

The use of silicone gel sheeting in the management of hypertrophic and keloid scars

A systematic review of the use of a topical silicone gel therapy in the management of abnormal scarring

Most wound healing is well controlled, but over-abundant deposition of collagen may result in hypertrophic or keloid scarring.¹ These scars are raised, hard, lumpy and erythematous, and pruritis is invariably a distressing symptom.² The prime clinical feature distinguishing keloid from hypertrophic scarring is that keloid scar tissue progressively encroaches on the surrounding normal skin. Hypertrophic scarring is confined to damaged tissue; it also increases in dimension, but by pushing out its margins, rather than by invasion of surrounding tissue.³

Predisposing factors

Hereditary factors may contribute to a heightened susceptibility to abnormal scar formation,⁴ and several authorities believe that this is specifically the case with keloid scarring, which may occur in the apparent absence of predisposing clinical factors such as trauma or surgery.⁵⁻⁸ In scarred children, hypertrophy is particularly common compared with keloid scarring, which is rare.^{9,10} Abnormal scarring is unknown in animals,^{4,11} and has not been reported in people with albinism.⁷ Its prevalence is increased in the black and Hispanic populations,^{4,7,12} and it has been claimed that keloid scarring occurs with a female:male ratio of 3:1.¹³ Nemeth⁷ suggests that men did not present with keloid scarring of the earlobe until just prior to 1993, when ear-piercing became fashionable in the male population.

Specific body sites have an increased predisposition to develop abnormal scar-

Abnormal scarring; Hypertrophic scarring; Keloid scarring; Silicone gel sheeting; Topical silicone gel

ring, in particular, the presternum, upper back, ears and neck, the upper arms over the deltoid area, the pectoral area of the chest and the lower face.⁴ Hypertrophic scarring is more common across relaxed skin tension lines and flexor surfaces.¹⁰ Excessive scar formation is very rare in the eyelids, penis and areola of the breast; only a small number of cases of corneal keloid have been reported.¹²

Treatment

It has been suggested that hypertrophic scarring can be improved with appropriate surgery, but this is usually unsuccessful with keloids, and may exacerbate the problem.⁷ Recurrence of a keloid scar is probably due to the fact that the new surgical wound is prone to the same mechanical, immunological and biochemical forces as the original scar.¹⁴

Treatments for hypertrophic scarring

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vary and may not be scientifically based.¹⁵ Many studies have been poorly controlled and have produced conflicting results.¹⁶ Treatments include surgical excision, various intralesional and topical pharmacological preparations (specifically steroids), laser surgery, radiation therapy, ultrasound, cryotherapy, cosmetic camouflage, compression therapy, and, since the early 1980s, topical application of silicone gel sheeting.^{12,17-19}

Silicone gel sheeting

Conclusions from experience of using topical silicone as a treatment for scars and contractures following burn injuries were first published in 1983.¹⁷ Silicone gel has been produced in other forms, including cream compounds,²⁰ oil or gel with additives such as vitamin E²¹, combined with other dressing media,²² and as custom-made silicone applications.²³

TABLE 1. HIERARCHY OF EVIDENCE

Category	Type of study	References
1	Systematic review or meta-analysis	None
2	Randomised controlled trial	Sproat et al, ³⁰ Carney et al, ³⁴ Quinn, ³⁵ Gold, ³⁶ Lee et al ³⁷
3	Controlled trial without randomisation	Ahn et al, ³⁹ Ahn et al, ⁴⁰ Dockery and Nilson ⁴¹
4	Quasi-experimental trial	Perkins et al, ¹⁷ Gibbons et al, ³² Quinn, ³⁸ Gold, ⁴² Mercer, ⁴³ Murdoch et al, ⁴⁴ Ohmori ⁴⁵
5	Case report/series	Quinn et al, ²⁸ Ahlering, ⁴⁶ Kavanagh et al, ⁴⁷ Tilkorn et al, ⁴⁸ Burkhardt and Weitz, ⁴⁹ McNee ⁵⁰
6	Narrative/opinion	Perkins et al, ¹⁷ Williams, ²⁶ Laude, ³¹ Davey, ⁵¹ Gollop, ⁵² van den Helder and Hage ⁵³



This review is confined to commercially produced silicone gel sheeting. Formerly obtainable only on prescription, this has been available since 1998 as an over-the-counter preparation.

Silicone gel sheeting is a soft, self-adhesive and semi-occlusive sheet, available in two sizes. It is made from medical-grade silicone (cross-linked polydimethylsiloxane polymer) reinforced with a silicone membrane backing^{24,25} giving that increases durability and ease of handling.²⁶ It is recommended for treatment of abnormal scarring, and as a prophylactic therapy in newly healed wounds to help prevent hypertrophic scarring.^{25,27}

Its precise mode of action is unknown; Quinn et al have stated that any beneficial effect is not due to properties related to pressure, temperature, oxygen tension or occlusion.²⁸ Other researchers suggest that hydration and occlusion are the probable basis of any therapeutic action.^{20,29} It has also been suggested that the softening and reduction of scar tissue results from the hydration of the stratum corneum, or the release of a low-molecular-weight silicone fluid from the gel.³⁰ Silicone gel sheeting is impermeable to many bacteria and other micro-organisms and appears to be inert, since it neither inhibits microbial growth nor alters it in any way.²⁸

No contraindications are described in relation to concurrent use of systemic medications. Moreover, silicone gel sheeting is safe for use with children. It has been suggested that it is more acceptable than intralesional steroid injection and surgical incision,³¹ but some believe that it may not be a viable option for children because of perceived negative results.³²

Methodology

Topical silicone gel therapy is a relatively new treatment. An initial review revealed few studies that seemed worthy of further exploration. This review is particularly concerned with efficacy in relation to scar appearance and size, discomfort (especially pruritis) and mobility. Preliminary searches confirmed that no systematic reviews on management of hypertrophic scarring existed, and very few randomised controlled trials had been performed. A systematic review of the literature pertaining to the application of topical silicone gel sheeting in the management of abnormal scarring was therefore initiated.

