

**Silicone Materials for
Topical Treatment of Scars**

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Introduction

The recently updated clinical recommendations publication from the International Advisory Panel provides important guidance on scar treatment. Prominently mentioned in these guidelines is early and frequent use of silicone-based therapies, which is shown by key emerging medical studies to provide benefits in the prevention or minimization of scars resulting from disease, a range of traumas including surgery, burn or injury, as well as stretch marks associated with rapid weight change (Gold, 2014).

Each year over 100 million patients acquire scars, mainly as a result of surgery and trauma (Bayat, 2003). Even scars from common skin conditions such as acne affect 40 to 50 million people in the U.S. alone (The Burden of Skin Diseases, 2004). Scars affect countless individuals from all geographies and demographics: many suffer psychological trauma, depression, stigmatization and overall decreased quality of life due to these disfiguring scars. This situation represents a tremendous opportunity for products which can help to prevent or improve the physical condition, and thus potentially minimize mental distress for afflicted individuals.

Let us examine the phenomena of scars, as well as the beneficial silicone-based scar treatments which can bring value to patients and product manufacturers alike.

What is a scar?

Most scars are comprised of fibrous tissue formed as a result of the human body's wound healing process following injury to the skin. Most every wound results in scarring to some degree. Scar severity can be affected by factors such as wound type, genetic predisposition, tissue tension or prolonged inflammation during wound healing. The human body's typical response to a wound is independent of wound causation; whether accidental or intentional, injuries caused by trauma, laser treatments, diseases or surgery are predisposed to heal following the same sequence of biological repair.

The wound healing process

The first step in the body's response to repair a recent wound is to stop bleeding, if any. The intermediate result is often formation of eschar, the medical word for scab. A relatively new practice is to keep the wound moist and prevent a dry eschar, since it is noted that eschar formation can correlate with greater scar prominence.

The next phase in the wound healing sequence is called the inflammatory response, during which white blood cells travel to the site of injury to remove dead tissue and foreign materials such as debris and bacteria.

At this point, proliferation occurs as blood vessels form and a special cell type, called fibroblasts, generate new fibrous tissue. Collagen is deposited into the region, establishing granulation tissue on which dermal tissue forms covering the area. A delay in this process (epithelialization) can result in more pronounced scarring, whereas good progress through the wound healing cascade helps to minimize the incidence of scar formation. The new tissue resulting from this stage is deposited quickly, lacking alignment; if the tissue remains in

this disorganized, less-densely packed state, a raised or "hypertrophic" scar could be the result.

In the remodeling phase, sometimes called maturation, excess tissue is removed by cellular physiologic processes, including the action of fibroclasts. Unlike the tissue-generating fibroblasts, fibroclasts help to break down and remove superfluous tissue. Acting together, fibroclasts and fibroblasts enable tissue remodeling. Raised scars lower as the collagen and connective tissue fibers align to the appropriate form, becoming more organized and dense. This phase can be influenced by stress and movement, and is a component of wound contraction.

Types of scars

Scars can be classified several ways. Temporal classification usually differentiates the maturity level; immature scars at various stages of formation can be red, itchy or painful. Some will mature normally and flatten with time during the remodeling phase, but others remain problematic. Hypertrophic scars, characterized by an erythematous (red and inflamed), raised appearance confined to the border of injury, can be classified as linear (e.g., along a surgical incision) or widespread (e.g., burns or other injuries affecting skin expanses). Some scars are classified as keloids, which are characterized by focally raised scars that can expand beyond the immediate area of injury, and often bring pain and itch to the patient. These may occur soon after injury or be delayed, and typically do not abate on their own. Doctors may further classify keloids as minor or major based on the protruding dimension and other features. Minor keloids are only slightly raised and generally have limited spread beyond one year. Major keloids generally protrude more than 5 millimeters, and can continue to expand over the years.

