KATHY FARQUHAR

Silicone gel and hypertrophic scar formation: A literature review

KEY WORDS
Burns
Cicatrix
Silicone elastomers
Wound healing

ABSTRACT Since 1982 a number of studies have investigated the use of silicone gel sheets in the prevention and reduction of hypertrophic scar formation. The statistical significance of several of these studies has been reduced by poor standardization of research methods, and the lack of a reliable and valid method of assessing hypertrophic scarring. When these studies are considered together, however, several clinically significant trends become apparent. The application of silicone gel appears to normalize the texture, colour, evaluation, and occurrence of subjective complaints (i.e., pain and pruritis) typically associated with hypertrophic scarring. These results are independent of the patient's age, method of attachment of the gel, or the location, age, or cause of the scar. The most appropriate treatment protocol for the application of silicone gel has yet to be determined. Current literature suggests that daily wearing tolerance be developed over the course of one to two weeks, the gel and scar be cleaned twice daily, and skin monitored regularly for signs of irritation. The optimal duration of treatment has not been established. Further research using standardized procedures and valid, reliable methods of measurement are required before this treatment can be ethically used to replace more established treatment techniques. However, the literature currently available would indicate that silicone gel may be an effective treatment technique for the prevention and reduction of hypertrophic scar formation following burn injury.

RÉSUMÉ Depuis 1982, différentes études se sont penchées sur l'utilisation des feuilles en gel de silicone pour la prévention et la diminution des cicatrices hypertrophiques. L'interprétation statisique de plusieurs de ces études a été réduite à cause d'un manque d'uniformité des méthodes de recherche, le manque d'une méthode fiable et valide pour l'évaluation des cicatrices hypertrophiques. Toutefois, lorsque ces études sont regroupées, plusieurs tendances cliniques significatives ressortent. L'application du gel de silicone semble normaliser la texture, la couleur, l'épaisseur et la fréquence des malaises subjectifs (i.e. douleur et démangeaisons) typiquement associés aux cicatrices hypertrophiques. Ces résultats sont indépendants de l'âge du patient, de la méthode de mise en place du gel, de la cicatrisation, de l'âge ou de la cause de la cicatrice. Le protocole de traitement le plus approprié pour l'application du gel de silicone reste cependant à déterminer. La documentation actuelle suggère que la tolérance quotidienne se fasse sur une période de deux semaines, le gel et la cicatrice devant être nettoyés deux fois par jour et la peau vérifiée régulièrement pour la détection de signes d'irritation. La durée optimale du traitement n'a pas été établie encore. Des recherches futures utilisant des procédures standardisées et des méthodes de mesures fiables et valides sont nécessaires avant l'utilisation sécuritaire de ce traitement en remplacement des techniques déjà éprouvées. Toutefois, il ressort de la documentation actuelle disponible que le gel de silicone peut être une technique de traitement efficace pour la prévention et la diminution des cicatrices hypertrophiques consécutives aux brûlures.

Kathy Farquhar, B.Sc., OT(C) is an Occupational Therapist at George Jeffrey Children's Treatment Centre, 507 N. Lillie St., Thunder Bay, Ontario, P7C 4Y8.

Hypertrophic scarring can be a devastating consequence of burn injury, affecting both appearance and function. Effective treatment of hypertrophic scar formation has long been the subject of controversy in the literature. At present, the most widely accepted technique for the prevention and reduction of hypertrophic scarring is the application of pressure by a variety of means including custom-fitted splints and pressure garments (Quinn, Evans, Courtney, Gaylor, & Reid, 1985). However, uniform pressure is often difficult to achieve. In attempting to design a system which would provide uniform pressure to all anatomical regions, Perkins, Davey, and Wallis (1982) discovered that the application of silicone gel sheets alone had therapeutic effects on burns ranging from newly healed wounds to mature scars. A number of studies have since been completed investigating the effectiveness of the gel sheets; however, no conclusive evidence has been presented regarding the most appropriate use of the gel sheets in the therapy process. The mechanism of action by which the results occurred is as yet unknown (Quinn, 1987).