Review objectives

This review was designed to answer the question: 'How effective is topical sili-

cone gel sheeting as a treatment for hypertrophic and keloid scarring?' Subsidary questions were formulated to address this broad clinical question, in order to guide the collection of literature and focus the review:

Question 1 Does the application of silicone gel sheeting improve the appearance of hypertrophic or keloid scarring?

Question 2 Does it reduce irritation and discomfort for the patient?

Question 3 Does it improve mobility and function in patients with excessive scarring complicated by disabling contractures?

Question 4 Do patients with abnormal scars experience ease of use and application of silicone gel sheeting?

Inclusion and exclusion criteria

It is recognised that the use of inclusion and exclusion criteria may introduce a degree of bias, but these were defined for the purposes of this review.

Inclusion criteria This review includes published and unpublished literature produced in or after 1983, in the English language (translation was not feasible due to lack of time and financial constraints). It was acknowledged that this decision could lead to the introduction of selection bias by excluding potentially valid contributions. Work had to be received by end of August 1998 to allow time for review and analysis.

The literature must also relate to:

- The application of silicone gel sheeting to either established scars or new, freshly healed scars (including newly healed skin-graft sites)

- The efficacy of topical silicone gel sheeting rather than the intralesional application of silicone in the management of abnormal scarring

- The application of silicone gel in sheet form rather than other preparations, such as creams, or in conjunction with added substances or materials

- Its application without any additives, such as vitamins, or combined with any other dressing media (apart from tapes, crêpe bandages or elastic stockinette used to secure the sheeting)

- The application of silicone gel sheeting that is produced by a recognised manufacturer, rather than a substance made, or customised, by clinical practitioners

- Its application as a cutaneous treatment only

Exclusion criteria Literature was excluded according to the following criteria:

- Multiple publication of the same data; articles were scrutinised to ensure that

the same data were not published under different titles or in different journals

- Animal or *in vitro* studies.

Data collection

The following electronic databases were accessed: Medline, Cinahl, BIDS (Bath Information and Data Services). Searches of the following databases, which contain consolidated and peer-reviewed studies, were also conducted: Cochrane library, Cochrane controlled trials register, Cochrane database of systematic reviews, database of abstracts of reviews of effectiveness (DARE) and Bandolier (an evidence-based healthcare journal). *Journal of Wound Care, Wound Repair and Regeneration* and *Journal of Tissue Viability* were all hand-searched. The Library of the Royal College of Surgeons of England and six medical libraries in the north west of England were visited and many papers were obtained from the the British Library. Recognised authorities on the subject were contacted as part of a postal search. Other articles were found either by chance or from references cited in the literature.

Results

A total of 52 items of literature were initially identified as relevant, five of which were unobtainable. Twenty did not meet the pre-determined criteria. The 27 articles reviewed were graded according to a 'hierarchy of evidence' tool based on an example provided by Guyatt et al³³. No systematic reviews or meta-analyses were found. Fifteen articles (56%) were identified as clinical trials, but the quality of these varied; five (33%)^{30,34-37} were randomised controlled trials, three (20%) were controlled trials without randomisation and seven (47%) had a quasi-experimental design. Six (22%) case reports were reviewed, and six (22%) narratives and opinions.

The literature was divided into categories, as shown in Table 1. The randomised controlled trials are summarised in Table 2. In consideration of the subsidiary questions, analysis of the systematic review produced the following results.

Question 1. Appearance of scarring

The issue of scar appearance, more than any other issue, was addressed by 18 articles.^{28,30,32,34-48}

Category 2 studies Five randomised controlled trials that addressed this topic were identified,^{30,34-37} as follows:

- Carney et al³⁴ are involved in the management of burns; one member of the

group represented a company engaged in the manufacture of silicone gel. This paper primarily evaluated the efficacy and safety of Cica-Care gel sheeting (now produced by Smith and Nephew) compared with Silastic gel sheeting (no longer produced in the UK in that form). There is no reference to commercial involvement, apart from citation details.

Forty-two patients, aged 2-60 years, with a total of 47 hypertrophic scars that could be divided into treated and control areas or two adjacent and comparable areas, were recruited from four hospitals in the UK. Subjects were randomly assigned to receive one of the two therapies. If a patient had been receiving any other form of treatment for the scarring, a period of one month had to have elapsed prior to admission to the trial. If the patient was already experiencing severe irritation, 'weeping' or blistering of the skin, treatment was contraindicated.

