REVIEW OF THE CLINICAL EFFICACY OF

SILICONE GEL SHEETING AND SILICONE GEL

IN THE PREVENTION AND TREATMENT OF SCARS

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KELO-COTE®
SCAR TREATMENT

For the management of old and new hypertrophic and keloid scars resulting from general surgical procedures, trauma, wounds and burns.

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Objective: To compile a literature review of the clinical efficacy of silicone-based therapy (sheeting and gel) in the prevention and treatment of scars.

Methods:

Silicone gel sheeting- and silicone gel clinical studies were identified from several sources, with an emphasis on citations in authoritative publications as opposed to a broad, computerised search of databases such as PubMed, Ovid or the Cochrane Library. Sources included: International Guidelines [1-5], Systematic Reviews [6-9], internal Medical Information searches and existing materials. Duplicate results were removed from the search and the remaining publications were summarised in a format adopted by Nedelec et al [5] and Mustoe [6]. Clinical studies are presented chronologically in publication-date order (irrespective of study type) and additionally classified as 'Prevention' (**P**) or 'Treatment' (**T**). Where a critical appraisal of the study had been recently performed [5], the Level of Evidence provided by the study was included, according to published criteria [10] (see Table 3).

Results:

Silicone gel sheeting has been used effectively in scar management since the 1980s. However, the sheeting cannot be used near joints, on large anatomical areas, and on areas in which skin is difficult to cover due to its motility or contours. If the sheets are taped to the skin, patients often fail to comply, especially on unclothed areas. Patients must also wash the sheets regularly to prevent infection or rashes. Silicone gel has been studied extensively and shown to be as effective as silicone gel sheeting in managing abnormal scars without side effects. When applied correctly, silicone gel dries quickly and forms a nearly invisible sheet. Another advantage is that silicone gel can be applied under facial makeup to hide scars.

Conclusion:

An algorithm for hypertrophic and keloid scar prevention and management has been developed by an international advisory panel and was recently updated [3]. According to this algorithm, silicone-based products are preferred and currently recommended as the first-line option for preventing and treating excessive scarring after surgery or trauma [3,4]. The efficacy and safety of this gold-standard therapy has been demonstrated in many clinical studies. Indeed, of the non-invasive options, silicone sheets and silicone gels are the only preventive and therapeutic measure for which there is enough supporting data to make evidence-based recommendations. When clinicians have a choice of silicone-based products for scar management, the most appropriate management modality should be arrived at by focusing on each patient's scar location, lifestyle and likelihood of compliance throughout the scar prevention- or treatment process.

N.B.: Some of the publications reviewed make reference to off-label use of medicines. This is for information only and is not intended to be promotional.

Table 1. Studies on the efficacy of silicone gel sheeting in scar management.
(N.B.: for a list of abbreviations, please refer to the legend at end of the table)

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Ahn et al., 1989; prospective, within-subject, controlled trial; (**T**)	• n = 10 • 14 HTS	• Tx = SGS applied for 8/52 for at least 12hrs/d • Control = intra-individual, untreated, mirror-image or adjacent scars	• Baseline, 4, 8, 12 wks • Photographs • Biopsy specimens • Elastometer (before/after Tx) • Photography and elastometry repeated 4/52 after Tx end	• All scars Tx for at least 12 hrs/d showed clinical improvement at 4/52 • Elastrometrically, Tx scars improved vs. their baseline and vs. control at 4, 8 and 12 wks ($P < 0.05$); control scars remained unchanged • SGS well tolerated with occasional transient rash or superficial maceration	[11]
Ahn et al., 1991; prospective, randomised, within-subject, Cohort Study; (**P + T**); Level of Evidence 3	• n = 48 • Group 1 = 29 Sx scars, all but two <40 yrs, n = 10 were lost to follow-up • Group 2 = 19 HTS, age range 3–78 yrs, burns, Sx scars, spider bite	• Tx = SGS secured with adhesive tape and worn >12 hrs/d • Control = no treatment • Group 1—half of the surgical excision assigned to Tx or control • Group 2—half of the surface area of HTS assigned to Tx or control	• Baseline, 1 and 2/12 • Scar volume • Photograph • Elastometer • Homemade global scar assessment	• Increased scar volume of Sx scars at control sites (1/12 $P = 0.03$; 2/12 $P = 0.003$) • No statistically significant reduction in scar volume of HTS • Increased scar elasticity in Tx'd HTS compared to baseline at 1/12 ($P = 0.019$) and 2/12 ($P = 0.0001$) and compared to the control (1/12, $P = 0.005$; 2/12, $P = 0.0001$) • HTS elasticity treatment effect plateaued at 2/12	[12]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Sproat et al., 1992; prospective, investigator-masked, within-subject, RCT; (**T**); Level of Evidence 2	• n = 14 • Mean age = 41–81 yrs • Scar age: 4 mos–3 yrs • Post sternotomy scars	• Scar divided into two: half Tx with SGS 12 hrs/d x 12/52, other half Tx with TCA injection 40 mg/mL	• Photographs, length, width, height, blinded assessment • VAS for pain Injection	• 11/14 patients favoured SGS ($P < 0.05$) • 82% of the blinded observers preferred SGS results • Pain with injection = 6.7 ± 3.0 VAS • Symptomatic complaints improved with SGS 2.9 ± 1.44 d sooner than TCA ($P < 0.05$) • Scar height decreases with both Tx • Side effects: 64% with TCA, 1% with SGS	[13]
Carney et al., 1994; prospective, intra-individual RCT; (T); Level of Evidence 2	• n = 42 • Mean 23.2 (2–60 yrs) • 92% burns	• Group 1—SGS (Silastic) and control (intraindividual) • Group 2—SGS (Cica-Care) and control (intraindividual) • Group 1 and 2—worn as much as possible	• Extensometer • Homemade evaluation (colour, texture, general condition, patients' opinion)	• Group 1—improvement was significantly greater in Tx'd vs. control at 2/12 (extensibility $P < 0.0001$; colour $P = 0.005$; texture $P = 0.001$) and 6/12 (extensibility $P < 0.03$; texture $P = 0.012$) • Group 2—improvement was significantly greater in Tx'd vs. control at 1/12 (extensibility $P < 0.03$), 2/12 (extensibility $P < 0.001$; colour $P = 0.008$; texture $P = 0.001$) and 6/12 (extensibility $P < 0.04$; colour $P = 0.007$; texture $P = 0.002$) • Adverse reactions: pruritus, skin irritation • No statistical difference between the Groups	[14]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Gold, 1994; controlled Case Series study; (**P + T**); Level of Evidence 4	• n = 34 (n = 21 group 1; n = 8 group 2; n = 5 group 3) • Sx and burn	• SGS >12 hrs/d × 12 wks • Group 1—17 HTS, 4 keloids where half of the scar was Tx'd, half of the scar was control • Group 2—Sx site was treated after removal of keloid • Group 3—HTS from burn	• Baseline, 1, 2 3 mos • Evaluated by Dr and patient (thickness, colour, overall effectiveness; 0 - no change and 3 – complete resolution)	• No statistical comparisons provided • Group 1—scar thickness moderate reduction: Patient = 33.3%, physician = 47.6%; Colour change moderate: Patient = 19.1%, Dr = 42.9%; Overall moderate effectiveness: Patient = 23.8%, Dr = 52.3% • Group 2—1 treated site resulted in recurrent keloid • Group 3—4 of 5 minimal change; one moderate	[15]
Katz, 1995; Case Series study; (**T**); Level of Evidence 4	• n = 34 (36 chronic scars >3 mos) • n = 14 (14 fresh scars <3 mos)	• SGS >12 hrs/d × 2 mos	• Baseline, 2, 6 mos • Dr and patient assessed redness, elevation based on photographs	• No statistical comparisons provided • 20/36 Chronic scars improved after Tx • 11/14 Fresh scar—no HTS developed after 6 mos • Dermatitis occurred with three patients	[16]
Fulton, 1995; Case Series study; (**P + T**); Level of Evidence 4	• n = 20 • HTS or keloids after skin trauma or fresh Sx scars	• SGS 12–24 hrs/d × 8–12 wks • Tx and control scars • Intralesional TCA injection in persistent cases (7/20)	• Baseline, 1, 2, 4, 6 mos • Evaluated by patient and Dr. (texture, colour, thickness, and pruritus) • Photographs • Punch biopsy for silica content	• No statistical comparisons provided • 85% softened or resolved HTS (17/20) • no silica content difference in SGS and Control	[17]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Palmieri et al., 1995; RCT; (**T**); Level of Evidence 2	• n = 80 • 18–63 yrs • Scar age: 3 mos–2 yrs post-injury • HTS or keloids post-trauma or burns	• Group A—SGS + vitamin E • Group B—SGS • Worn between 10 pm & 8 am	• Evaluation at 4 and 8 wks • Photographs for colour, size and cosmetic appearance • Itch, pain	• At 4/12 Group A 85% improved by more than 50% and Group B 55% ($P < 0.01$) • At 8/12 Group A 95% improvement by more than 50% and Group B 75% ($P < 0.05$)	[18]
Lee et al., 1996; Case Series; (**T**); Level of Evidence 4	• n = 26 participants (15F, 11M) with 45 scars • Mean age 26 (3–52 yrs) • Scars <6/12 old • Burns, operative scars, tattoo scars, keloids	• Group 1—SGS (Sil-K) • Group 2—SGS (Epiderm) • Held in place with adhesive strip, tubigrip or bandage • 6/12 Tx	• Baseline, monthly for 6 mos • 3-point scale (0 = worse, 1 = remained the same, 2 = improved) for colour, texture, thickness, and regularity	• No statistical comparisons provided • Improvement reported in both the groups (90% improvement in colour and texture, 80% improvement in regularity, 50% improvement in thickness) • Some patients complained of itch and Maceration	[19]
Cruz-Korchin, 1996; prospective, within-subject, Cohort Study; (**P**); Level of Evidence 3	• n = 20 • Bilateral mammoplasty 14 d post-operatively	• Bilateral breasts: one control, one Tx • SGS postoperative day 14, 12 hrs/d × 2/12	• Baseline, 1, 2, and 6 mos • Appearance (raised Vs. flat) • Photography • Observation	• At 2/12—25% of treated breasts were hypertrophic, 60% of nontreated were hypertrophic ($P < 0.05$) • At 6/12—25% of treated breasts were hypertrophic, 55% of nontreated were hypertrophic ($P < 0.05$) • Skin irritation in two patients	[20]