This paper examines, through a review of the literature, the effectiveness of silicone gel sheets in the prevention and reduction of hypertrophic scar (keloid) formation following burn injury. The process of hypertrophic scar formation is described and a critical review of the relevant literature regarding the efficacy of silicone gel application in the prevention and reduction of hypertrophic scar formation is presented, followed by an overview of the methods currently available for measuring hypertrophic scars. Finally, a protocol for the use of silicone gel sheets in the treatment of burns, given the current knowledge base, is proposed along with suggestions for further research.

Hypertrophic Scar Formation

The process of tissue healing occurs in four stages: inflammation, fibroplasia, scar maturation, and wound contracture (Fess & Philips, 1987). Inflammation is characterized by an influx of healing agents to the injured tissue. Fibroplasia involves the formation of granulation tissue, and the synthesis and deposition of collagen. This phase results in dense tissue made up primarily of randomly oriented collagen fibers. Scar maturation is characterized by the continuous synthesis and breakdown of collagen resulting in a strengthening of the tissue; if synthesis occurs at the greater rate than breakdown, a hypertrophic scar may result (Fess & Philips, 1987). This continued metabolic activity of seemingly mature scars forms the basis of attempts to modify or reduce mature scars through the application of pressure (Law, 1982). Wound contracture begins two to three days post-injury and leads to a significant decrease in the diameter of the wound at the cost of tightening of the surrounding tissues (Fess & Philips, 1987).

According to Law (1982), filaments known as myofibroblasts are present in granulation tissue and abundant in immature scars, while being generally absent from older mature scars. These filaments attach to the surrounding tissues by way of foot plates and subsequently contract in a manner similar to smooth muscle. This contraction of the scar tissue results in the formation of collagen whorls and nodules.

Hypertrophic scars are characteristically red, raised, and itchy or painful (Ohmori, 1988). A keloid possesses these three characteristics and extends outside of the boundaries of the original wound (Law, 1982). The somewhat subjective nature of these definitions makes it difficult to measure objectively the severity of hypertrophic scarring and the effects of various treatment techniques aimed at preventing and reducing it.

Effectiveness of Silicone Gel in the Treatment of Hypertrophic Scarring

Silicone gel sheets are a relatively new approach to the prevention and reduction of hypertrophic scarring. Studies of the action of the gel sheets have been inconclusive, and evidence regarding the efficacy of the treatment technique has only recently begun to appear in the literature. Reviewed below is the literature currently available on the mode of action and effectiveness of the application of silicone gel in the treatment of hypertrophic scars.

Mode of Action

Quinn et al (1985) investigated both the properties of the gel (mechanics, bacteriology, water vapor transmission rate, and appearance in the scanning electron microscope) and the physical (pressure, temperature, oxygen tension, and hydration and occlusion) and chemical (silicone fluid) effect of the gel on scars. These investigators found that the gel had an extensibility approximately equal to that of skin; therefore, it is sufficiently elastic to cover joints while still allowing normal movement. Bacteriological investigations revealed that the gel is impermeable to bacteria and neither inhibits nor enhances bacterial growth. In the scanning electron microscope the surface of the gel appears flat and non-porous. With respect to the physical effects on the scar, it was determined that: 1) the pressure exerted by the gel is negligible in terms of any therapeutic effect; 2) the gel does not cause any lasting change in the temperature of the scar tissue; and 3) the gel has no effect on the rate of oxygen transmission to and from the scar. However, the gel has an evaporative water loss approximately half that of skin although the scar does not look or feel wet upon

removing the gel sheet. A related test discovered that creating the same hydration effect by applying a gel sheet with a occlusive covering did not have the same therapeutic effect following a 2 month trial as did application of the gel sheet alone. These findings suggest that hydration may play a role in the action of gel sheets but that a factor intrinsic to the gel sheets is partially responsible for their therapeutic effect.

Quinn et al (1985) suggest that this factor is a low molecular weight silicone fluid released from the gel onto the scar surface in situ. Studies investigating the effects of immersion in silicone fluid on burn wounds and hypertrophic scars provide some support for this idea. Helal, Chapman, Ellis, and Gifford (1982) treated 45 patients with a variety of wounds using silicone immersion therapy. They found that this treatment led to decreased pain during movement, increased mobilization, decreased drying of the scar tissue, earlier separation of necrotic and infected tissues, and a decreased need for surgical intervention. Miller, Hardy, and Spira (1965) investigated the effects of silicone immersion therapy on the hands of eight patients with severe burn injuries. Treatment resulted in increased mobilization, decreased pain, and early separation of the eschar allowing early grafting. Such results support the idea that a low molecular weight silicone fluid released from the gel may play a role in the efficacy of the application of silicone gel to hypertrophic scars. The hydration effects of the gel described by Quinn et al (1985) may also have some effect on scar tissue.