Mechanical characteristics of the scars were measured objectively in the control and treated areas, before and after treatment, with an extensometer.³⁸ Patients were given detailed instructions on application and maintenance of the sheeting and encouraged to use it for as many hours each day as possible. Therapy was continued for six months and, if adverse reactions occurred, discontinued until resolution. Patients were reviewed monthly during treatment then at three and six months after treatment was discontinued. Assessment forms were completed at two and six months, when a general assessment of the scar was performed, including measurement with the extensometer. The colour and state of the scar was assessed using a scale that indicates the degree of softening and blanching.⁴⁹ The areas were photographed at each visit and conditions were 'standardised', but no details of these parameters are given.

After two months, 93% of the lesions treated with one preparation and 86% treated with the other were rated as improved, compared with 12% of untreated areas; after six months, these figures were 93%, 100% and 38% respectively. The extensibility of scar areas treated with one or other treatment was significantly greater than that of untreated areas after two months ($p < 0.001$) and six months ($p < 0.04$). There was no statistically significant difference between the two treatments. Adverse effects, described as 'not major', were reported.

■ Donald³⁵ examined a sample population of patients with hypertrophic scarring, who were referred to an Australian hospital over a six-month period. This paper was received from a commercial healthcare company in response to the postal search, and it is not known if it is published. Subjects were randomised to treatment with two different presentations of silicone gel sheeting, one acting as the control. Thirty-one subjects were recruited, aged 18 months to 65 years. Sixteen were randomly assigned to one treatment group and 15 to the other. They were assessed at six weeks and three months using the Vancouver assessment scale,⁵⁰ a tool for evaluating scars on the basis of tissue pigmentation, vascularity, pliability and scar height. There was no statistical difference between the two products, although subjective improvement was reported by all patients with respect to the colour, height and texture of their scars. One product demonstrated greater durability in use and fewer complications than the other.

■ In a three-phase trial conducted in Nashville,³⁶ the author acknowledged that the therapeutic material was provided by a company. Phase 1 aimed to assess the efficacy of silicone gel sheeting in 21 subjects with hypertrophic or keloid scars; Phase 2 assessed its effectiveness in preventing recurrence of keloid scarring following laser removal in eight patients; Phase 3 consisted of five patients with burn scars.

In Phases 1 and 3, the scars were divided into two equal areas, one acting as the untreated control. Patients applied the sheeting to the study area for a minimum of 12 hours a day for 12 weeks. In Phase 2, one keloid scar was treated with silicone gel sheeting from 24 hours postoperatively and a second, on the same part of the body, acted as the untreated control. In Phases 1 and 3, patients and clinicians evaluated the changes in scar thickness and colour, and 'overall effectiveness of the product' every four weeks. Photographs were taken on entry to the trial and at all follow-up assessments, but there is no mention of standardisation in this respect.

Phase 2 patients were evaluated in the same way as Phases 1 and 3, but it is unclear how the area was evaluated after laser removal of the scar. Differences in recurrence rates were assessed. Moderate reduction in scar thickness in the treated area in Phase 1 patients occurred in 33% and 48% of the scars, as assessed by

patient and physician respectively; moderate improvement in colour in 19% and 43% respectively. Overall improvement was observed by 57% of subjects and 24% noted moderate improvement. Clinician evaluation indicated 43% with some improvement and 52% with moderate improvement. The five patients in Phase 3 noted a moderate improvement in one out of the five treated areas, whereas the clinician observed moderate improvement in two out of five. In Phase 2, the recurrence rate of keloid scarring was reported as one of eight treated scars and three of eight non-treated scars.

■ A group from Singapore³⁷ compared the treatment of hypertrophic scars, postoperative scars, tattoo scars and keloids using two types of silicone gel sheeting. Twenty-six patients with a total of 45 scars were entered into the study and the scars were randomly assigned to receive one or other treatment. Twenty-eight scars were allocated to one type of sheeting and 17 to the other. Methods of randomisation are not reported. The treatment was used for 24 hours per day for six months, being removed for washing once in each 24-hour period.

Patients were assessed each month when scars were photographed and rated with respect to colour, texture, thickness and regularity. Both treatments resulted in an improvement of 90% in colour and texture, 80% in regularity and 50% in thickness. Overall improvement in at least two parameters was reported for 80% of the scars after six months. Complications included rashes, pruritis, skin maceration and dryness; these are similar to those reported above.³⁴⁻³⁶ The number of patients reporting adverse effects, however, is not stated; one discontinued treatment due to skin maceration.

■ Researchers in a Canadian department of plastic surgery compared topical silicone gel sheeting with the standard treatment of steroid (Kenalog) injection for established hypertrophic sternal scars following cardiac surgery.³⁰ Financial help in the form of a grant and the supply of materials from a company is acknowledged.