Study (author, year, design)	Subjects/ numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Niessen et al., 1998: prospective, within-subject, RCT; (**P**); Level of Evidence 2	• n = 155 (100% F) • Mean age = 31 (14–69 yrs) • Breast reduction Sx scars	• Group 1—SGS (Sil-K) (n = 80) • Group 2—SGS (Epiderm) (n = 75) • Group 1 and 2 were randomly assigned to left lateral and right medial or left medial and right lateral with the remainder as control • Tx initiated 3 d post-operatively, 24 hrs/d × 3 mos • SGS applied with stretch tension and fixed with micropore • Control—micropore only	• Baseline, 1, 2, 4, 6 mos • Thickness (ultrasound) • Blood flow (laser doppler) • Colour (chromameter) • Pain (VAS) • Itch (VAS) • Punch biopsy, ruler	• 119 participants completed the study • Developed HTS: 64.3% at 3 mos, 56.6% at 6 mos, 35.3% at 12 mos • Occurrence of HTS increases with ease of tanning ($P < 0.02$) • No difference between 2 silicone Tx'd sites • Increased HTS at Tx sites relative to control: at 6 mos ($P = 0.006$); at 12 mos ($P = 0.02$) • Several patients developed skin irritation	[21]
Tan et al., 1999; controlled intra-individual Cohort Study; (**T**); Level of Evidence 3	• n = 17 (3 scars/ subject) • Age: 19–40 yrs • Keloids • Acne and spontaneous	• Group 1—control • Group 2—SGS 12 hrs/d • Group 3—TCA 0.1 mL/site every 4/52	• Baseline, 4, 8, 12/52 • Length, width, height of keloids • Colour, texture • Pain/itch • Responsive or non-responsive	• No significant change for the control or SGS group • 94% improved with TCA injections by 12/52 ($P < 0.05$) • SGS group: 18% became softer, 6% became less red, 75% were less itchy • TCA group: 70% became softer, 59% became less red, 50% were less itchy, and 60% less painful	[22]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Wittenberg et al., 1999; intra-individual RCT; (**T**); Level of Evidence 2	• n = 20 (19 scars) • (15F, 5M) • Mean age = 49 yrs. • Mean scar age = 32 mos • Sx scars	• Same scar in 3 groups: SGS, laser, and control • SGS >12 hrs/d x 24 wks • Laser 4 Tx at 8 wk intervals	• Baseline, 8, 16, 24, 40 wks • Blood flow/volume (laser doppler), elasticity, punch biopsy • Self-assessment of pain, itch, and burning • Scar volume	• No difference between Tx and control groups • Itch (P = 0.005), burning (P = 0.01), and blood flow (P = 0.001) decreased with time • Scar volume: overall time effect (P = 0.02), only control showed a significant reduction from baseline to 40 wks (P = 0.007)	[23]
Borgognoni et al., 2000; prospective, parallel-group, controlled, comparison study; (**T**)	• n = 20 • Recurring keloids • Sx excision	• Group 1 - SGS • Group 2 – no Tx • Tx 3 mos	• Scar height: • Flat = no recurrence; • Height < 50% of excised keloid = partial recurrence; • Height > 50% of excised keloid = recurrence	• Group 1 patients had a reduced incidence of keloid recurrence vs. Group 2 patients	[24]
Paquet et al., 2001; controlled clinical trial; (**T**)	• n = 11 • Keloid scars	• Tx = 585 nm flashlamp-pumped pulsed-dye laser (1-3 Tx sessions) • Control = 9 keloids covered by SGS	• Clinical assessment • Remittance spectroscopy (redness, pigmentation)	• Clinical report of redness decrease in Tx group not confirmed spectrophotometrically • Redness of keloids not improved in control group • Side effects were not disclosed	[25]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
de Oliveira et al., 2001; prospective, intra-individual RCT; (**T**); Level of Evidence 2	• n = 26 (41 HTS and keloids) • 15–53 yrs • Scars >3 mos old • Acne, Sx, spontaneous, trauma, earring, infected wound, herpes	• 2 scars Tx'd same patient: 1 SGS, 1 NSGS • Untreated control scar if more than two scars • Wear 24 hrs/d × 4.5 mos	• Baseline, 30, 60, 90, 120, 135 d • Pain, itch (relief vs. no relief) • Induration • Linear measure • Colour • Intracicatricial pressure (only measured at 135 d)	• No difference in linear measures SG and NSG (length P = 0.5247; width P = 0.3354) • No difference SG vs NSG for colour, itch, pain, induration, and intracicatricial pressure • Significant when compared to control (length P = 0.0139; width P = 0.0011; colour P < 0.001; induration P < 0.0001; intracicatricial pressure = 0.0152)	[26]
Gold et al., 2001; prospective, RCT; (**P**); Level of Evidence 2	• n = 96 • Stratified into low risk (n = 50) and high risk (n = 46) • Mean 38.5 yrs (low risk); 34.8 yrs (high risk) • Removal of skin lesions (benign and malignant tumours, sebaceous cysts, HTS, keloids)	• Tx group—SGS (12–24hrs/d applied 48 hrs/post-surgery, sutures/staples removed 7–14 d) • Control group—routine post-operative care • 6/12 Tx	• 2, 4, 8, 12, 16, 20, 24/52 post-Sx • Physician observation • Patient's opinion (discomfort, embarrassment, colour height, texture, function) • Photographic assessment • No details provided about any of the scales	• Low risk group—no difference between the treatment and control • High risk group—reduction in percentage who developed HTS or keloid (P = 0.072) but not statistically significant • Individuals undergoing scar revision surgery—Increased rate of prevention (P = 0.035) (n = 4 Tx group vs. n = 10 control)	[27]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
So et al., 2003; prospective, assessor-blinded; RCT; (**T**)	• n = 28 outpatients (25 completers, 7F, 18M) • CEG group mean age 38 (19-57 yrs) • EEG group mean age 47 (31-61 yrs) P = 0.03 • HTS burn scars but not on face	• CEG group-routine instruction + SGS (Cica-Care) • EEG group-routine instruction + education package + SGS • Wear SGS from 12hrs/d to 24hrs/d	• Baseline, 1, 2, 3, 4, 5 and 6 mos • Daily duration of SGS use (compliance) • VSS • Digital photography (smoothness, border height, thickness, pigmentation) • Patient VAS (pain, itch, pigmentation, hardness, elevation)	• EEG group wore SGS for 21.8 hrs/d vs. 10.1 hrs/d in CEG group (P < 0.001) • EEG group had better VSS scores vs. CEG group for pigmentation (P = 0.02), height (P = 0.03), pliability (P = 0.02) at 6 mos • Patient VAS scores were better in the EEG group vs. CEG group for itch (P = 0.01), colour (P = 0.02), hardness (P = 0.01), elevation (P = 0.01) at 6 mos • Digital photography showed better ratings for border height (P = 0.002), thickness (P = 0.01) in the EEG vs. CEG at 6 mos	[28]
Li-Tsang et al., 2006; prospective, investigator-masked, RCT; (**T**); Level of Evidence 2	• n = 45 • Mean 29.65 ± 17.6 yrs • Chinese subjects with scar >3 mm thick • Burns, trauma	• Tx group—SGS (Cica-Care; 24 hrs/d) + 15 min massage 2x/d with lanolin • Control—15 min massage with lanolin • 6 mos Tx	• Baseline, 1, 2, 4, 6 mos • Spectrocolorimeter (colour) • Tissue ultrasound palpation system (thickness) • VSS (pliability) • Pain (VAS) • Itch (VAS)	• Decreased thickness over 6/12 in Tx group relative to control (P < 0.01) • Increased pliability over 6/12 in Tx group relative to control (P < 0.01) • No statistically significant difference in itch, pain, or colour	[29]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Majan, 2006; prospective, RCT; (**T**); Level of Evidence 2	• n = 11 (100% F) • Control group mean age 28.8 (20—43 yrs) • Tx group mean age 29.4 (22–40 yrs) • Post-Sx scars	• Tx group—SGS • Control—no treatment • Wear up to 23 hrs/d • Tx initiated 2/52—2/12 post-Sx and continued for 12 mos	• Baseline, monthly until 6 mos and 12 mos • VSS • Dr and patient overall assessment at baseline and 12 mos	• No statistical comparisons provided • All scars improved (VSS) • Overall assessment: Dr rated 5/5 in Tx group as very good or good, patients rated 4/5 very good or good • One patient experienced skin reaction	[30]
