scar assessment. The second group had a linear scar, with half being treated with a SG and half treated with a NSG. Both treatments resulted in reduced scar elevation at 1 month and 1 year. Scuderi and colleagues[35] recruited 85 participants who underwent bilateral mammoplasties and randomly assigned each breast to NSG or SG. In both the groups, scar elevation, as measured by optical profilometry, increased from baseline to 1 month but reduced from 1 month to 1 year. The scar width increased across time for both the groups, but was significantly less in the NSG-treated group. Signorini and Chementontit[36] randomly assigned 148 participants with recent surgical scars to either SG treatment or to an untreated control group. At 6 months, post treatment scars were classified as normal, mildly hypertrophic, hypertrophic, or keloids. Significantly more incisions were classified normal when treated with SG than the untreated control. Sproat and colleagues[37] performed an intra individual RCT with 14 participants who had sternal scars post sternotomy. Half of the scar was treated with SGS and half with TCA. Significantly more participants favored the SGS treated half and 82% of the blinded evaluators preferred the SGS treated portion based upon photographic assessments. Widgerow and colleagues[40] evaluated 120 participants who were divided into four groups: 1) n = 60 participants post surgical incisions, with half of their surgical scar assigned to treatment with NSGS plus microporous tape and half assigned to the control group which was treated with microporous tape only; 2) n = 20 participants with two surgical sites, one assigned to the treatment group and the other to the control group; 3) n = 10 participants post bilateral breast surgery, each assigned to treatment or control; and 4) n = 30 participants who received treatment and compared to historic controls. Using the POSAS, scars were graded as normal, mildly hypertrophic, hypertrophic, or keloids. At 2 and 6 months, the treated scars in group 1 were significantly more likely to be graded as mildly hypertrophic. They were also less thick and stiff. At 6 months, the treated incision scar in group 2 was more likely to be graded as mildly hypertrophic and was less stiff and thick. At 2 months, the breasts in group 3 that received treatment were more likely to be graded as mildly hypertrophic and less itchy. In group 4, there was a significant reduction in scar severity compared to historic controls. Wigger-Albert and colleagues[41] reported on 60 participants who received SGS treatment to half of their scar and NSGS to the other half for 12 weeks. Using a homemade patient scar index questionnaire, both scars significantly improved at 4 and 8 weeks, but to a greater extent for the NSGS-treated scars. Redness, as assessed by the chromameter, was also significantly less at 8 weeks in the NSGS treated group. Wittenberg and colleagues[42] reported on 20 participants whose scars were divided into three sections that were treated with SGS, laser, and untreated controls. There was no difference between the treatment and control scars except for scar volume, which showed a significant reduction with time in the control group after 40 weeks. Itching, burning sensation, and blood flow significantly reduced in all groups over time.

Of the RCTs that included nonburn or unspecified scars, the majority (14 out of 18) reported a positive treatment effect, although the comparison groups were variable including NSG, NSGS, zinc oxide, TCA, laser, or untreated controls. None of the studies reported whether they performed a power analysis, including those studies that had a negative effect[17,29,32,42]; therefore, it is not possible to determine whether their sample size was too small to detect an effect, potentially resulting in a type 1 error. Seven of the RCTs applied gels or gel sheets to newly healed incisions and all but one[29] reported less scar formation with the application of SG, SGS, or NSGS[18,19,21,33,36,40] compared to controls, but no difference when NSG was compared to SG.[35] Ten of the RCTs applied gels or gel sheets to established scars.[17,18,20,24,31,32,34,37,41,42] Three of these studies did not find an effect, but Berman and Flores[17] compared SGS to silicone cushions and Phillips and colleagues[32] and Wittenberg and colleagues[42] only included 20 and 19 scars respectively, in their analysis. Of the remaining seven studies, all found a positive treatment effect using SG,[18,20,34] NSG,[20,34] SGS,[24,37] NSGS[24,41] or SGS in combination with Vitamin E and TCA.[31]

## Rehabilitation-Specific Treatment Information

The rehabilitation-specific information within citations was usually limited, but those that did provide

information made the following recommendations. The gel sheet or gel should extend approximately 5 mm beyond the scar margins, should be applied for several hours the first day and then increased by two-hour increments every other day until the patient is able to wear it for up to 23 hours/day. It should be taken off daily and gently washed in clear water with a hypoallergenic soap and air dried or patted dry with a lint free cloth. The description of how the gel sheets were held in place was very variable, including skin tape (ie, Hypafix™/Fixumull®), Tubigrip®, custom fabricated pressure garments, self adherent properties of gel sheet, etc., with no apparent consensus or formal evaluation of which method was most advantageous.