Review of Recent Studies

Since 1982 several studies have been published which appear to support the efficacy of silicone gel in the treatment of hypertrophic scarring. However, because the application of pressure through the use of pressure garments or custom-fitted splints has produced clinically significant results for a number of years, it would be unethical for a therapist to implement a relatively new treatment technique without statistically and clinically significant results supporting its effectiveness. Therefore, it is important to critically evaluate the studies which are available in order to make informed decisions, and to identify gaps in the literature which require further investigation. To this end, six studies are assessed below according to research design, method of measurement, and results. The following table summarizes the subjects, control measures, designs, methods of measurement used, and significant results of these studies.

Perkins, Davey, and Wallis (1982) were the first to study the effects of silicone gel sheets on burn scars. They incorporated gel sheets into the treatment regimes of children recovering from burn injuries (newly healed burns to 12 years post-injury). While the authors fail to describe clearly the protocol for application, the gel sheets were apparently applied for increasing periods of time until they were tolerated continuously. No method of measurement or duration of treatment is reported. It is assumed that the subjects were chosen by convenience sampling and no techniques were employed to reduce the effects of confounding variables such as spontaneous improvement or improvement due to adjunctive therapies.

The authors report that significant improvement occurred in all 42 patients. For those subjects with contracted scars, surgery was avoided in one case and only minimal surgery was required in the other. However, no information is available regarding the standardization, reliability, or validity of the methods used by the experimenters to measure hypertrophic scarring. Although the results cannot be considered as statistically significant, the finding that the treatment is pain-free may be clinically significant.

Quinn, Evans, Courtney, Gaylor, & Reid (1985) evaluated the effects of the application of silicone gel to 40 hypertrophic scars or keloids, rated initially with respect to texture, colour, and extent to which the scar was raised. Silicone gel was then applied to all scars and secured by a variety of means. Scars were again rated after 2 months of treatment. It is assumed that sampling was performed according to convenience.

The texture of the scars was assessed using a device which was not clearly described in the study (it is assumed to be an elastometer) and through subjective assessment by the examiner. Colour was judged by observing whether the scar blanched when an unspecified amount of pressure was applied, and through the use of comparative photography. The extent to which the scar was raised was also evaluated using comparative photography. No rating scales or set protocols for assessment are discussed in the study. There is no evidence provided regarding the reliability and validity of the measurement techniques employed. Because of these shortcomings, caution must be used in accepting the findings.

Improvement in at least one of the variables measured was observed in all 40 cases following a 2 month application of silicone gel, apparently unrelated to the method by which the gel was attached. The authors suggest that there is a reduction in pruritis upon application of silicone gel to the scar; however, there is no indication of how this was assessed. They also state that silicone gel should be worn continuously but that therapeutic effects can be achieved with a wearing schedule of only 12 hours per day. No statistical analysis of the results is presented; the statistical significance is therefore unknown.

Despite this lack of statistical support, the results are to some degree clinically significant, suggesting that