Kelemen et al., 2007; controlled, comparison study; (**T**); [Hungarian]	• n = 24 • Primary linear HTS Sx scars	• Group 1 – TCA (n = 12) • Group 2 – SGS (n = 12)	TBC	• TCA and SGS both effective • TCA had rapid effect and lasted longer vs. SGS • In linear HTS, SGS is first-line and TCA is second-line • For recurrent HTS, TCA is recommended as first-line	[31]
Karagoz et al., 2009; RCT; (**T**); Level of Evidence 2	• n = 32 (45 scars) (20F, 12M) • Mean age 24 (3–55 yrs) • Scar age <6 mos • HTS postburn injury	• Group 1—SG (Scarfade), 2x/d • Group 2—SGS (Epi-Derm), 24 hrs/d • Group 3—onion extract, 2x/d • 6 mos Tx	• Baseline and 6 mos • VSS • Photograph	• Before and after Tx differences for each group ($P < 0.05$) • Significantly better improvement in group 1 vs. 3 and 2 vs. 3 ($P < 0.05$) • No difference between group 1 and 2 • Skin maceration: two patients in group 2	[32]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Harte et al., 2009; RCT; (**T**); Level of Evidence 2	• n = 22 (9F, 13M) • Mean age = 36.8 (16–64 yrs) • Mean TBSA 15 (1–55%) • 14 U/E, 8 L/E • <6 mos post-injury • HTS post-burn injury	• Group A—pressure therapy • Group B—pressure therapy + SGS • 23 hrs/d, replace every 7 d	• Baseline, 12 and 24 wks • VSS • Patient diary	• Overall reduction of VSS scores for both groups at 24 wks • No difference between group A and B at 12 or 24 wks • Power analysis determined 192 participants per group would be required, therefore results are under-powered	[33]
Wigger-Albert et al., 2009; intra-individual RCT; (**T**); Level of Evidence 2	• n = 60 (44F, 16M) • Mean age = 38.2 (16–61 yrs) • Scar age = 49.6 (3–355 mos) • Aetiology not specified	• Scar divided into two: half Tx with SGS and half Tx NSGS (polyurethane) • 12 wks Tx • Remove SGS and NSGS up to 1 hr/d	• Baseline, 4, 8, and 12 wks • Primary outcome: Patient's questionnaire overall SI • Redness (chromameter) • Clinical scar assessment modified	• SI: significantly improved at 4/52 ($P < 0.0001$) and 8/52 ($P = 0.012$); improvement was significantly more pronounced for polyurethane at 4/12 ($P < 0.0001$) and 8/12 ($P = 0.012$) • Redness: lower for polyurethane at 8/52 ($P = 0.0016$)	[34]
Momeni et al., 2009; prospective, placebo-controlled, double-blind, intra-individual RCT; (**T**); Level of Evidence 2	• n = 38 (18F, 16M) • Mean age 22 (1.5–60 yrs) • HTS post-burn injury	• HTS divided into 2 sides—side 1 = SGS; side 2 = NSGS (propylene glycol and hydroxyethyl cellulose sheeting) (referred to as placebo control) • Tx initiated 2–4 mo post-injury • Worn 24 hrs/d	• VSS • Baseline, 1, 4 mos • Pigmentation, vascularity, pliability, pain, itch	• Side 1—at 4/12 all scores except pain were significantly lower in the SGS group than the NSGS ($P < 0.05$) • Side 2—No significant change at 1/12 or 4/12	[35]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Perez et al., 2010; RCT; (**T**); Level of Evidence 2	• n = 30 (15 completers) • HTS or keloids • Aetiology not specified	• Group 1—TCA + SGS + vitamin E (2x/d) • Group 2—onion extract gel (3–4x/d) • Group 3—placebo control (2x/d) • Tx period 16/52	• Baseline, 4, 8, 12, 16 wks scar volume • Investigators evaluation of induration, erythema, pigmentation, pain, itch, cosmetic assessment • Patient satisfaction • Spectrometric intracutaneous scope	• At 16/52 relative to baseline: group 1 improved on volume ($P = 0.01$), length ($P = 0.02$), induration ($P < 0.01$), erythema (< 0.01), pigmentation, ($P < 0.01$), investigator evaluation ($P < 0.01$), patient satisfaction ($P = 0.04$); group 2 volume ($P = 0.01$), length ($P = 0.02$), width ($P = 0.02$), induration ($P = 0.03$); group 3 volume ($P = 0.02$), patient satisfaction ($P = 0.01$) • Significant improvement: group 1 vs. 3—investigator cosmetic evaluation ($P < 0.01$), induration ($P < 0.001$), pigmentation ($P < 0.001$), erythema ($P = 0.01$); group 2 vs. 3: investigator cosmetic evaluation ($P < 0.01$), induration ($P < 0.001$), pigmentation ($P < 0.001$), tenderness ($P < 0.05$) • Overall satisfaction: group 1 and 2 >76/100	[36]
Rhee et al., 2010; RCT; (**P**); Level of Evidence 2	• n = 40 • Mean age = 31.7 (16–51 yrs) • Asian participants after scar revision or mass excision	• Group 1—SGS x 12 hrs/d x 3 mos • Group 2—control	• Evaluation at 2/52, 1/12, and 3/12 • Pigmentation, vascularity, height using a photograph	• No differences at 2/52 • 1/12 SGS showed decrease in height ($P < 0.0024$) • 3/12, SGS showed decrease in pigmentation ($P < 0.0002$), vascularity ($P < 0.0002$) and height ($P < 0.00001$) • 2 patients developed skin rash	[37]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Li-Tsang et al., 2010; RCT; (**T**); Level of Evidence 2	• n = 104 (84 completed all assessments) • Mean age 21.8 ± 18.7 • Mean scar age 14.9 ± 30.8 mos • Burns, trauma	• Group 1—pressure garments (24 hr/d except hygiene) • Group 2—SGS (Cica-Care) • Group 3—pressure garments + SGS • Group 4—control • 6 mos Tx • Pressure garments and SGS worn 24 hrs/d except for hygiene	• Baseline 2, 4, 6 mos • Spectrocolorimeter (colour) • Tissue ultrasound palpation system (thickness) • VSS (pliability) • Pain (VAS) • Itch (VAS) • Patient satisfaction (interview)	• Thickness: group 3 improved at 2/12, 4/12, and 6/12 and group 1 at 6/12 ($P < 0.001$) relative to control but no difference between Tx groups ($P = 0.066$) • Pliability: at 6/12 all groups improved ($P < 0.001$); group 3 was significantly more pliable than control at 2/12 ($P = 0.002$) and 4/12 ($P < 0.0001$) • Pigmentation: at 6/12 all groups were lighter and more yellow ($P < 0.001$) • Pain: group 2 ($P = 0.001$) and group 3 ($P = 0.004$) reduced relative to control • Itch: authors report reduced itch for all Tx groups but data indicates an increase for group 1 from baseline to 6/12	[38]
Quddus-ur-Rehman et al., 2012; prospective, RCT; (**T**)	• n = 72 (43F, 29M) • HTS and keloids	• Intralesional TCA • SGS • Sx and postoperative TCA • Sx and postoperative radiotherapy • Sx alone	• Clinical assessment	• 20% recurrence rate with TCA • 25% recurrence rate with SGS • 25% recurrence rate with Sx and TCA • 50% recurrence rate with Sx and postoperative irradiation • 20% recurrence with Sx alone • In both the SGS and Sx/TCA groups, 50% patients had excellent results • Best results were with TCA and SGS (latter especially when introduced early) and combined modalities for HTS	[39]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Braam et al., 2015; three-arm RCT; (P)	• n = 36 • paediatric cancer patients • HTS post-VAP removal	• Group 1 - SGS applied 14 dys post-Sx; worn for 2/12 • Group 2 – SGS applied 14 dys post-Sx; worn for 6/12 • Group 3 – no Tx • Follow up at 1 yr	• Clinical assessment (7 timepoints) • Modified VSS	• For hypertrophy, no significant differences • Between Group 1/Group 2 vs. Group 3 • At 1 yr follow up, smaller scars seen in Group 1 vs. Group 2 (P = 0.04), but not between Group 1 vs. Group 3 (P = 0.22) • No strong evidence to support the use of SGS after VAP removal	[40]
Kim et al., 2016; prospective, blinded, intra-individual, RCT; (**P**)	• n = TBC • Scars from bilateral hallux valgus (bunion) Sx	• Group 1 – Tx: SGS applied to one foot for 12/52 after suture removal • Group 2 – Control: no Tx for scar on other foot • Tx for 3 mos	• Clinical evaluation at 4, 12 wks • VSS • Scar symptoms (pain, itch) • AEs (rash, maceration)	• At wks 4 and 12, VSS scores for Group 1 vs. Group 2 were significantly better (P < 0.05) except for scar length • AEs for Group 1 vs. Group 2 were lower at 12/52 (P < 0.05)	[41]