Factors affecting scarring

Scars can vary by severity, relating to several different factors. Patients may have a genetic tendency to form scars; for example, while keloids can afflict individuals of all races, generally people with dark skin are more susceptible, hence a greater prevalence to keloid disease among persons of Asian and African descent. Although emerging science suggests a possible correlation between genotype and hypertrophic scar severity making a genetic test conceivable, this relationship is not confirmed by adequate study (Thompson, 2013).

Another factor which can impact scar severity is mechanical tension. Presence of tension in scars is a major factor in development of hypertrophy (Gold, 2014). Prolonged inflammation, longer than 14 days, can influence scar severity as well (Mustoe, 2011). Inflammation, a normal component of wound healing, can be exacerbated by infection, the presence of non-viable tissue or foreign bodies in the wound, and delayed healing. For example, burns that fail to re-epithelialize within 21 days virtually always result in scarring, even in children; partial thickness burn wounds that re-epithelialize within ten days virtually never result in scars.

While previous research attention was on the dermis, recently focus has turned to the epidermis and its involvement with

inflammation. Interestingly, wounds of the mucosa (tissue comprised in part of epithelial cells, like the epidermis) often heal without scar incidence, whereas healing of the skin can often have the undesirable result. The epidermal level plays a key function as the inflammatory first responder of the body's largest protective organ; upon injury, it initiates a cascade of biologic signaling pathways to modulate inflammation, control trans-epidermal water loss and restore barrier function (Mustoe, 2011).

Preventive treatment

While most people try their best to avoid injury and surgery which might result in scars, sometimes trauma is inescapable. Strategies to minimize scars as they form include: maintaining a moist wound environment; removing tension from the healing wound; and refraining from the use of materials like latex or acrylic adhesives which might exacerbate the injury, as they are overly aggressive and can cause damage to delicate tissues, as well as reactions in pre-sensitized patients. For high risk wounds, silicone-based products are the preferred preventative measure (Gold, 2014).

The timing for the first application of a silicone material is typically after one month of re-epithelialization (Gold, 2001). While some silicone topical preparations can be directly applied to open wounds, silicone gel sheeting products are typically indicated for use only on closed wounds.

Clinical evidence supports the use of silicone gel sheeting (SGS) as a prophylactic treatment (Mustoe, 2002). SGS should be worn for a minimum of 12 hours/day; when worn for longer periods, twice daily washing is recommended. A non-sheet form of topical silicone gel might be preferable in some circumstances; for example, to cover large areas, areas of flexion, on the face, and/or in hot-humid climates. Studies have shown topical silicone to be as effective in scar treatment as the silicone gel sheeting form (Sandhofer, 2012) (Mustoe, 2008).

Corrective treatment

While prevention is preferable, there are situations in which the scar has already formed and treatment is clearly indicated. Scars can decrease one's quality of life for obvious and various reasons. Scars can cause conspicuous disfigurement, and in less severe cases, merely be aesthetically displeasing due to raised appearance (hypertrophy), discoloration (erythema) or hardness (inelasticity). Residual pain and itching is sometimes associated with scars, as well as potentially inhibited growth in children. Any or all of these conditions can cause psychological sequelae, including but not limited to: depression, low self-esteem, stigmatization, impairment of activities of daily living and post-traumatic stress disorder.

When to begin corrective treatment of an existing scar remains open to debate, though it is generally agreed that treatment should begin once the scar has reached a static, unchanging state. Aggressive treatment of a scar which is still actively healing can exacerbate scar formation and be counterproductive to good cosmetic result. However, during remodeling, passive

treatment with silicone-based topical preparations might provide benefit. Application to the open wound may result in re-epithelialization in as soon as 7 days, without formation of granulation tissue. Topical treatment may continue for a duration of three months (Sandhofer, 2012).