Table 1
Overview of Recent Studies

Author	Subjects	Control of Confounding Variables	Design	Method of Measurement	Significant Results
Perkins et al. (1982)	n=42 Ages 4 mos to 16 yrs	No control groups or tissue samples are reported	Pressure with gel (n=20) Gel applied prior to planned surgical intervention (n=2) Gel alone (n=20)	Not described	Treatment was reported to be pain free
Quinn et al. (1985)	n=40	No control groups or tissue samples are reported	Gel applied 12 to 24 hrs/day using crêpe bandages, adhesive tape, silicone-based adhesive, or pressure garments	Subjectively assessed by the experimenter, comparative photography, unspecified device	All cases were reported to show improvement at 2 mos Decreased pruritis Results appear to be independent of age of scar or method of attachment
Ahn et al. (1989)	n=14 scars in 10 patients Ages 19 to 78 yrs	Control area of scar tissue on same scar or on paired anatomical site Standardized measurement procedures	Gel applied up to 24 hrs/day for 8 weeks. Scars were assessed at 4, 8, and 12 weeks	Clinical evaluation, comparative photography, elastometry, punch biopsy specimens	All scars showed improvement at 4, 8 and 12 weeks No improvement was seen in 3 cases treated less than 12 hrs/day Effectiveness not related to patient age, scar age, scar location, or method of attachment
Ohmori (1988)	(n=51) n=48 at completion	No control groups or tissue samples are reported	Silastic sheets applied 8 to 12 hrs/day using adhesive tape for 2-14 months	Rated number of scar symptoms which improved	Effectiveness is independent of the age, location, or cause of the scar
Quinn (1986)	(n=122) n=71 at completion	No control groups or tissue samples are reported	Silicone gel was applied 24 hrs/day using crêpe bandages, adhesive tape, silicone-based adhesive, or pressure garments	Comparative photography, elastometry	Reduced pruritis Early re-epithelialization and no evidence of later scarring in unhealed wounds
Mercer (1989)	n=22 scars in 18 patients	No control groups or tissue samples are reported	Gel was applied 24 hrs/day using adhesive tape, support bandages, or pressure garments	Rated by experimenter as to texture, colour, and height, comparative photography (reported to be ineffective)	Improvement in 86% Improvement is independent of patient age, scar age, or method of fixation Painless, unobtrusive, few side effects, inexpensive

silicone gel can affect all three characteristics of hypertrophic scars and can be effective in treating both new and established hypertrophic scars. Although this research failed to disprove the null hypotheses that silicone gel is ineffective in preventing and reducing hypertrophic scarring, further research is warranted.

Ahn, Monafo, and Mustoe (1989) studied the effects of the application of silicone gel sheets to 14 hypertrophic scars in 10 patients. In this experiment silicone gel was applied to a 6 cm by 7 cm area of scar and fixated using a crepe bandage, gauze and adhesive tape, an elastic bandage, or an elastic compression garment. The gel was to be worn for at least 12 hours per day but patients were requested to wear it 24 hours per day if possible, removing it briefly twice daily to clean the scar. Prior to application of the gel the scars were photographed, measured elastometrically, clinically evaluated, and biopsy specimens were taken. At 4 weeks the photographs and elastometric readings were repeated. Following 8 weeks of treatment the photographs, biopsy specimens, clinical evaluation, and elastometric readings were repeated and treatment was stopped.

It is assumed that the subjects were chosen by convenience sampling as no formal sampling procedure was described. All subjects showed evidence of hypertrophic scarring (2 months to 4 years post-injury) from either burn injuries (12 of the 14 scars studied), spider bite (1 scar), or surgical incision and drainage (1 scar). The authors recognize that the number of subjects is small; they suggest that the data should therefore be considered preliminary and that the findings cannot be generalized to the treatment of children as all subjects studied were adults, and children are generally considered to have a greater tendency toward the formation of hypertrophic scars.

Each scar being treated was compared to a control area of scar tissue either on the same scar on the paired anatomical site. This procedure and the authors' choice of measurement techniques significantly reduce the possible effects of confounding variables.

The investigators standardized the procedure for comparative photography by keeping constant the lens aperture, exposure time, photographic backdrop, and subject distance. The procedure was made more objective by including a colour-control strip in the picture. The elastometer is described in detail along with evidence that the measurement formula used correlates closely with the reciprocal of Young's modulus which the experimenters consider to be an accurate measure of cutaneous elasticity. An attempt was made to ensure that all biopsy specimens were taken perpendicular to the scar surface in order to obtain an objective assessment of the extent of raising of the scar. Specimens were also assessed as to their vascularity, inflammatory changes, number of fibroblasts, and evidence of the presence of silicone in the tissue. Clinically, the scars were assessed according to scar texture, colour, thickness, durability, presence of pruritis, and permissible range of motion. This assessment was made by noting the proportion of initially evident items which were improved following treatment. Patients rated the results of treatment as good, average, poor, or unacceptable, and indicated whether or not they wished to continue treatment. The use of such scoring systems increased the reliability of the subjective ratings of both the experimenters and the subjects. In summary, the use of standardized procedures and a relatively reliable and valid measurement tool (the elastometer) greatly increases the study's validity and thus the significance of the results obtained.