AEs, adverse events; *CEG*, conventional education group; *c/o*, complained of; *CO*, cohort; Dr, doctor; *EEG*, enhanced education group; *F*, female; *HTS*, hypertrophic scars; *M*, male; *L*, left; *L/E*, lower extremity; *n*, sample size number; *NSGS*, non-silicone gel sheets; *POSAS*, Patient and Observer Scar Assessment Scales; *R*, right; *RCT*, randomised controlled trial; *SG*, silicone gel; *SGS*, silicone gel sheets; *SI*, scar index; *Sx*, surgery; TBC, to be completed; *TBSA*, total body surface area; *TCA*, triamcinolone acetonide; *Tx*, treatment; *U/E*, upper extremity; *VAP*, venous access port, *VAS*, visual analogue scale; *VSS*, Vancouver scar scale; *x/52* or *wks*, number of weeks; *x/12* or *mos*, number of months; Italicized author names: These publications appeared in the Cochrane Collaboration Review, 2013. Ref [8]; Author names in red type: Alliance Medical Information does not have full publication PDF, only the Abstract; If known, clinical studies are classified as 'Prevention' (**P**) or 'Treatment' (**T**).

Table 2. Studies on the efficacy of silicone gel in scar management.

(N.B.: for a list of abbreviations, please refer to the legend at end of the table)