Medical devices for scar treatment

A variety of medical devices are, and have historically been, used in the treatment of scars. Silicone gel sheeting was first introduced to the market by Spenco Medical Corporation in 1982 (Perkins, 1982); today, there are several brands, including Cica-care® from Smith & Nephew. SGS is shown to be as effective as steroid injections for reduction in the symptoms and appearance of sternal hypertrophic, as well as burn and surgical scars. International Panel meta-analysis concludes SGS is effective in treatment and prevention of hypertrophic scars in high risk patients (Mustoe, 2011). Orthotic garments, such as ace bandages and splints, have been used in the treatment of scars due to the efficacy attributed to the mechanical effects of compression. Silicone can be the skin-contacting surface of these devices, or can be added as a protective layer; SGS has low friction properties, making it ideal for use inside splints to both prevent further injury and scarring (Perkins, 1982) (Gupta, 2011). Some practitioners have seen merit in the use of paper tape to help treat erythematous hypertrophic scars; however, this treatment is recommended for use in just low-risk patients, based on consensus opinion rather than clinical evidence (Gold, 2014).

Another medical device worthy of mention was recently introduced by Neodyne Biosciences, Inc., embrace® Active Scar Defense. The innovative, patented design enables placement of elastic silicone dressing across a wound, even one closed by sutures, to remove tension from the wound to the distal ends of the dressing (Neodyne Biosciences, Inc., 2015). Unloading tension at surgical incisions and other wounds can enable healing with less propensity for severe scarring, thereby significantly improving appearance (Lim, 2014).

Topical preparations with silicone excipients

Silicone can provide extra value by not only acting as a beneficial scar treatment measure on its own: it can also serve as an excipient which helps to carry and deliver other active ingredients common to topical scar treatment preparations, such as sunscreen UV blockers; vitamins A, C & E; onion extract; anti-inflammatory steroids; antibiotics and hyaluronic acid. The role of sunscreens in scar prevention should not be underestimated, as fresh epithelium is particularly prone to discoloration from the sun. While many topical preparations include the antioxidant vitamin E, and its application directly on scars has on occasion been advocated, new information indicates that scars are not improved and contact dermatitis may result. Vitamin C is an important factor in collagen synthesis, which is a vital part of wound healing. The efficacy of onion extract, a "natural" active in several inexpensive OTC topical scar preparations, has been questioned due to shortcomings in the evidence base. Topical steroids have little

to no effect on reducing scar thickness or appearance. Triple antibiotic ointments are a common recommendation to help prevent infection, while providing the side benefit of maintaining a moist wound environment. Hyaluronic acid (HA), used in the injectable as well as topical form for treatment of scars, is a naturally-occurring hydrogel material that can hold 1,000 times its own weight in water. It has been noted that the amount of HA present in the body diminishes with age, and older individuals are more prone to scarring than infants; hence by association, HA scar treatments have naturally been considered. Like silicone, hyaluronic acid can help to retain moisture in the skin, which may be associated with faster healing and reduced scarring.