Fourteen subjects were randomised to treatment in one half of the scar with the steroid injection. Silicone gel sheeting was applied to the other half of the scar for 12 hours per day for 12 weeks. Randomisation was achieved by allocating treatment according to a prescribed ran-

TABLE 2. SUMMARY OF RANDOMISED CONTROLLED TRIALS USING SILICONE GEL SHEETING (SGS)

Author/date/ref	No of subjects	Intervention	Outcome
Carney et al (1994) ³⁴	42 subjects (47 scars)	Comparison of two types of SGS	Statistically significant increase in scar extensibility with both interventions; No significant difference between the two interventions; One treatment reported to be easier to use
Donald (1995) ³⁵	31 subjects	Comparison of two types of SGS	Subjective improvement in colour, height and texture of scar in both groups; No difference in effectiveness on Vancouver assessment scale
Gold (1994) ³⁶	<i>Phase 1:</i> 21 subjects <i>Phase 2:</i> 8 subjects <i>Phase 3:</i> 5 subjects Total: 34 subjects	<i>Phase 1:</i> SGS to one randomly assigned portion of scar; other portion as control <i>Phase 2:</i> SGS to area after keloid removal by carbon dioxide laser; adjacent area as control <i>Phase 3:</i> SGS to scars after thermal injury; half the scars treated as in Phase 1	<i>Phase 1 (Patient evaluation)</i> No significant improvement: 19%; Some effectiveness: 57%; Moderate effectiveness 24% <i>Phase 2 (Recurrence)</i> Treated keloids: 1 (13%); Untreated keloids: 3 (38%) <i>Phase 3 (Patient evaluation)</i> Some improvement: 80% Moderate improvement (20%)
Lee et al (1996) ³⁷	26 subjects (45 scars)	Comparison of two types of SGS	No significant difference between the two interventions; Approximately 80% improvement in two or more of set parameters for both treatments
Sproat et al (1992) ³⁰	14 subjects	Comparison of SGS with intralesional steroid injection	Patient preference showed SGS superior to steroid treatment

domised sequence that specified which half of the scar, for each patient, was to receive the treatment. This is the only study reviewed here that describes how randomisation was achieved, and the only one in which results were evaluated by 'blinded' observation. Patient ranking of symptoms was performed, and scar size was measured by a 'blinded' observer.

The primary outcome was patient preference for one or other treatment. Eleven of the 14 subjects preferred the silicone gel. The mean time to symptomatic improvement, as assessed by the patients, was significantly shorter for silicone gel sheeting than for steroid treatment. Pre- and post-treatment photographs were evaluated for colour and appearance by five independent observers at 12 weeks. In 82% of cases, the observers preferred the scars treated with silicone gel sheeting. A complication rate of 7% (transient rash in one patient) was reported.

Category 3 studies The issue of appearance of abnormal scarring was addressed in all three articles in this category.

■ A controlled trial without randomisation was designed by Ahn et al.³⁹ Treatment was applied to 14 scars, for a period of eight weeks, in 10 adults aged 19-78 years. The treated scars and untreated, 'mirror-image' or adjacent control scars were photographed, biopsy specimens taken, and elastometric measurements performed before and after treatment. Photographic conditions were standardised, and photography and elastometry were repeated four weeks after treatment was discontinued.

All scars treated for at least 12 hours per day had improved clinically after four weeks, with further improvement during the second four weeks of treatment. Minor adverse reactions were reported. The authors stated that the perceived efficacy did not appear to be related to patient age, scar age or location, or the method of attachment of the treatment. Despite concerted efforts to obtain reliable colour photographs, the researchers did not consider that these depicted the impressive extent of flattening. They also reported that, although flattening and softening of the scars con-

sistently occurred, scar hyperaemia persisted in many, if not most, instances.

■ In subsequent work, Ahn et al⁴⁰ undertook a trial with two groups (48 patients), with application of silicone gel sheeting to a portion of their scar for at least one month. One group was made up of 29 subjects with surgical incisions made within the previous three months; hypertrophic scarring was either not present or had appeared only recently. The other group of 19 subjects had hypertrophic scars, the majority of which followed burn injury. The conduct of the study was similar to this group's previous work.³⁹

Serial measurements were taken as before,³⁹ with the addition of measurement of scar volume in post-surgery scars; this was calculated by weighing casts of the scars after one and two months. In patients with established hypertrophic scars, elasticity was significantly increased in the treated scars compared with baseline at one month ($p = 0.019$). There was a corresponding improvement that persisted for at least six months. In the post-surgery group, 19/29 completed at least

one month and were assessed. Of the 10 patients (with 11 pairs of scars) who did not complete one month of treatment, the majority were young men with truncal scars, who had little concern about scar appearance. Test and control scars did not differ at study entry but control scar volumes were significantly greater than those of test scars at one month ($p = 0.03$) and two months ($p = 0.003$). Clinical assessment corroborated the quantitative findings. Adverse reactions were reported but none was said to be serious.

■ A study in Seattle reported the effects of topical silicone gel sheeting to scars on the lower extremities of 94 patients aged 11-73 years.⁴¹ Not all applications of the intervention were compared to a control as the therapy was applied 'on a portion or all' of the scar, and applied for 24 hours per day for up to two months, being removed only for bathing and for cleaning or replacement. Improvement was assessed by both patients and clinicians. Eighty patients had true hypertrophic scars and these were found to respond at much better than those with keloid scars. The overall success rate was reported as being high, with 95% greatly or somewhat improved.

Category 4 studies: Scar appearance was addressed in six of the seven quasi-experimental trials in Category 4.

■ In an uncontrolled study, the treatment was used in five children aged 2-12 years, each with a hypertrophic scar.³² The age of scarring was 2-16 months and the duration of treatment was 0.25-8 months (mean 4.25). The patients were instructed to wear the treatment for at least 12 hours per day. The Vancouver assessment scale⁵⁰ was used to evaluate the effects of therapy, with positive results in three of the five cases. These included reduction in scar size, thickness and vascularity, softening of the scar and more uniform pigmentation. However, many negative responses were also documented, including rash, skin breakdown, cessation of scar responsiveness, problems with application of the sheeting and poor durability of the medium. The authors conclude that Silastic gel sheeting may not be a viable option for treatment of children with this problem. With a study of this size it is difficult to accept their findings as conclusive.