Three instances of superficial maceration of the skin occurred; in all cases the method of fixation was elastic compression garments. One of the three patients was forced to discontinue treatment as a result while the other two were able to continue treatment by decreasing the daily wearing time to 12 hours. In three other patients a rash developed beneath the gel, attributed to poor local hygiene. All complications were reversed by temporarily removing the gel or by decreasing the daily wearing time to 12 hours.

All scars showed improvement on clinical evaluation at 4 and 8 weeks. These improvements were found to persist at 12 weeks, 4 weeks after cessation of treatment. Similarly, elastometric readings showed statistically significant increases in elasticity at 4, 8, and 12 weeks while the paired control scars remained unchanged. No evidence of inflammation or the presence of silicone was noted in the biopsy specimens. No clinical improvement was evident in three scars which had been treated less than 12 hours per day and treatment of these scars was discontinued by the subjects prior to completing the study. The effectiveness of silicone gel application was not considered to be related to patient age, scar age, scar location, or method of attachment. Comparison of elastometric readings from the treated scar with those from the paired control scar using the Student paired t-test indicated significant improvement in the treated scars at all measurement intervals. Despite the small sample size, these results are both statistically and clinically significant.

Ohmori (1988) investigated the effectiveness of silastic sheet application to 48 keloid scars, all of which were initially red, elevated, and accompanied by subjective complaints such as itchiness or pain. Treatment consisted of the application of a silastic sheet directly to the scar with fixation using adhesive tape; the sheets were cleaned at least weekly with soap and water. At the completion of the study each scar was

classified according to the presence or absence of redness, elevation, and subjective complaints, as excellent (absence of all three characteristics), good (absence of two characteristics), fair (one characteristic was affected), or poor (no response was observed).

Subjects are assumed to have been chosen by convenience sampling as no sampling procedure is described. Initially 51 scars were included in the sample; however, 3 of these were dropped due to sensitivity to the adhesive tape. Results were reported from the treatment of 48 keloid scars in 46 patients. The ages, causes, and locations of scars are unspecified.

The treatment protocol described by Ohmori (1988) is standardized, but the variation in duration of the treatment between cases makes it difficult to determine the degree of effectiveness of silastic sheet application as the ultimate results for many of the treated scars are unknown. Ohmori fails to describe the method by which scar characteristics were assessed. It is assumed that subjective evaluation by the experimenter was the basis for the results presented, but the reliability of such an assessment is unknown. Although valid, defined characteristics of keloid scars were used, the validity of the results is questionable due to the lack of reliability and the subjective nature of the assessment.

When the study was published, 6 of the keloid scars were classified as excellent, 24 as good, 12 as fair, and 6 as poor. From these results Ohmori concluded that silastic sheets are effective in treating keloid scars and that there is no correlation between the effectiveness of treatment and time elapsed since the scar appeared, location, or cause of the keloid. The statistical significance of these results cannot be determined from the published report.

In light of the results of other studies using silicone gel in the treatment of hypertrophic scars, Ohmori's (1988) study can be considered clinically significant. It describes a favourable response to the application of silastic sheets for 8 to 12 hours per day in a substantial number of keloid scars.

Quinn (1986) reports a study of 122 patients recovering from burn injuries. Scars were photographed at the beginning of treatment and subsequently every 2 months. At each 2 month visit the scars were rated according to texture (measured by elastometer), colour and thickness (both measured by comparative photography). Results were reported following 2 months of silicone gel application using crêpe bandages (for scars located on limbs), adhesive tape (for scars located on the face and neck), silicone adhesive (for scars in anatomical depressions), or pressure garments ("for scars that are slow in responding to treatment", p.7); the criteria for inclusion in the latter group are unspecified. The time of application of gel was unspecified; Quinn (1986) reports that 24 hours per day is ideal, but that 12 hours per day is sufficient.

Subjects were selected using criteria that are unclear. No methods for reducing the effects of possible confounding variables are described. The method of measurement employed in the study appears to be standardized; however, no data are provided regarding its reliability and validity as a means of measuring hypertrophic scars.