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Sebastian et al., 2004; multi-centre, observational study; (**T**) [German]	• n = 111 (70F, 41M) • Age range <20->60 (62.4% between 20-49 yrs) • HTS/keloid scars • 72% via Sx, 18% via accidents and burns • Scar age: <2 yrs (75%)	• SG (Dermatix; Kelo-cote formulation) • Median duration of treatment 2.3 mos (45.7%, 2 mos; 24.8%, 3 mos)	• Dermatologist and patient assessments • Efficacy: reductions in redness, pain, hardness, elevation and itchiness • Tolerability	• 80.1% patients and 75.7% physicians rated efficacy as good/very good • 89.2% patients and 84.5% physicians rated tolerability as very good • Physicians rated efficacy: • 80% good/very good for HTS • 82.3% good/very good for minor keloids • 70% good for major keloids • Changes in efficacy scores between baseline and last evaluation were statistically significant (P = 0.005) for all parameters tested	[42]
Chan et al., 2005; prospective, double-blind, within-subject, placebo-controlled, RCT; (**T**); Level of Evidence 2	• n = 50 Asian patients • Median age 61 (26–77 yrs) • Sternal scar post-cardiac Sx	• Upper and lower portion of the scar randomly assigned to Tx and the control group • Tx group—SG (Scarfade) • Control—NSGS • Applied 2x/d • Subjects blinded to group allocation • 3/12 Tx	• 2/52, 6/52, 3/12 postoperative • VSS • Pain (3-point scale) • Itch (3-point scale) • Digital image (rater blinded to group allocation) • Compliance	• Tx group significantly better on all outcome measures (pigmentation P = 0.02; vascularity P = 0.001; pliability P = 0.001; height P = 0.001; pain P = 0.001; itch P = 0.02) • Tx group gradually improved between 6/52 and 3/12 • Control group gradually worsened over time • 74% perfect compliance, 24% forgot sometimes, 2% forgot most of the time	[43]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Sepehrmanesh et al., 2006; prospective, multi-centre, open label, non-controlled, large-scale observational study; (**T**)	• n = 1,522 (1065F, 457M) • Mean age 36 (1-94 yrs) • HTS/keloid scars (Sx, accident, burns, other causes; 50% not previously Tx) • Scar age: <3 mos (92%), up to 4 yrs (8%)	• SG (Dermatix; Kelo-cote formulation) 2x/d for Tx and observational period of 2-6 mos (maximum of 10 mos) • In 83.8% of cases no secondary Tx were instigated	• Physician and patient assessments • 4-Point Likert Scale (none, mild, moderate, severe) • Height; colour; pliability; itching; pain/ tenderness • Treatment satisfaction • Tolerability	• 70-84.2% physicians reported improvement in scar symptoms • 69.8-85.1% patients reported improvement in scar symptoms • 98.7% physicians and 98.2% patients rated tolerability as very good/good • Satisfaction was rated equally by physicians and patients • 26 AEs observed in 23 patients (1.5%; burning, redness or itching)	[44]
Murison et al., 2006; prospective, non-controlled, Case Series study; (**T**); Level of Evidence 4	• n = 6 • Age range 30–58 yrs • Scar age 3–6 mos to 4–5 yrs • Aetiology not specified	• SG (Dermatix; Kelo-cote formulation) • Tx = 2x/d x 8/52	• Digital photographs • Modified VSS: redness, elevation, hardness, itch, tenderness, pain • Spectrophotometric intracutaneous scope (SIS)	• No statistical comparisons provided • Modified VSS Improved for all subjects • SIS—7.2% decrease in collagen, 3% increase in blood flow	[45]
Signorini et al., 2007; prospective, RCT; (**P**); Level of Evidence 2	• n = 148 • Mean age = 53.5 (5–82 yrs) • Scar age: 10 d–3 wks • Recent Sx scar	• Tx group: SG (Dermatix; Kelo-Cote formulation 2x/d x 4 mos) • Control group	• Baseline, 1, 2, 3, 4, and 6 mos • Overall evaluation (Grade 1 = normal, 2 = mildly hypertrophic, 3 = hypertrophic, 4 = keloid)	• 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 ($P < 0.001$)	[46]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Chernoff et al., 2007; prospective, within-subject, Cohort study; (T); Level of Evidence 3	• n = 30 bilateral active scars • HTS, keloids or post-laser exfoliation erythema • Aetiology of HTS and keloids not specified	• Group 1 (n = 10)—SG (Dermatix ; Kelo-Cote formulation) (2x/d) • Group 2 (n = 10)—SGS (morning and night) • Group 3 (n = 10)—SG (morning) and SGS (night) • Bilateral scar—no treatment control • Tx time for all groups = 90 d	• Optical profilometry (surface topology, elevation) • Homemade evaluation (erythema, scar symptoms [irritation, skin maceration] and difficulty using)	• Group 1, 2, and 3 were significantly less elevated ($P < 0.001$) and groups 1 and 2 were significantly less red ($P < 0.001$), less symptomatic ($P < 0.001$) vs. untreated control scar • SG was easier to use that SGS ($P < 0.001$) • Group 3 participants rated improvement most favourably	[47]
Fonseca-Capdevila et al., 2007; multi-centre, prospective, open-label, controlled, comparison study; (P); [Spanish]	• n = 131 (79F, 52M) • Mean age 31.4 years • Sx excision of benign skin lesions	• Group 1 – SG (Dermatix; Kelo-Cote formulation) • Group 2 – SGS (Mepiform) • 2x/d for 1/12	• Follow up at 2, 4, 6 mos after excision • Patient and physician Tx rating: redness; hardness, itching; pain • 4-point Likert scale • Tolerability	• SG and SGS both reduced redness by a mean of 1.1 and 0.7 points, respectively ($P = 0.126$) • SG and SGS both improved hardness by a mean of 0.9 and 0.6 points, respectively ($P = 0.168$) • Overall improvement in SG Tx scars was 4.1 points vs. 3.2 point in the SGS group • Topical SG was significantly better tolerated (97.3% good/very good) vs. SGS (63.9%) ($P < 0.001$)	[48]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Lacarruba et al., 2008; uncontrolled, open label Case Series study; (**T**); Level of Evidence 4	• n = 8 (6F, 2M) • Mean age 29 (12–49 yrs) • <90 d post-trauma or surgery	• SG (Kelo-cote?) applied 2x/d • 6 mos Tx • Three patients with control scars	• Baseline, 1, 2, 3 mos • Scar thickness by ultrasound • Clinical evaluation of size, redness and texture	• No statistical comparisons provided • Mean scar thickness reduced by 37% (range: 20-54%) (4 mm before Tx [range: 3.4–6.1]; 2.5 mm after Tx [range: 2.1–3.2]) • Two patients c/o itch	[49]
de Giorgi et al., 2009; RCT; (**P**); Level of Evidence 2	• n = 110 (55F, 55M) • Group A = 65 (32F, 33M) (mean age 52 yrs, range 26–81) • Group B = 45 (23F, 22M) (mean age 48 yrs, range 23–76) • Fresh Sx scars	• Group A = SG (brand not specified) + zinc oxide 2x/d × 60 d • Group B = zinc oxide cream	• 1, 2, 3, 4, 6, 8 mos post Sx • Scar alterations (keloids, HTS, diastasic scar, atrophic scar) • Pain and itch VAS	• Abnormal scar formation: group A 27% Vs. group B 55% (P = 0.038) –Keloids: group A 0% vs. group B 11% –HTS: group A 9% vs. group B 22% –Pain: group A 20% vs. group B 47% –Itch: group A 9% vs. group B 35%	[50]
Puri et al., 2009; Case Series study; (**T**); Level of Evidence 4	• n = 30 (2:1 male:female ratio) • Age range 5–60 yrs • HTS and keloid • Scar age range: <1/12–>6/12 • Aetiology not specified	• SG (Kelo-cote?) • Tx = 2x/d x 0.25–8 mos	• Evaluation 1x/12 × 6 mos • Graded: I = normal, II = mildly hypertrophic, III = hypertrophic, IV = keloid	• No statistical comparisons provided • 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) • Side effects were few • Allergic rxn to SG seen in 1 case; mild desquamation was seen in 2 cases	[51]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/ duration	Scar evaluation	Main results/outcome	Ref.
Bianchi et al., 2010; prospective RCT; (**T**)	• n = 30 (15F, 15M) • Mean age = 37 (18-73 yrs) • Post-trauma and Sx facial scars	• Group 1 – SG (Dermatix) (7M, 8F), Tx 2x/d • Group 2 – base cream (8M, 7F), Tx 2x/d and massage (10 min)	• POSAS • Baseline and 2 mos	• POSAS scores decreased from baseline to 2 mos in Groups 1 and 2 for nearly all items (no statistical analyses performed): • In Group 1, total POSAS patient score decreased from 23.17 to 12.86 (-10.31); total observer score decreased from 25.56 to 11.39 (-14.17) • In Group 2, total POSAS patient score decreased from 24.85 to 12.35 (-12.5); total observer score decreased from 24.75 to 10.03 (-14.72) • In Group 1 and 2, greatest patient score improvement in colour, stiffness, thickness and overall opinion • In Group 1 and 2, greatest observer score improvement in vascularization, pigmentation, pliability and overall opinion • In Group 1, itch worsened with a total score increase of 1.52 to 1.73	[52]
Spencer, 2010; Case Series study; (**P**); Level of Evidence 4	• n = 7 • Sx excision—skin cancer	• Linear scar divided into two: half with SG (Kelo-cote), half control • SG 2x/d for 3 mos	• Baseline, 1, 3 mos • VSS and Dr evaluations • Mexameter for erythema and pigmentation	• No statistical comparisons provided • No difference in erythema and pigmentation between the groups • 5/7 SG group were better than control as assessed by physician • 4/7 SG group were better than control on VSS	[53]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Radwanski et al., 2010; prospective, open-label study; (**P**)	• n = 128 (69 completers) mixed race population • 97-98%F • Age range = 15-65 yrs • Recent Sx scars = 67.2% normal, 21.8% HTS	• SG (Kelo-cote) 2x/d • Tx 3-6 mos	• Baseline, initial (1/12), intermediate (2-5 mos), final (3-6 mos) Tx phase • VSS • QoL questionnaire	• 31.3% (n = 40) voluntarily discontinued due to early favourable results • Total median VSS scores decreased from ca. 8 (initial assessment) to ca. 4 (intermediary assessment) (P < 0.0001) • Erythema, relief and flexibility statistically-significantly improved • Erythema and flexibility showed a rapid response; relief improved between initial and final assessments (P <0.0001) • 62% considered efficacy excellent; 28% good; 7% moderate; 3% unsatisfactory • There was a 6.25% (n = 8) incidence of AEs (erythema and itchy skin, which improved on Tx holiday)	[54]
van der Wal et al., 2010; prospective, intra-individual, double-blind, RCT; (**T**); Level of Evidence 2	• n = 23 (13M, 10F) • 46 scars post-burn injury • Mean age = 38 (18–69 yrs) • Mean scar age = 123 (36–338 d)	• Group 1– SG (Dermatix) • Group 2—placebo control • 2x/d • mean Tx time = 263 (195–347d)	• Baseline, 1, 3, 6, 12 mos • POSAS, dermaspectrometer	• Group 1: decreased itch at 3/12 (P = 0.018) at 6/12 (P = 0.013); decreased roughness at 3/12 (P = 0.014) relative to baseline • Redness and pigmentation, no statistical difference • Significant treatment effect: observer's relief scores (P = 0.012) were lower at 3/12 with SG Tx than the control	[55]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Stoffels et al., 2010; prospective, randomized, placebo-controlled, double-blind, split-scar comparison study; (**P + T**); [German]	TBC	• Group 1 – silicone spray (brand not specified) • Group 2 – placebo • Tx 3 months	• POSAS	• After 3 mos of Tx, patient scale of POSAS demonstrated that patient satisfaction with the silicone application was significantly higher vs. placebo	[56]
Scuderi et al., 2010; RCT; (**T**); Level of Evidence 2	• n = 150 (89F, 61M) • Mean age = 32 (18–52 yrs) • HTS age = 6–24 mos • Sx and traumatic scar	• Group A— (n = 107) (asymmetrical): NSG (cyanoacrylates) • Group B— (n = 40) (linear): half SG, 2x/d; half NSG (cyanoacrylates) (3 layers every 3–5 d) • Tx 3 mos	• Baseline, 1, 3, 6, 12 mos • Global scar assessment • Colour (photograph), overall softening, width (ruler), length (caliper), elevation (optical profilometry) • VAS—itch, colour, pliability, thickness, relief	• Group A—89.7% improved on global scar assessment • Group B—Scar elevation reduced in both the groups at 1/12 (SG $P < 0.0001$) (NSG $P < 0.0001$) and 1 yr (SG $P < 0.0001$) (NSG $P < 0.0001$) • One patient developed skin rxn	[57]
Scuderi et al., 2011; intra-individual RCT; (T); Level of Evidence 2	• n = 85 • Mean age 32 (18–52 yrs) • Bilateral mammoplasty	• One breast Tx with NSG (cyanoacrylate) every 3–5 d for 3mos • One breast Tx with SG, 2x/d x 3/12	• Baseline, 1, 3, 6, 12 mos • Scar width (ruler), length (caliper), elevation (optical profilometry), texture • VAS: itch, colour, pliability, thickness, relief	• Elevation: increased between baseline and 1/12 (NSG and SG $P < 0.0001$); decreased between baseline and 1 yr (NSG $P = 0.0182$; SG $P = 0.0174$) • Scar width: increased between baseline and 1 yr (NSG and SG $P < 0.0001$); increased in width significantly less with NSG Tx ($P < 0.0001$) • 3 patients experienced skin rxn to NSG	[58]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Steinstraesser et al., 2011; intra-individual RCT; (**P**); Level of Evidence 2	• n = 38 (11F, 17M) • Mean age = group 1—42.3 ± 13.3; group 2—43.1 ± 13.7 • Burns	• Randomly assigned to Tx groups: 1) SG (Dermatix) + pressure vs. pressure alone or 2) SGS (Mepiform) + pressure vs pressure alone—no information provided about allocate to pressure alone • 12 mos Tx	• Baseline, 2/52, 2, 6, 12, 18 mos • Clinical assessment, VSS, redness (chromometry), profilometry, photographs • PRIMOS optical 3-D system to measure scar surface microtopography	• 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) ($P < 0.001$) but there was no difference between the groups; redness SG and SGS + pressure (15.4 ± 2.2–11.0 ± 2.1) ($P < 0.001$) and pressure alone (15.9 ± 2.2–11.3 ± 2.3) ($P = 0.003$) but there was no difference between the groups • Profilometry improved between 2 and 18 mos for SG + pressure (323.1 ± 197.5–257.6 ± 178.3; $P = 0.047$) but not SGS + pressure or pressure alone • Pain decreased with SG and SGS + pressure and pressure alone ($P = 0.005$) but there was no difference between the groups • Itch decreased with SG and SGS + pressure ($P = 0.005$) and pressure alone ($P = 0.003$) but there was no difference between the groups • 31.5% SGS + pressure developed a skin reaction, but these were local rxns (contact dermatitis or skin maceration)	[59]