Not all publications reported on whether any adverse events occurred, but those reported included skin reactions, dermatitis, itch, or skin breakdown. These issues occurred with both SGS and NSGS.[16,17,23,27,29,32–35,37,38,45,46,48,52,55,58,61–64,69] Gels or gel sheets are contraindicated if a patient has a known allergy, but since different products contain different ingredients, individual products may be well tolerated by some individuals and not others. Interestingly, a number of studies also reported a reduction in itching and/or pain,[18,19,26,31,32,37–40,44,46–48,53,60,70] suggesting that these symptoms may actually improve with gel or gel sheet treatment. If an adverse skin reaction does occur, the gel sheet should be discontinued until complete recovery has occurred. When reinitiated, this process should progress more slowly and particular attention should be paid to skin hygiene. If the skin reaction reoccurs, the gel sheet should again be discontinued until complete recovery, but when it is reinitiated the maximum wearing time should be limited to 12 hours/day (Figure 2). The gel sheet should be replaced when it begins to fray or becomes difficult to handle. It should be noted that gels and gel sheets may constitute a choking hazard for small children; therefore they should only be applied if the child is unable to gain access to them.

The study that was removed after full review due to the fact that it did not address the authors' PICO question did examine the effect of patient education on compliance/adherence.[15] The authors reported that participants who viewed a 26-minute instructional video tape, in addition to standard verbal and written instructions (a one-page handout), wore their SGS for more than twice as long as the participants who only received standard verbal and written instructions (21.8 ± 3.0 hours/day vs 10.1 ± 7.5 hours/day). They also reported that participants who had enhanced patient education had improved outcomes on the VSS and subjective participant evaluations, suggesting that thorough education should be included as part of the rehabilitation intervention plan.

The majority of studies that applied SG had the participants apply the products 2x/day[18,19,23,30,34,35,39,44,62,65,67,71]; however, one study[44] had the participants apply it 3x/day. One study examined the application of SG during the day and SGS during the night[44]; thus the participants were asked to apply it only once per day. The one group that reported on NSG had the participants apply three layers every three to five days. No adverse reactions were reported for the SG, but they were reported for the NSG.[34,35] The authors reported that incorrect application occurred when excessive quantities were applied and that reinstruction on correct application of the product resulted in improved participant comfort in applying the product.[35]

It must be emphasized that gel or gel sheet product prescription requires proper clinician followup and good clinical judgment when evaluating the wearing schedule and management of any adverse events.

## DISCUSSION

The objective of the review was to systematically evaluate the available evidence for the use of gels and gel sheets for the treatment of hypertrophic scars and keloids that occur after burn injury. Unfortunately, the number of studies and quality of evidence specifically focusing on burn survivors is lacking; thus, the decision was made to include all patient populations to strengthen the conclusions and recommendations. Confident conclusions cannot be drawn from the literature that restricted recruitment to burn survivors, since level one data does not exist and findings from the RCTs were inconsistent. The inconsistency of the findings may be a result of methodological limitations of the studies and/or the fact that they were underpowered.

In total, there were 23 case series reviewed, with the vast majority reporting a positive effect. It is difficult, however, to conclude that this constitutes a real treatment effect, since HTS is well known to spontaneously improve with time. It has been recommended by a panel of experts that in order to provide proof of efficacy of therapies intended to prevent or reduce scar formation, intra individual or self controlled RCT designs should be used where the treatment and control sites are anatomically matched.[76] Of the 27 RCTs reviewed, the vast majority reported positive results, but comparison between studies is