■ In an uncontrolled trial, Gold⁴² treated 11 patients with hypertrophic scarring secondary to surgery or trauma; the scars were evaluated by patients and clinicians

for colour, thickness and overall effectiveness of treatment. Ten patients aged 16-42 years with a total of 16 scars completed the study and were assessed.

Moderate improvement was noted in scar thickness by 81% of patients and in scar colour by 75%; 100% noted moderate overall effectiveness. Clinician evaluation revealed moderate improvement in thickness in 50% and colour in 69%, with moderate overall effectiveness in 94%. One scar was rated by the clinician as achieving 'complete resolution', and no adverse reactions were reported. Gold recognises that the study design is inadequate and may lead to inherent bias. He considers this preliminary work before embarking upon a more recent trial.³⁶

■ A plastic surgeon in Bristol applied silicone gel sheeting to keloid scars that had resulted from causes other than burn injury.⁴³ The treatment was given to 18 patients, aged 3-64 years, with a total of 22 scars. Treatment was applied for six months, initially for one hour per day, increasing to eight hours, after which patients were advised to wear it continually, removing it only for washing or while participating in sports. Results were assessed after one month and then at intervals of two or three months. Scars were photographed and graded for texture, colour and height. Nineteen (86%) scars showed an improvement in one or more parameter; nine (41%) improved in all three parameters and a further nine in two parameters. Texture was the first to alter, usually in the first 2-3 months of treatment; colour and height changed more slowly. Adverse reactions were reported as 'mild'. Due to lack of standardisation, the photographs were unhelpful in assessing the majority of scars.

■ A group at the London Hospital undertook an uncontrolled trial involving the application of silicone gel sheeting to nine keloid scars in seven patients.⁴⁴ The treatment was applied for 24 hours per day, being removed and changed during bathing; patients were reviewed monthly for up to three months. Evidence of benefit was usually observed at the first clinical assessment; all patients apparently experienced some benefit. The authors do not report how they assessed progress in this small number of patients. They found it 'striking' that all patients experienced some benefit but 'felt that efficacy would be improved by the concomitant use of a potent topical steroid'; no scientific rea-

soning is offered for this suggestion. One case report is also discussed, describing the application of silicone gel sheeting in conjunction with a potent topical steroid.

■ In an open study, 49 subjects with keloid scars were treated with silicone gel sheeting.⁴⁵ Three discontinued treatment because of sensitivity to the adhesive tape – this may be due to the method of application, which involved taping the gel 'tightly' across the scar for 8-12 hours daily. Results were obtained from 48 scars in 46 patients. Participants were advised to wash the silicone gel sheeting with soap and water at least once each week, which would almost certainly increase the risk of skin breakdown and subsequent maceration or rash. Manufacturers now recommend gentle washing once or twice per day. Duration of treatment varied from 2-14 months and the scars were evaluated according to redness, elevation and subjective complaints, such as an itchiness or painful sensation. Results were classified into four characteristics; excellent = response in all three characteristics, good = response in two characteristics, fair = response in one characteristic and poor = no response. Six scars had an excellent response, 24 good, 12 fair and six poor.

■ The first reported study to discuss the use of silicone gel sheeting in relation to the management of hypertrophic or keloid scars was undertaken in a burns unit in an Australian children's hospital and published in 1983.¹⁷ The authors' treatment regimen was used in 42 patients with healed scars following burn injury, with no understanding of the perceived benefits. Application was by 'trial and error'. Patients were aged four months to 16 years and the injuries ranged from newly healed burns to mature scars up to 12 years old.

It is unclear whether or not this is a retrospective description of results. Twenty patients were already receiving pressure treatment when the intervention was introduced. All 42 patients not only showed 'significant improvement' but also found the treatment to be virtually pain-free. This paper is a frequently cited reference, but it contains no robust scientifically controlled evidence.

■ Quinn specifically investigated the mode of action of silicone gel sheet,³⁸ and examined, to a lesser degree, the efficacy of the intervention in the manage-

ment of hypertrophic scarring. The treatment was applied to 125 patients with a total of 129 hypertrophic or keloid scars. Scar improvement was rated after two months on the basis of texture (measured by extensometer), colour and thickness. Colour and thickness were measured by photography but there is no mention of standardisation or specific results using this method.

Improvement was reported in one or two of these criteria in 65 scars and in all three criteria in 10; 37 patients did not return for follow-up. Adverse events were reported, including pruritis and rash which were normally eliminated with frequent washing of the scar and the sheeting. In three cases, tissue breakdown occurred and the author recommended that the gel should not be applied until healing was completed.

Categories 5 studies The remaining literature that addressed the question of appearance consists of four papers presenting single or multiple case reports (Category 5).

■ A nurse in San Francisco discusses the management of a patient who received 30% second- and third-degree burns to his abdomen and eventually developed 'tightness, pain and elevation' of the scars.⁴⁶ Over a period of two years he received various treatments, including topical steroids and pressure therapy. Within three months of commencing treatment with silicone gel sheeting he noticed a marked decrease in scar colour, pain, thickness and firmness. The patient continued with the treatment, replacing it every three months; resolution of the problem is not reported.