Study (author, year, design)	Subjects/ numbers and wound type	Intervention/ duration	Scar evaluation	Main results/outcome	Ref.
Sandhofer et al., 2012; Observational study; (**P + T**)	• n = 105 • Dermatology Sx • Mainly: tattoo removal, HTS, acne, wrinkles	• SG (Stratamed) • Add-on Tx to 5 procedure types (laser, excision, 5-FU/TCA, radiotherapy, dermabrasion) • Tx = 3 mos	• Follow-up at 1-12 mos • Clinical assessment • Photographs • Patient satisfaction	• No statistical analyses presented • In laser resurfacing, qualitative improvements observed in reduction of inflammatory response and no cases of erythema • Patients reported a significant decrease in reddening, itching and tightness • In Sx excision, scar formation exceeded clinical expectations • SG is well-suited for a range of dermatological indications and as a combination therapy • Well tolerated with no contact sensitization or gel-related infections • Patient compliance was v high	[60]
Chittoria et al., 2013; prospective, intra-individual, placebo-controlled, double-blind RCT; (**P**)	• n = 50 Asian patients (20F, 30M) • Median age = 25.5 (1-75 yrs) • Scars = 100 HTS at donor site of skin grafting • Scar age = >10 d but <3 wks after Sx	• Group I – 50 scars with control gel • Group II – 50 scars with SG ('semi-liquid, stick-type'; brand not specified) • Tx 2x/d for 8/52	• Assessment at 2, 6, 8 wks postoperative follow up • VSS	• 74% (n = 37) had good compliance; 24% (n = 12) had moderate compliance; 2% (n = 1) had poor compliance, as no scar formation • No subjects in Group I or Group II had TEAEs • Hypertrophy was noted in 94% (n = 47), mainly in Group I • VSS scores (vascularity, height, pliability and total) gradually increased for Groups I and II from 2/52 to 8/52, but always higher for Group I • At 8/52, mean vascularity score was 1.84 (Group I) vs. 0.56 (Group II) (P <0.01) • At 8/52, mean height score was 2.16 (Group I) vs. 0.82 (Group II) (P <0.01) • At 8/52, mean pliability score was 2.9 (Group I) vs. 0.9 (Group II) (P <0.01) • At 8/52, mean total score was 9 (Group I) vs. 3 (Group II) (P <0.01)	[61]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Riedel et al., 2013; prospective, controlled, split scar study; (**P**)	• n = 20 (19 completed) • Chest scars following costal cartilage harvest	• Linear scar divided into two: half with SG (brand not specified), half control • SG 2x/d for 3 mos	• Subjective comparison (VAS) • Objective measurement (elasticity, moisture, colour)	• In VAS assessment, better Tx result was recorded by n=8; a worse Tx result by n=10 and no difference by n=1 • No significant differences seen in the objective measurements	[62]
Medhi et al., 2013; prospective, open-label trial; (**P**)	• n = 36 (13M, 23F) • Mean age = 35.7 yrs • Post-Sx scars (10 dys – 3 wks previously) • Majority of scars were abdominal • 80.7% were mildly HTS to HTS	• SG (Kelo-cote) • Tx = 2x/d for 3/12 • 9 mos follow-up phase (mos 3-6, 6-9, 9-12)	• Baseline, 1, 2, 3, 6, 9, 12 • VSS • Photographs • Scar morphology (4-point scale; Grade 1 (normal) – Grade 4 (keloid)) • Dermatology Life Quality Index (DLQI) • Dr/patient satisfaction (4-point scale)	• Statistically significant improvements in scar measurement scores from baseline to 2/12 were seen for height ($P = 0.002$); pigmentation ($P = 0.03$); pliability ($P = 0.0039$); vascularity ($P = 0.0195$) • There is a significant difference in baseline vs. month 3 QoL scores ($P < 0.0313$) • At Tx end, Dr was 'completely satisfied' or 'satisfied' in 79% cases; 54% of patients were 'completely satisfied' or 'satisfied'	[63]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/ duration	Scar evaluation	Main results/outcome	Ref.
Kong et al., 2014; prospective, placebo-controlled, patient-blinded RCT; (**P**)	• n = 100 (96 completers) • 11M, 85F • Mean age = 68.5 (50-83 yrs) • TKA Sx scars	• SG (Kelo-cote) vs. placebo (petrolatum) • Tx = 2x/d for 1/12	• VAS – 3, 6, 12 mos for pain and itching • VSS • Knee Society Score • Photographs • Range of Movement (goniometer)	• At 3, 6, 12 mos post-operation, mean VAS pain scores with SG (3.89, 3.2, 2.5) vs. mean VAS pain scores with placebo (4.1, 3.14, 2.92) were not significant (P = 0.644, 0.886, 0.201, respectively) • At 3, 6, 12 mos, mean VAS pruritus scores with SG (3.18, 2.28, 2.05) vs. mean VAS pruritus scores with placebo (3.92, 2.64, 1.9) were not significant (P = 0.113, 0.352, 0.615, respectively) • At 3, 6, 12 mos, VSS parameters for SG vs. placebo were not significant except: • Pigmentation: at 6 mos, SG (mean score 1.84) vs. placebo (mean score 2.12) (P = 0.031); at 12 mos, SG (1.5) vs. placebo (1.92) (P = 0.004) • Height: at 6 mos, SG (mean score 1.3) vs. placebo (mean score 1.6) (P = 0.019); at 12 mos, SG (0.86) vs. placebo (1.14) (P = 0.044) • At 12 mos, no differences in Knee Society scores in the groups (P = >0.05)	[64]
Kim et al., 2014; prospective, open-label, RCT; (**P**)	• n = 30 Koreans (25 completers; 9M, 16F) • Mean age = 37.52 (21-75 yrs) • Prior Sx, 2 wks – 3 mos	• Group I – SGS (n = 15) • Group II – SG (n = 15) (Kelo-cote) • Tx = 3 mos	• Baseline, 1, 3 mos • Photography • VSS (2 independent observers) • Patient questionnaire (1 (improved) – 10 (aggravated)) – scar appearance, symptoms and convenience of Tx	• At 3 mos, all scars Tx with SGS and SG had improved visibly in terms of pigmentation, height, irregularity and overall size • At 1 and 3 mos from baseline, there was no difference in VSS scores in Group I vs. Group II (P > 0.05); at 1/12, there was a -0.455 pain score change in Group I vs a 0.143 change in Group II (P = 0.033) • In patient questionnaire, at 1 and 3 mos from baseline there was no difference in outcome measures in Group I vs. Group II (P > 0.05); at 3/12, inconvenience use score in Group I was 3.818 vs. 1.571 in Group II (P = 0.015)	[65]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Bucko et al., 2015; multi-centre, double-blind RCT, (**T**)	• n = 44 (38 completers) • Age range = 18-65 yrs • HTS/keloid scars • Scar age = 3 mos – 1 yr • VSS minimum total score of 3	• Group 1 – n = 22, Hydrogel (Celacyn) • Group 2 – n = 22, SG (Kelo-cote) • Tx = 3x/d for 8/52	• Baseline, 14, 28, 56 (end of Tx), 84, 112 d (follow-up) • VSS at all visits • Scar symptoms (itch, pain) at all visits • Investigator Global Assessment (IGA) • IGA on d 56, 112 (v good, good, moderate, unsatisfactory) • Patient satisfaction on d 56, 112 (v good, good, moderate, unsatisfactory)	• At d 56, mean total VSS decreased by -2.1 points (Group 1) and -1.28 (Group 2) • At final visit (d 112), mean total decreases in VSS were -2.7 (Group 1) and -1.83 (Group 2) • Pain and itch decreased in both Groups, (Group 1 vs. Group 2 P > 0.05) • IGA rated efficacy as good/v good in 30% patients in Group 1 vs. 27.8% patients in Group 2 at d 56 • IGA rated efficacy as good/v good in 55% patients in Group 1 vs. 27.8% patients in Group 2 at d 112 • Patient satisfaction was good/v good in 40% of Group 1 vs. 