Of the 122 patients admitted to the trial, 4 were found to have non-hypertrophic scars, 4 had unhealed burn wounds, 30 did not return for assessment, and 13 had to discontinue treatment following the development of a rash. Of the remaining 71 that completed the trial, 33 showed improvement in one of the three variables measured, 29 improved in two of them, and 9 in all three variables. In the 4 patients with unhealed burn wounds, the application of silicone gel led to early re-epithelialisation, and no evidence of scarring was observed in later assessment. Subjective ratings indicated a reduction in pruritis. The statistical significance of these results is reduced by the sampling procedure used, by the questionable reliability and validity of the method of measurement, and by the large dropout rate in the study.

These results can be considered clinically significant, however, in that improvement was seen in a large number of patients following the application of silicone gel. The subjective reduction in pruritis is also clinically significant.

Mercer (1989) applied silicone gel for 6 months to scars assessed initially according to texture, colour, and height. Silicone gel was applied for 1 hour the first day and application was increased by an hour each day until the scars tolerated the gel for 8 hours. Patients were then instructed to wear the gel continuously with short breaks for washing and sports. The gel was fixated using adhesive hypoallergenic tape in 15 patients, support bandages in two patients, and a custom-made pressure garment in another case. After 1 month patients were reassessed. Treatment continued with assessment at 2 to 3-month intervals.

Subjects are assumed to have been chosen by convenience sampling. The average age was 19 (range 3-64), 7 patients were female and 11 were male, and the average age of the scars was 35 months (range 9-120). Three patients had previously been treated with intralesional steroids, and three had undergone surgical excision procedures without success.

No standardized procedure for the measurement of the scars is described; the method used is similar to that used by Quinn et al (1985). Mercer (1989) reports that comparative photography was ineffective in measuring the majority of scars as the procedure was not standardized. As noted previously, the subjective nature of the measurement system described by Quinn et al decreases the reliability and validity of the results.

Mercer (1989) found that silicone gel application resulted in improvement in 86% of the treated scars. Texture was observed to be the first variable to improve (in approximately 2-3 months of treatment), followed by improvements in colour and elevation. Mercer reports that this pattern is similar to that seen in scars treated using pressure garments. He also observed that only one scar treated in this study showed evidence of post-treatment rebound, a lower rate of incidence than in scars treated with pressure therapy. These findings support the assertion of Quinn et al (1985) that scar improvement is independent of the patient's age, age of the scar, or the mode of application. Although the lack of standardized, reliable, valid measurement methods seriously reduces the statistical significance of the study results, these findings, taken in conjunction with the findings of studies described previously, can be considered clinically significant as can characteristics of the gel such as painlessness, unobtrusiveness (especially in the treatment of small keloids), low incidence of side effects, and relatively low cost.

Measurement of Hypertrophic Scarring

The difficulty in objectively measuring hypertrophic scar formation has led to the use of a variety of rating scales and measurement devices. Studies to date have used unique rating systems (Gallagher, Goldfarb, Slater, & Rogosky-Grassi, 1990; Mercer, 1989; Ohmori, 1988; Quinn et al, 1985), comparative photography (Ahn et al, 1989; Quinn et al, 1985), elastometric readings (Ahn et al, 1989; Quinn et al, 1985), scar tissue biopsies (Ahn et al, 1989), and subjective ratings by patients (Ahn et al, 1989). The use of unique measurement systems in the majority of studies investigating the efficacy of silicone gel treatment has reduced the statistical significance of their conclusions. Very few of these measurement methods (aside from the elastometer described by Ahn et al (1989) as a measure of scar extensibility) are supported by evidence of reliability and validity.

Sullivan, Smith, Kermode, McIver, and Courtemanche (1990) developed a system for rating burn scars in an attempt to increase the objectivity of burn scar assessment. The assessment considers the scar qualities of pigmentation, vascularity, pliability, and elevation. Standardized definitions are provided for each rating score on each of the characteristics being considered, and directions for assessing each characteristic (through observations and measurements) are standardized and specific. In attempting to determine the reliability and validity of the assessment, 73 scars were assessed by three different occupational therapists. Statistical analysis indicated a significant level of agreement among raters which appears to increase with experience. The characteristics being assessed are valid indicators of hypertrophic scarring by definition. This would indicate that, with training and further statistical support regarding reliability, this rating system could be employed as a standardized, reliable, and valid method for measuring hypertrophic scarring.