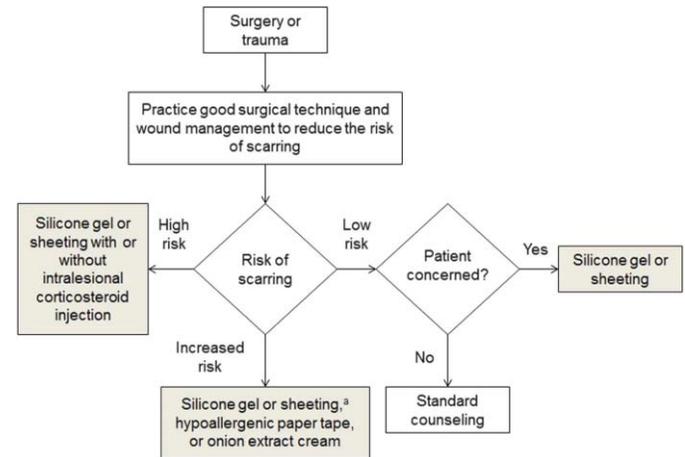
Alternative scar treatments

While alternatives to silicone treatments of scars do exist, none are without drawbacks. Injection directly into scar tissue has been popular, and is still recommended in very specific instances. For example, the International Advisory Panel recommendation calls for intralesional corticosteroids or 5-fluorouracil for treatment of major, high-risk keloid scars. The latter is a chemotherapy drug used in topical preparations for skin cancers; however, it is contraindicated due to anemia, leukopenia, thrombocytopenia, pregnancy, bone marrow-depression and infection. Side effects include pain at the injection site, hyperpigmentation, skin irritation, and skin ulceration. Corticosteroids, such as Triamcinolone, while generally less serious, are also not without side-effects, and are contraindicated for children. Every drug has side-effects, and these risks must be considered in selection of scar treatment regimes. Should the benefit of injection therapy be judged to exceed the risk, the treating physician should not discount the value of combining silicone anti-scar products with the drug treatment.

Other treatment regimes in scar management include pressure therapy, laser therapy, cryosurgery, dermabrasion, and fractional radiofrequency skin rejuvenation. Many of these treatment programs require repeat visits, which can be expensive and prolong healing times. Pressure therapy has a long history of use based mainly on empiric evidence; however, meta-analysis has shown only a small improvement in the appearance of hypertrophic scars by mechanical compression. Laser therapy can include such side effects as transient swelling (edema), redness (erythema), and purple spots (purpura). Cryosurgery, which involves the freezing of scar tissue, could lead to permanent hyperpigmentation, skin atrophy, and pain at the treatment site (Gupta, 2011). Dermabrasion involves mechanical removal of the outside layer of the skin, followed by re-epithelialization and ideally, normal wound healing. Fractional radiofrequency skin rejuvenation is a common therapy in the correction of acne scars, with results shown to be beneficial in some cases. Following treatment, patients are advised strict sun protection, along with re-epithelizing agents containing cyclomethicone, a type of silicone, and sodium hyaluronate, the sodium salt of hyaluronic acid. Silicone scar therapy can be combined with many of these other treatment regimes, possibly resulting in a beneficial synergistic effect.

Scar revision surgery

In extreme cases, a patient might elect to remove the scar through revision or excision plastic surgery. This treatment is aggressive, and is a considered decision for patients at higher risk for recurrence. This procedure is followed by the standard algorithm for preventing hypertrophic or keloid scars after surgery or trauma; prophylactic measures taken to reduce rate of recurrence include silicone gel or sheeting, with or without intralesional corticosteroid injection, at all risk levels (Gold, 2014).



Algorithm for preventing hypertrophic or keloid scars after surgery or trauma. ^a preferred option. (Gold M. H., 2014) Adapted from (Mustoe, 2002). Reprinted with the kind permission of Dr. Mustoe.

The benefits of silicones in scar treatment

Silicones can provide efficacy and benefit to various scar treatment product forms in a variety of ways. Silicones have been indicated for patients of all risk levels, whether for prophylactic or active treatment, and can offer both patients and formulators safety of use through biocompatibility and bio-stability. Silicones have been shown to be compatible with the majority of drug classes, and are suitable for use by most people, regardless of age, race, or medical condition (Kadzinski, 2015). In general, silicones used for these therapies are non-toxic, hypo-allergenic, non-comedogenic material, and are non-adherent to tissue, helping to prevent treatment complications for patients with sensitive skin and allergies (Draelos, 1997).