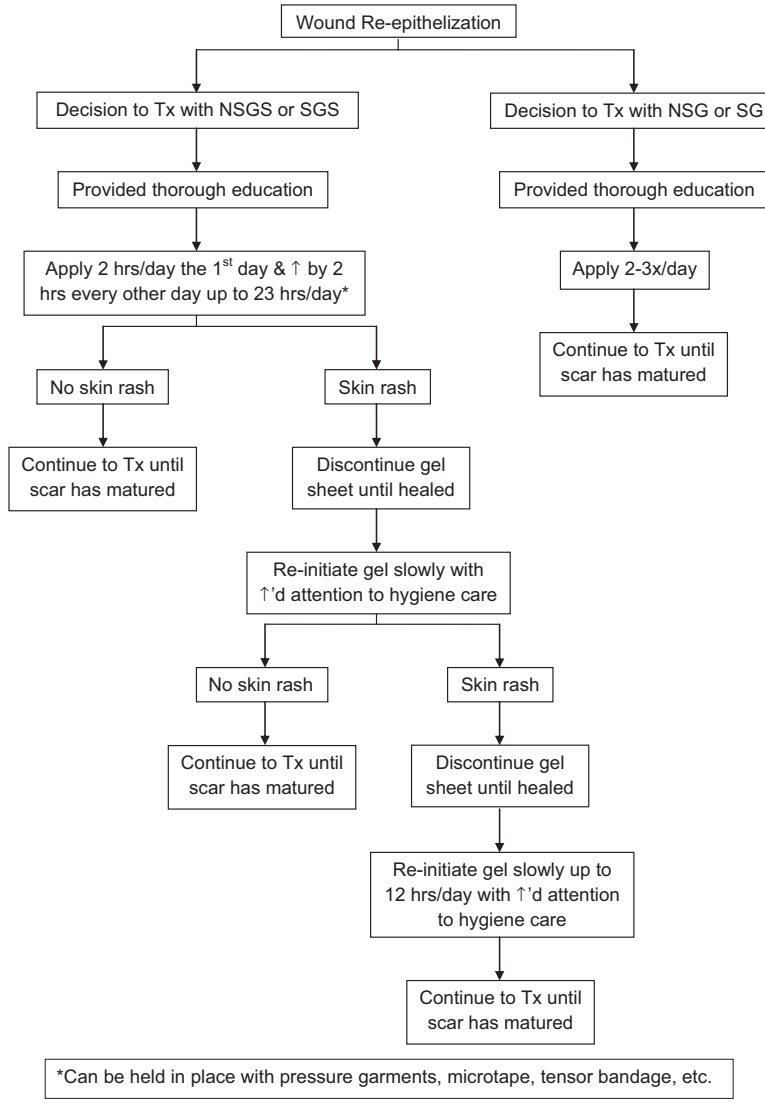


**Figure 2.** Expert opinion and evidence based rehabilitation specific algorithm for postburn scar treatment with nonsilicone or silicone gels and gel sheets. NSGS, nonsilicone gel sheet; SGS, silicone gel sheet; Tx, treat; ↑, increase.

difficult since many studies were making comparisons to other treatments rather than to a no treatment control. Therefore, if their data confirmed that the gels or gel sheets were as effective as the comparison treatment and resulted in a significant change over time that does not rule out the possibility that the improvement could be due to spontaneous resolution. If only those RCTs that recruited exclusively burn survivors are summarized, no conclusions about treatment benefit can be drawn, but the methodological limitations of these studies, as described above, must be considered. There does seem to be some evidence that pathological scar formation can be prevented in fresh surgical wounds, but this finding has not been investigated in burn survivors. A number of studies have reported including participants with keloids,[16,20,21,30–32,43,44,46,50,51,54,55,63,67,68] but did not report diagnostic details for their classification or whether these participants responded in a similar manner to the other participants. Three case series included only participants with keloids,[53,64,66] all of which reported a positive treatment effect, but two received a rating of <5 on the critical appraisal.[64,66] One study reported itch reduction with SGS,[47] but described superior outcomes after TCA injections. Only one study[58] reported treating mature scars and showed no treatment benefit.

Many of the reports, both in the burn scar–only literature and other populations, continue to use subjective or home made scar evaluations to determine if there is a treatment effect. There has been extensive discussion in the literature recently about

the clinimetric properties of scar assessment tools.[76–80] It is imperative that any subjective scar scales used for scar evaluation be published tools that have well established clinimetric properties, so that study findings can be repeated by other investigators and comparisons can be made between the studies. Objective measurement tools have been recognized as the accepted standard for the assessment of skin characteristics,[73,74,80] while recognizing that the patient's opinion of their scar should also be evaluated.[77–79]

There is a need for methodologically rigorous studies that only include scars that form after a burn injury, so confident conclusions can be drawn about whether burn survivors' scars benefit from the application of gels or gel sheets. Future studies would allow for stronger conclusions if they addressed the limitations in the current literature. An appropriate a priori power analysis should be performed to determine the sample size that would be required to avoid a type 1 error. Post hoc analyses performed in two separate investigations[22,38] concluded that 192 participants per group would be required when using the VSS as an outcome measure, but this analysis would need to be repeated if a different outcome measure was used. Objective instrumentation should be used to evaluate scar characteristics such as thickness, pliability, vascularity, and profile or contour, in addition to patient opinions about the benefits of treatment. Intra individual and no treatment controls should be included to limit the intra individual variations associated with scar formation and treatment response, as well as spontaneous resolution over time. The question of whether scarring after a burn injury can be prevented has yet to be addressed. This would require that contralateral or anatomically adjacent wounds with the same injury and recovery profile be compared across time, which would be difficult due to the traumatic and unpredictable nature of burn injury; however, this would make an important contribution to the literature. Laser doppler imaging to determine the depth of the burn may help to select comparable wounds and has been correlated with longterm scar outcomes.[81] In order to recruit sufficient participant numbers and increase the generalizability of the results, multicentre trials using clinimetrically sound subjective and objective scar assessment tools are strongly recommended.

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## **Appendix 1.** Search strategy.

1. Silicone gels/
2. Silicone elastomers/
3. Silicon*.tw.
4. (gels or gel).tw.
5. Cica care.tw.
6. Or/1–5
7. Cicatrix, hypertrophic/
8. (hypertrophic adj3 scar*).tw.
9. Hypertrophic cicatrices.tw.
10. Hypertrophic cicatrix.tw.
11. Or/7–10
12. 6 and 11
13. Cicatrix, hypertrophic/th
14. Limit 13 to "review"
15. 12 or 14