DISCUSSION

In exploring the effectiveness of silicone gel sheets in the prevention and reduction of hypertrophic scar (keloid) formation following burn injury, both the statistically and clinically significant results of available studies must be considered. The majority of the studies discussed in this paper can be seen to have at least minor experimental flaws which reduce their statistical significance; however, taken together the results indicate a number of clinically significant trends.

In general, the current literature indicates that silicone gel sheets are effective in preventing and reducing hypertrophic scars. Improvements in the texture, colour, and elevation of hypertrophic scars have been observed in a number of studies (Ahn et al, 1989; Mercer, 1989; Quinn et al, 1985). Reduction of subjective complaints of patients and statistically significant increases in the elasticity of the scar tissue have also been found (Ahn et al, 1989). Decreased pain (Perkins et al, 1982) and a reduction in pruritis typically associated with hypertrophic scarring (Quinn et al, 1985) have been evident in other studies.

Results appear to be independent of the age of the patient (Ahn et al, 1989), the method of attachment (Ahn et al, 1989; Quinn et al, 1985), location of the scar (Ahn et al, 1989; Ohmori, 1988), age of the scar (Ahn et al, 1989; Ohmori, 1988), and cause of the scar (Ohmori, 1988). Preliminary data indicate that early application of silicone gel sheets to unhealed burn wounds may be effective in reducing the occurrence of hypertrophic scar formation (Quinn, 1986); however, further research in the form of controlled studies is required in this area. Complications were observed in a small percentage of subjects in several of the studies presented (Ahn et al, 1989; Mercer, 1989; Ohmori, 1988) which varied in severity from transient skin irritation or rash to skin maceration requiring cessation of treatment. The majority of complications were reversed simply through temporary removal of the gel or a reduction in the amount of time per day that the gel was applied.

The treatment protocol for the application of silicone gel varies among the studies discussed. Some of them suggest that, once tolerance is established, the silicone should remain in situ continuously (Mercer, 1989; Quinn et al, 1985; Quinn, 1986). In contrast, Ohmori (1988) advocates application of the gel for 8 to 12 hours per day, while Ahn et al (1989) report that significant improvement can be achieved by applying the gel for 12 hours or longer (no improvement was

noted in a small number of patients who wore the gel for less than 12 hours per day; treatment was discontinued within 2 months in these subjects). In view of these variations it is advisable that clinicians err on the side of conservatism (i.e., 12 hours per day) pending more conclusive findings. Several studies indicate that tolerance must be developed over one to two weeks (Mercer, 1989; Perkins et al, 1982). The silicone gel sheets must be removed and cleaned, and local hygiene must be maintained in the area of the scar. The longevity of the gel sheets varies between manufacturers; recommended protocols for the replacement of the gel sheets can be obtained from medical suppliers.

Fixation has been achieved in various experiments through the use of crêpe bandages, adhesive tape, silicone-based adhesive, or pressure garments. However, the occurrence of superficial maceration in three patients studied by Ahn et al (1989) corresponded with the use of pressure garments or elastic compression as a means of fixation. Further investigations are required to determine the most appropriate mode of attachment for silicone gel sheets in the treatment of hypertrophic scars.

More research is also necessary to establish the optimal duration of treatment. Improvements have been noted as early as 4 weeks after the initiation of treatment (Ahn et al, 1989). The possibility of a ceiling effect (i.e., a point at which no further gains are seen) has yet to be investigated.

Reviewing the literature currently available regarding the efficacy of silicone gel sheets in the prevention and reduction of hypertrophic scars generates several suggestion for future studies in order to increase the confidence which can be placed in the results. The use of control tissue samples greatly increases the statistical significance of the study results by decreasing the possibility of confounding by other variables. Similarly, it would be advisable that the treatment protocol, measurement procedure, method of attachment, and any adjunctive treatment be standardized. The use of a large sample size would increase the statistical power of results obtained, and the isolation of paediatric subjects would eliminate the possible effects of age-dependent variations in hypertrophic scar formation.