44.4% of Group 2 at d 56 • Patient satisfaction was good/v good in 45% of Group 1 vs. 55.6% of Group 2 at d 112 • 18.2% of Group 1 and 35% of Group 2 reported TEAE (mild-moderate) • Infections: 4.5% (Group 1) and 15% (Group 2) • GI disorders: 4.5% (Group 1) and 5% (Group 2)	[66]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Goldberg, 2016; observational pilot study; (**P**)	• n = 15 (4F, 11M) • Mean age = 55.9 yrs • Linear Sx scars	• SG (Recedo) • Tx = 2x/d for 84 d	• Baseline, 14, 28, 56, 84 d evaluation • VSS • Observer Scar Assessment Scale (OSAS) • Subject satisfaction • Photographs • AEs	• Median total VSS score reduction vs. baseline was significant at 14 d (P = 0.0015), 28 d (P = 0.0034), 56 d (P = 0.0002) and 84 d (P = 0.0005) • VSS score reduction at 84 days vs. baseline was significant for pliability (P = 0.002), vascularity (P = 0.002), height (P = 0.0078) and pigmentation (P = 0.002) • Median total OSAS score reduction vs. baseline was significant at 14 d (P = 0.0012), 28 d (P = 0.0009), 56 d (P = 0.0002) and 84 d (P = 0.0002) • OSAS score reduction at 84 days vs. baseline was significant for vascularization (P = 0.001), thickness (P = 0.0005) and pigmentation (P = 0.0005) • Median pruritus score decreased from 2.5 to 1.0, becoming significant at 56 d (P = 0.0078) and 84 d (P = 0.0078) • 84.6% rated Tx as excellent, v good or good after 3 mos	[67]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/ duration	Scar evaluation	Main results/outcome	Ref.
Stewart et al., 2016; open-label, single-centre, cohort study; (**T**)	• n = 36 (26F, 10M) • 29 completers • Mean age = 32.5 (16-60 yrs) • HTS (n = 34)/keloids (n = 2) from Sx, trauma, burns	• Cohort 1 – SG (Silgel STC-SE) on scars < 6 mos old • Cohort 2 – SG (Silgel STC-SE) on scars 6 mos – 2 yrs old • Tx = 2x/d for 16 wks	• Baseline, 1, 4, 8, 12, 16 wks • Skin hydration (corneometry) • Skin moisture evaporation • Skin elasticity • Scar measurements • Patient questionnaire (5-point VAS) • Photograph image analysis	• Mean scar width and height showed decreases but were not validated statistically • Mean scar length decreased from baseline to wks 4-16 for all scars ($P < 0.05$); at wk 8 for Cohort 1 only ($P = 0.043$) and wks 8-16 for Cohort 2 ($P < 0.05$) • Skin hydration differences of Cohort 1 vs. Cohort 2 were slight and not statistically significant • Skin moisture evaporation showed v little observable change and fluctuated between the groups • No statistically significant differences in skin elasticity changes detected at any timepoint • High resolution photographs showed visual improvements in scars • For Cohort 1, there was a statistically significant decrease in redness at wks 8 and 16 ($P = 0.0376$ and $P = 0.0069$, respectively) • For Cohort 2, there was a statistically significant decrease in redness at wk 16 ($P = 0.0254$) • In subjective assessment, by wk 16, 90% patients agreed that scar appearance had improved; 86% reported that scar redness had reduced; 72% agreed that size of scar had been reduced	[68]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Fabbrocini et al., 2016; RCT; (**T**)	• n = 20 • n = 12 with keloids and n = 8 with HTS • Sx scars	• Group A – Tx of 100% scar with skin needling (Dermapen) and 50% with SG (Kelo-cote) • Group B – Tx of 100% scar with SG and 50% skin needling	• Clinical photographs • Scar thickness • Skin ultrasound • Modified VSS	• Group A - mean improvement of 68% on combination Tx vs 52% on skin needling ($P < 0.01$) • Group B – mean improvement of 63% on combination Tx vs. 47% on SG Tx ($P < 0.01$) • Patient compliance was good	[69]
Peek et al., 2016; Pilot study; (**P**)	• n = 20 (13F, 7M) • Median age = 7.65 (1.51-15.13 yrs) • VAP scars after cancer Tx	• SG (Dermatix) vs. MCT vs. NAT • Tx = 6 mos	• Baseline, 3, 6, 12 mos after VAP removal • POSAS • Photographs with 2x blinded assessors	• After VAP removal, MCT had lower POSAS scores vs. NAT at 6 mos and 12 mos ($P = 0.017$; $P = 0.042$ at 6 and $P = 0.01$; $P = 0.01$ at 12 mos for, respectively, patients and observers) • SG had lower POSAS-patient score vs. NAT at 3 mos ($P = 0.022$) but not POSAS-observer score ($P = 0.116$)	[70]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/ duration	Scar evaluation	Main results/outcome	Ref.
Grigorovici et al., 2017; prospective, comparative, randomised, open-label study; (**P**)	• n = 100 (93 completers, 100%F) • Mean age = 50.4 (22-75 yrs) • Post-thyroid Sx scars	• SG (Regen-Sil) group (n = 46) • SG (Strataderm) group (n = 47) • Tx = 1x/d for 3 mos	• Baseline, 1, 3 mos • VSS • Photographs • Patient/Dr satisfaction (5-point scale: 1 (weak) to 5 (excellent))	• After 1/12, only vascularity (P = 0.008) and itchiness (P = 0.036) were statistically significantly decreased in favour of patients on Regen-Sil • After 3/12, all VSS parameter scores were statistically significantly reduced (P < 0.05) in favour of Regen-Sil except itchiness (P = 0.24) • 95.65% patients (Regen-Sil) vs. 82.98% patients (Strataderm) recorded 'v good – excellent' satisfaction for cosmesis after 3 mos • 97.83% patients (Regen-Sil) vs. 82.98% patients (Strataderm) recorded 'v good – excellent' for overall satisfaction after 3 mos • Physicians rated overall satisfaction for 95.66% patients (Regen-Sil) vs. 74.47% patients (Strataderm) as 'v good – excellent' after 3 mos	[71]
Marini et al., 2017; Case Series study; (**P + T**)	• n = 4 • Scars after laser Tx, non-healing scalp wounds, chronic relapsing xerotic eczematous cheilitis, burn scars	• SG Tx (brand not specified)	TBC	• Excellent clinical results • User-friendly, convenient, increased comfort and compliance	[72]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Meseci et al., 2017; prospective, intra-individual; blinded-assessors; RCT; (**P**)	• n = 50 (39 completers) • Age range = 28-52 yrs • Gynaecological conditions • HTS and keloids after abdominal incision	• Tx group – half scar Tx with SG (Dermatix) 2x/d; half Tx with methylprednisolone cream, every other 2 d • Control group – no Tx • Tx = 3 mos	• Baseline, 3, 6 mos • Modified VSS • Scar thickness - ultrasound • Patient satisfaction – 4-point scale (unsatisfied, slightly satisfied, satisfied, v satisfied) • TEAEs – every 2 mos	• Height, pigmentation, vascularity, pliability and total MVSS scores significantly decreased at 6/12 vs. 3/12 for all groups • MVSS scores of all parameters differed among the groups at 6/12 ($P < 0.05$): • At 6/12 follow-up, there was no statistical difference in MVSS score between steroid and SG in pigmentation ($P = 0.197$), pliability (0.67) or total score ($P = 0.136$) • At 6/12, steroid cream achieved a lower MVSS score than SG on scar height (0.48 vs. 0.86, $P = 0.043$) and vascularity (0.95 vs. 1.52, $P = 0.047$) • No patients experienced TEAEs during Tx • At 6/12, patient satisfaction with steroid Tx was similar to that with SG ($P = 0.116$): 48% patients on steroid were v satisfied; 33% on SG were v satisfied	[74]