■ One case of hypertrophic scarring following toxic epidermal necrolysis is described.⁴⁷ Scarring was widespread over the patient's back and buttocks, resulting in reduced mobility of the neck and shoulders. The intervention was applied for six weeks with a retention bandage, and with a custom-made pressure garment for a further four weeks. The authors observed softening of the scars in the initial two weeks, and continued improvement over the ensuing eight weeks, when full range of neck movement was regained. A 'marked' improvement in cosmetic appearance was noted.

■ In 1985, Quinn et al²⁸ investigated the mode of action of silicone gel sheeting in 39 patients with hypertrophic scars and

one with a keloid scar. Patients were aged 1-67 years and the duration of the scars varied from one month to 12 years. After two months of treatment some improvement was reported, which did not appear to be related to patient age or method of attachment of the sheeting.

■ Three case reports are presented by a group of dermatologists and plastic surgeons in Germany.⁴⁸ All discuss management of keloids with silicone gel sheeting following excisional surgery and positive results are reported.

Question 2. Irritation and discomfort

A total of only six articles in this review refer to this problem, in general terms and with little detail. None exclusively addresses pruritis and its associated discomfort. Of the literature that does consider the issue, there is one randomised controlled trial (Category 1)³⁴ and one controlled trial without randomisation (Category 2).³⁹ The remaining four articles comprise three trials performed without randomisation or controls (Category 4)^{17,44,45} and one case report (Category 5).⁴⁶

■ In the randomised controlled trial by Carney et al,³⁴ irritation (as described by the patient) was assessed on a scale of 0-5, but no results related to this assessment are published. The authors point out that pruritis is often a feature of hypertrophic scarring and that it affected 48% of subjects on entry to the trial; this makes it difficult to identify irritation as an adverse effect of the therapy.

■ Ahn et al³⁹ included pruritis as a parameter in the clinical evaluation of therapy but make no specific referral to this in their results. They present some brief case reports and discuss a hypertrophic scar in a 21-year-old woman; following two months of treatment with silicone gel sheeting, the scar was softer, flatter, paler and more durable, and the pruritis had subsided.

■ In a study of seven patients with keloid scarring, itching was 'markedly relieved' in one and 'fully relieved' in two patients following topical silicone gel therapy.⁴⁴

■ Ohmori⁴⁵ included a subjective assessment of 'an itchy or painful sensation' in the parameters for a non-randomised and uncontrolled trial of silicone gel sheeting as treatment for 49 patients with keloid scars. Again, there is no specific reporting of the outcome concerning this factor.

■ Quinn advises that 'careful attention to hygiene, silicone gel eliminates the pruritis normally associated with immature hypertrophic scars',³⁸ but does not explain further.

■ In Ahlering's case report,⁴⁶ pruritis is briefly mentioned as a presenting complaint but it is not stated whether this was influenced by treatment with silicone gel sheeting.

Question 3: Mobility and function

Five of the articles reviewed here consider this issue.

■ One controlled non-randomised trial³⁹ pays brief attention to this serious problem, stating that 'permissible range of motion (if applicable)' will be clinically evaluated. This issue is not referred to in the results section.

■ Perkins et al¹⁷ give more consideration to the subject, but do not offer any rigorous data. They report what appears to be anecdotal evidence concerning the first patient to receive treatment with silicone gel sheeting, for contractures due to abnormal scarring. The patient was unable to flex the metacarpophalangeal joints in his right hand, due to hypertrophic scarring following burn injury; within 30 minutes of application, they report that he was able to move these joints through to full flexion.

■ The remaining articles do not provide objective or robust evidence on this question. Four case reports are entirely concerned with the effect of silicone gel sheeting on hypertrophic scarring that caused disabling contractures following surgery for excision of cancerous tumours.⁴⁹ One patient gained improved range of motion and the remaining three regained full range of motion.

■ The use of silicone gel sheeting is reported for scar contractures in four patients sustaining burns or trauma to the hands or arms.⁵⁰ The authors maintain that all four had 'greatly improved' range of motion.

Question 4. Ease of use and application

This issue was referred to in almost all the work reviewed. The majority of authors considered the treatment easy to use. For the most part, discussion around application and ease of use for the patient was incidental. Some authors gave more consideration than others to

the durability of silicone gel sheeting, usually when a comparison was being made between two different products, as in three of the randomised controlled trials.^{34,35,37} These researchers did not specifically ask about ease of application. Gibbons et al³² considered that durability of the sheeting was a problem with most of their patients. Replacement was on a daily basis in some patients because it was 'too difficult to handle'. Neither Gold⁴² nor Murdoch⁴⁴ provide any objective validation of the ease of use and application for the patient.

Conclusion

The 18 articles addressing Question 1 were of varying quality and validity. All but one³² recommend future use of the intervention as positive results were reported. These results were all based on assessment of the appearance of the lesions and the majority of researchers reported that the patient was involved in that assessment. Weighing up this collective evidence, despite its sparsity and subjectivity, this researcher considers that the intervention appears to improve the appearance of hypertrophic and keloid scarring.