The need to use valid, reliable, standardized assessments of hypertrophic scarring cannot be overemphasized. Elastometric readings as discussed by Ahn et al (1989) provide an objective, valid and reliable method for assessing scar elasticity. The Burn Scar Assessment developed by Sullivan et al (1990) appears to be a reliable method for assessing pigmentation, vascularity, pliability, and height, although further inter-rater reliability studies are required before its reliability can be assumed. The use of appropriate statistical analysis, such as that used by Ahn et al (1989), is required to establish the significance of research findings. Studies of longer duration would be useful in determining the existence of a ceiling or rebound effect (i.e., whether there is a degree of reversal in the improvements seen in the treated scars). Finally, given the current trends in burn scar treatment, it would be useful to perform a comparative study of the effects of silicone gel and of pressure treatment in the prevention and reduction of hypertrophic scarring.

SUMMARY AND CONCLUSIONS

Although much more research is required for full confidence, the literature currently available tends to support the effectiveness of silicone gel as a means of preventing and reducing hypertrophic scarring following burn injury. It is up to the individual therapist to determine whether the clinical significance of the study findings is sufficient to warrant its use.

Studies to date indicate that silicone gel is effective in improving the texture, colour, and elevation, and in ameliorating subjective complaints such as pain and pruritis typically associated with hypertrophic scars. Results appear to be independent of the patient's age, the method of attachment of the gel, or the location, age, or cause of the scar. Given the variations in treatment protocols seen in the literature, it is advisable to apply the gel for increasing periods over the course of 1 to 2 weeks until it can be tolerated for approximately 12 hours per day. The gel should be removed for cleaning of both gel and wound at least twice per day. Gel should be fixated using crêpe bandages, adhesive tape, or silicone-based adhesive and skin should be monitored for signs of skin reaction. Finally, the manufacturer's recommendations should be followed regarding the replacement of gel sheets.

REFERENCES

Ahn, S.T., Monafo, W.W., & Mustoe, T.A. (1989). Topical silicone gel: A new treatment for hypertrophic scars. *Surgery, 106,* 781-787.

Fess, E. & Philips, C. (1987). *Hand splinting: Principles and methods.* Toronto: C.V. Mosby.

Gallagher, J., Goldfarb, I.W., Slater, H., & Rogosky-Grassi, M. (1990). Survey of treatment modalities for the prevention of hypertrophic facial scars. *Journal of Burn Care and Rehabilitation. 11,* 118-120.

Helal, B., Chapman, R., Ellis, M., & Gifford, D. (1982). The use of silicone oil for mobilisation of the hand. *The Journal of Bone and Joint Surgery. 64-B* (1), 67-69.

Law, E.J. (1982). Minimizing burn scar and contracture. In R.P. Hummel (Ed.), *Clinical burn therapy: A management and prevention guide.* (pp.301-320). Boston: John Wright PSG.

Mercer, N.S.G. (1989). Silicone gel in the treatment of keloid scars. *British Journal of Plastic Surgery. 42,* 83-87.

Miller, J., Hardy, S.B., & Spira, M. (1965). Treatment of burns of the hand with silicone dressing and early motion. *The Journal of Bone and Joint Surgery. 47-A,* (5), 938-943.

Ohmori, S. (1988). Effectiveness of silastic sheet coverage in the treatment of scar keloid (hypertrophic scar). *Aesthetic Plastic Surgery. 12,* 95-99.

Perkins, D., Davey, R.B., & Wallis, K.A. (1982). Silicone gel: A new treatment for burn scars and contractures. *Burns, 9,* 201-204.

Quinn, K.J. (1986). Silicone based scar therapy. *Care, Science and Practice. 4,* 7-9.

Quinn, K.J. (1987). Silicone gel in scar treatment. *Burns, 13,* S33-S34.

Quinn, K.J., Evans, J.H., Courtney, J.M., Gaylor, J.D.S., & Reid, W.H. (1985). Non-pressure treatment of hypertrophic scars. *Burns, 12,* 102-108.

Sullivan, T., Smith, J., Kermode, J., McIver, E., & Courtemanche, D.J. (1990). Rating the burn scar. *Journal of Burn Care and Rehabilitation. 11,* (3), 256-260

ACKNOWLEDGEMENT

The author wishes to thank Paul Cavanagh OT(C) for his assistance in the role of faculty advisor on this paper. Thanks also goes to Dr. Robin H. Farquhar who reviewed this article before submission. The preceding article is based on a paper submitted to the University of Western Ontario in accordance with the requirements for the degree of B.Sc.(OT).