Study (author, year, design)	Subjects/numbers and wound type	Intervention/duration	Scar evaluation	Main results/outcome	Ref.
Wiseman et al., 2017; non-double-blinded, assessor-blinded, RCT; (**P + T**)	• n = 135 (paediatric) • Age: up to 16 yrs • Scars: new burns • 16-18 yrs also recruited after Sx for scar reconstruction	• Group 1 – SG (Strataderm), n = 45, Tx 1x/d • Group 2 – Pressure garment therapy, n = 45 • Group 3 – SG + pressure garment, n = 45	• 2 Sites per person at baseline, 1/52, 3, 6 mos • Primary outcome: itch intensity and scar thickness • Secondary: colour, pigmentation, pliability, pain • Patient/Dr scar assessment • Costs, adherence, HRQoL, treatment satisfaction • TEAE	• Final data collection is occurring in February 2018	[73]

AEs, adverse events; *c/o*, complained of; *CO*, cohort; Dr, doctor; *F*, female; *5-FU*, 5-fluorouracil; *GI*, gastrointestinal; *(HR)QoL*, (health-related) quality of life; *HTS*, hypertrophic scars; *M*, male; *MCT*, meridian colour therapy; *n*, sample size number; *NAT*, no additional treatment; *NSG*, non-silicone gel; *NSGS*, non-silicone gel sheets; *POSAS*, Patient and Observer Scar Assessment Scales; *R*, right; *RCT*, randomised controlled trial; *rxns*, reactions; *SG*, silicone gel; *SGS*, silicone gel sheets; *Sx*, surgery; TBC, to be completed; *TCA*, triamcinolone acetonide; *TEAE*, treatment-emergent adverse event; *TKA*, total knee arthroplasty; *Tx*, treatment; *VAP*, venous access port; *VAS*, visual analogue scale; *(M)VSS*, (Modified) Vancouver Scar Scale; *x/52* or *wks*, number of weeks; *x/12* or *mos*, number of months; Italicized author names: These publications appeared in the Cochrane Collaboration Review, 2013. Ref [8]; Author names in red type: Alliance Medical Information does not have full publication PDF, only the Abstract; If known, clinical studies are classified as 'Prevention' (**P**) or 'Treatment' (**T**). The Kelo-cote formulation was under the brand name 'Dermatix' before September 2007.

Table 3. Ranking of studies and clinical trials by their respective levels of evidence, as defined by the Oxford Centre for Evidence Based Medicine (as reported in Sidgwick et al., 2015 [75]).

Level of evidence	Study type
1	• Systematic review of RCT • High-quality RCT
2	• Systematic review of cohort studies • Low-quality RCT • Cohort studies/non-randomised controlled trial
3	• Systematic review of case–control studies • Case–control studies
4	• Case series • Low-quality case–control studies • Low-quality cohort studies/non-randomised controlled trial
5	• Case reports • Expert opinions

RCT, randomised controlled trial

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