There was insufficient evidence to answer Questions 2 and 3. It is possible that pruritis is not a significant problem and the logical step may therefore be the instigation of research to establish this. Of the little work that has been done on mobility and function, physiotherapists and occupational therapists were the prominent clinicians. This appears to be an ideal area for a multi-professional randomised controlled trial.

Some researchers anecdotally reported satisfaction with the handling of silicone gel sheeting, but there was no evidence to answer Question 4, especially from the patient's point of view.

Limitations of the review process

Although the prime aim of this work was to produce a systematic review of all literature in relation to the research question, it cannot necessarily be claimed that this has been accomplished. For example, unknown or unpublished literature may exist. Performing a systematic literature review is not a completely objective activity and if workers are to remain wholly impartial when undertaking the task, there is a case for proposing that more than one researcher is employed.

It could be said that this systematic review has produced little robust litera-

ture and may even be viewed as a thorough critique of the literature. It was, however, guided by a clear research question and four clinical questions, which enabled it to be clearly focused. An explicit search strategy and inclusion and exclusion criteria should allow bias to be recognised by the reader and rigour to be demonstrated by the researcher. The lack of scientific study in the area reviewed has been demonstrated. ■

REFERENCES

- Munro, K.J.G. Hypertrophic and keloid scars. *J Wound Care*, 1995; **4**: 3, 143-148.
- Gollop, R. Burns aftercare and scar management. In: Bosworth, C. (ed). *Burns Trauma*. London: Baillière Tindall, 1997.
- Peacock, E.E., Van Winckle, W. *Wound Repair* (2nd edn). Philadelphia: WB Saunders, 1976.
- O'Sullivan, S.T., O'Shaughnessy, M., O'Connor, T.P.F. Aetiology and management of hypertrophic scars and keloids. *Ann R Coll Surg Engl* 1996; **78**: 168-175.
- Pape, S.A. The management of scars. *J Wound Care*, 1993; **2**: 6, 354-360.
- Chait, L.A., Kadwa, M.A. Hypertrophic scars and keloids. *S Afr J Surg* 1988; **26**: 95-98.
- Nemeth, A.J. Keloids and hypertrophic scars. *J Dermatol Surg Oncol* 1993; **19**: 738-746.
- Berman, B., Bielek, H.C. Keloids. *J Am Acad Dermatol* 1995; **33**: 1, 117-123.
- Muir, I.F.K. On the nature of keloid and hypertrophic scars. *Br J Plast Surg* 1990; **43**: 61-69.
- Stevens, D.R. Scars and scar revision. In: Grotting, J.C. (ed). *Reoperative Aesthetic & Reconstructive Plastic Surgery*, Vol 1. St Louis, MO: Quality Medical Publishing, 1995.
- Tredget, E.E., Nedelec, B., Scott, P.G., Ghahary, A. Hypertrophic scars, keloids, and contractures. *Surg Clin N Am* 1997; **77**: 3, 701-730.
- Datubo-Brown, D.D. Keloids: a review of the literature. *Br J Plast Surg* 1990; **43**: 70-77.
- Lee, C.P. Keloids: their epidemiology and treatment. *Internat J Dermatol* 1982; **21**: 9, 504-505.
- Alster, T.S., West, T.B. Treatment of scars: a review. *Ann Plast Surg* 1997; **39**: 4, 418-432.
- Carney, S.A. Hypertrophic scar formation after skin injury. *J Wound Care* 1993; **2**: 5, 299-302.
- Ellitsgaard, V., Ellitsgaard, N. Hypertrophic scars and keloids: a recurrent problem revisited. *Acta Chir Plast* 1997; **39**: 3, 69-77.
- Perkins, K., Davey, R.B., Wallis, K.A. Silicone gel: a new treatment for burn scars and contractures. *Burns*, 1983; **9**: 201-204.
- Dockery, G.L. Hypertrophic and keloid scars. *J Am Podiatr Med Assoc* 1995; **85**: 1, 57-60.
- Munro, K.J.G. Treatment of hypertrophic and keloid scars. *J Wound Care* 1995; **4**: 5, 243-245.
- Sawada, Y., Sone, K. Treatment of scars and keloids with a cream containing silicone oil. *Br J Plast Surg* 1990; **43**: 683-688.
- Palmieri, B., Gozzi, G., Palmieri, G. Vitamin E added silicone gel sheets for treatment of hypertrophic scars and keloids. *Internat J Dermatol* 1995; **34**: 7, 506-509.
- Davey, R.B., Wallis, K.A., Bowering, K. Adhesive contact media: an update on graft fixation and burn scar management. *Burns*, 1991; **17**: 4, 313-319.
- Hirshowitz, B., Lindenbaum, E., Har-Shai, Y. et al. Static-electric field induction by a silicone cushion for the treatment of hypertrophic and keloid scars. *Plast Reconstr Surg* 1998; **101**: 5, 1173-1183.