Silicones can be a cost-effective option, offering a wide range of form and convenience factors for scar treatment. In addition to being suitable for most consumer types, it can work as a standalone treatment option, as well as offering formulation compatibility as an excipient for active ingredients such as sunscreens, anti-inflammatories, analgesics, antipruritics (anti-itch), and antioxidants such as vitamins A, C, & E and hyaluronic acid. Silicones can be incorporated into a wide variety of medical device and topical scar product design configurations, including: cream, topical gel, lotion, spray,

roll-on, film-former, etc. Topical silicone products, which have been shown to be as effective as silicone gel sheeting, allow for versatility of application and use for a variety of reasons. Sheeting may be difficult to apply to intricate, delicate or compromised surfaces on the body, or areas with considerable flexion, e.g., joints. Topical preparations, however, can be applied exactly where needed, regardless of size or shape of a scar, and do not require the additional use of adhesive tapes. Topical preparations are also insensitive to ambient conditions, offering greater comfort and longevity of wear in hot and humid climates. The substantivity and durability of many silicones enables the maximization of contact time with the skin, for more beneficial and effective scar treatment (Puri, 2009).

The enhanced cosmetic appearance of topical silicone preparations also supports constant or longer wear, and better patient compliance. The glide and spreadability of topical silicones create a smooth canvas on which concealers and other cosmetics can be applied, helping to camouflage the scar. Several silicone materials themselves create a soft-focus, matte effect which can also mask the noticeability of scars; they contain spherical particles of a higher refractive index, which bend and diffuse light like a series of lenses (Starch, 2008).

Modes of action

Silicones can work to reduce the appearance of scars through a variety of mechanisms. Tightening of the skin from a topical preparation compresses the tissue, which may result in flattening and reduction of overall scar height (Gupta, 2011). Decades of use in topical preparations has shown that silicones can soften and protect dermal tissue. This feature helps to increase malleability of the scar tissue, resulting in a softer scar, and augmenting the effects of pressure therapy. This softening of the tissue can also improve mobility and flexion of underlying orthopedic joints, which may provide some relief for patients (Perkins, 1982) (Gupta, 2011).

Medical literature indicates the semi-occlusive hydrating properties of silicone have played a significant role in scar treatment. Silicones have been shown to moderately reduce trans-epidermal water loss (TEWL); the material in particular might strike the perfect balance between wounds drying out, and becoming macerated with moisture. Silicones can normalize the hydration state of the keratinocytes, signaling dermal fibroblasts to down-regulate extracellular matrix production. During wound healing, as the initial layer of basal epithelium forms, additional layers transform into strata, ultimately becoming the stratum corneum. The timing of complete restoration is not fully understood; however, the temporal effectiveness of semi-occlusive silicone dressings suggests this takes at least two months, generally longer, to reach homeostasis. TEWL measurements can quantify the progress of this wound healing step (Mustoe, 2011). Analysis of human hypertrophic scars has shown abnormalities including increased TEWL. Additionally, normalization of the skin's barrier function, and not just simply hydration of the stratum corneum, are reportedly responsible for the efficacy of

the scar treatment (Mustoe, 2008). Proper hydration may also reduce scar symptoms such as itching; this is particularly noted in burn patients (van der Wal, 2010).

Silicone (polydimethylsiloxane) is highly permeable to oxygen, the importance of which cannot be overstated in the wound healing process (Sen, 2009). Most silicones do not support microbial growth, protecting scar tissue from pathogenic microbial infiltration and hence, bacterial-induced collagen proliferation (Puri, 2009). These properties have even enabled the use of silicones as an accepted FDA skin protectant (21 CFR 347.10).

A topical preparation applied to the scar may result in an increase in skin temperature; even 1°C can increase blood flow, which in turn can result in the up-regulation of collagenase, leading to a decrease in collagen content of the scar, reducing scar volume, even if mature (Murison, 2006). Literature indicates a possible effect silicone might exert on the activity and growth factor production of cultured fibroblasts. The levels of growth factors, including fibroblast growth factor β , are modulated. Keratinocytes down-regulate multiple fibroblast genes modulating the extracellular matrix including connective tissue growth factor (CTGF) collagen type I and III, and fibronectin, even in the presence of profibrotic transforming growth factor beta, TGF β (Mustoe, 2011). Silicone may act on the epidermis to initiate signaling cascades that affect dermal fibroblasts, thus leading to a balance (stasis) in fibrogenesis and fibrolysis (Puri, 2009) (Mustoe, 2008). In particular, short-chain PDMS (polydimethylsiloxane, $v < 1,000$ cs) interacts with collagen, reducing fibrillogenesis, or the development of fine fibrils normally present in collagen fibers of connective tissue; whereas longer PDMS chains demonstrate little interaction with collagen (Kadzinski, 2015).