- Katz, B. Silastic gel sheeting is found to be effective in scar therapy. *Cosmet Dermatol* 1992; **6**: 1-3.
- Thomas, S. *Dressing Data Cards*, (Cica-Care). SMTL, 1997. Online: <URL: <http://www.smtl.co.uk/WWorld-Wide-Wounds/index.html>>
- Williams, C. Cica-Care: adhesive gel sheet. *Br J Nurs* 1996; **5**: 14, 875-876.
- Clugston, P.A., Vistnes, M.D., Perry, L.C. et al. Evaluation of silicone-gel sheeting on early wound healing of linear incisions. *Ann Plast Surg* 1995; **34**: 1, 12-15.
- Quinn, K.J., Evans, J.H., Courtney, J.M. et al. Non-pressure treatment of hypertrophic scars. *Burns* 1985; **12**: 102-108.
- Sawada, Y., Sone, K. Hydration and occlusion treatment for hypertrophic scars and keloids. *Br J Plast Surg* 1992; **45**: 599-603.
- Sproat, J.E., Dalcin, A., Weitauer, N., Roberts, R.S. Hypertrophic sternal scars: silicone gel sheet versus Kenalog injection treatment. *Plast Reconstr Surg* 1992; **90**: 6, 988-992.
- Laude, T.A. Skin disorders in black children. *Curr Opin Paediatr* 1996; **8**: 381-385.
- Gibbons, M., Zuker, R., Brown, M. et al. Experience with silastic gel sheeting in paediatric scarring. *J Burn Care Rehabil* 1994; **15**: 1, 69-73.
- Guyatt, G.H., Sackett, D.L., Sinclair, J.C. Users' guides to the medical literature. IX. A method for grading healthcare recommendations. *JAMA* 1995; **274**: 1800-1804.
- Carney, S.A., Cason, C.G., Gower, J.P. et al. Cica-Care gel sheeting in the management of hypertrophic scarring. *Burns* 1994; **20**: 2, 163-167.
- Donald, L. Comparison of 2 types of silicone gel sheets. *Australian/New Zealand Burns Association (ANZBA)*, 1995; 10-11.
- Gold, M.H. A controlled clinical trial of topical silicone gel sheeting in the treatment of hypertrophic scars and keloids. *J Am Acad Dermatol* 1994; **30**: 3, 506-507.
- Lee, S.M., Mgin, C.K., Chan, Y.Y., Ho, M.J. A comparison of Sil-K and Epiderm in scar management. *Burns* 1996; **22**: 6, 483-487.
- Quinn, K. Silicone gel in scar treatment. *Burns* 1987; **13**: S33-S40.
- Ahn, S.T., Monafu, W.W., Mustoe, T.A. Topical silicone gel: a new treatment for hypertrophic scars. *Surgery*, 1989; **106**: 4, 781-787.
- Ahn, S.T., Monafu, W.W., Mustoe, T.A. Topical silicone gel for the prevention and treatment of hypertrophic scar. *Arch Surgery* 1991; **126**: 499-504.
- Dockery, G.L., Nilson, R.Z. Treatment of hypertrophic and keloid scars with Silastic Gel Sheeting. *J Foot Ankle Surg* 1994; **33**: 2, 110-119.
- Gold, M.H. Topical silicone gel sheeting in the treatment of hypertrophic scars and keloids. *J Dermatol Surg Oncol* 1993; **19**: 912-916.
- Mercer, N.S.G. Silicone gel in the treatment of keloid scars. *Br J Plast Surg* 1989; **42**: 83-87.
- Murdoch, M.E., Salisbury, J.A., Gibson, J.R. Silicone gel in the treatment of keloids. *Acta Derm Venereol (Stockh)*, 1990; **70**: 181-183.
- Ohmori, S. Effectiveness of silastic sheet coverage in the treatment of scar keloid (hypertrophic scar). *Aesthetic Plast Surg* 1988; **12**: 95-99.
- Ahlering, P.A. Topical silastic gel sheeting for treating and controlling hypertrophic and keloid scars: case study. *Dermatol Nurs* 1995; **7**: 5, 295-297.
- Kavanagh, G.M., Page, P., Hanna, M.M. Silicone gel treatment of extensive hypertrophic scarring following toxic epidermal necrolysis. *Br J Dermatol* 1994; **130**: 4, 540-541.
- Tilkorn, H., Ernst, K., Osterhaus, A., Schubert, A., Schwipier V. The protruding scars: keloids and hypertrophic. Diagnosis and treatment with Silicon-Gel-Sheeting. *Polymers in Medicine*, 1994; **24**: 1-2, 31-44.
- Leung, K.S., Cheng, J.C.Y., Leung, K.Y. *In vitro* study of the mechanical properties of post-burn hypertrophic scar tissues. *J Burn Care Rehabil* 1984; **5**: 458.
- Sullivan, T., Smith, J., Kermode, J. et al. Rating the burn scar. *J Burn Care Rehabil* 1990; **11**: 3, 256-260.
- Burkhardt, A., Weitz, J. Oncologic applications for silicone gel sheets in soft-tissue contractures. *Am J Occup Ther* 1991; **45**: 5, 460-462.
- McNee, J. The use of silicone gel in the control of hypertrophic scarring. *Physiotherapy*, 1990; **76**: 4, 194-197.
- Davey, R.B. The use of contact media for burn scar hypertrophy. *J Wound Care*, 1997; **6**: 2, 80-82.
- Gollop, R. The use of silicone gel sheets in the control of hypertrophic scar tissue. *Br J Occup Ther*, 1988; **51**: 7, 248-249.
- van den Helder, C.J.M., Hage, J.J. Sense and nonsense in scar creams and gels. *Aesthetic Plast Surg*, 1994; **18**: 307-313.