Summing up, the medical literature has helped demonstrate that silicones contribute to the reduction of scar formation, severity and appearance through a variety of ways. These include notably: ideal mechanical properties similar to dermal tissues; semi-occlusive properties which strike the perfect moisture balance, as well as very high oxygen permeability; camouflaging optical effects; non-comedogenic, non-allergenic, biocompatible properties and complex scar-modifying biological mechanisms. In addition, silicone excipients can enable the incorporation of active ingredients such as sunscreens, antioxidants and pain- and itch-relieving medications. Consequently, silicones are the logical material choice for inclusion in the formulation of a wide range of scar treatment products.

Silicones in the scar treatment market

Silicones have contributed significantly to the scar treatment market due in part to the diversity of product forms enabled. The earliest market entry was the silicone gel sheeting device from Spenco®. This form has persisted since the 1980s, inspiring several similar products through the years, including the Cica-Care® product developed by Dow Corning and now available from Smith & Nephew. Silicone gel or elastomer can be incorporated in orthotic garment designs, cushioning and

protecting sensitive healing tissues. Another scar-reducing medical device recently introduced, embrace® Active Scar Defense from Neodyne Biosciences Inc., takes the concept of silicone sheeting one step further by additionally removing tensile stress from across the healing incision line. Topical preparations for scar treatment have gained particular acceptance and popularity due to the versatility and convenience these products offer. Silicone can be incorporated into these preparations and enable a multitude of forms, including film-forming gels, creams, ointments, roll-ons, sprays and oils.

The scar treatment product formulator is presented with a number of materials for their consideration. There have been attempts to reproduce the success of silicone gel sheeting devices, such as the use of simple adhesive tape, or sheeting made of soft polyurethane “gel”. While these inexpensive devices can help to control trans-epidermal water loss and to some extent apply mechanical pressure to the scar, this appears to be the extent of their benefit. Adhesive tape is typically manufactured with acrylic adhesive; however the general population is becoming increasingly sensitized to residual acrylate monomers most often found in these tapes (Waegemaekers, 1983). Several OTC products have incorporated onion extract, based on a single limited and arguably dubious efficacy study (Stozkowski, 1984). Subsequent study found it ineffective in improving scar height and itching (M. Hosnuter, 2007). The International Advisory Panel recommends that onion extract preparations are not as effective as silicone gel in topical or sheeting form (Gold, 2014).

Biocompatible, non-sensitizing silicone materials are universally accepted in healthcare product formulations, without limitations based on patient demographics including age, race, gender or pre-existing condition; as well as efficacious as both a prophylactic and corrective scar treatment option across the spectrum of wound types and healing stages.

Conventional Scars

The market of treatment-eligible patients is nearly unlimited—most everyone has at least one scar of various origin. Each year in the developed world 100 million patients acquire scars, resulting from 55 million elective operations and 25 million operations after trauma and other sources (Bayat, 2003). These can include general surgical procedures such as Cesarean section (C-section); nevus, lentigo, melanoma, basal cell, and squamous cell excision; cardiac, laparoscopic, and venous/varicose surgeries. Scars also result from plastic surgery procedures including liposuction; tattoo removal; and wrinkle treatments by ablation, skin tightening, blepharoplasty (eye lid) and face lifts. Even simple acne, which can result in disfiguring scars, affects 40 to 50 million people in the U.S. alone (The Burden of Skin Diseases, 2004).

Burn Scars

There is an incidence of four million burn scars per year in the developed world, 70% of which occur in children (Sund, 2000). From the early days, silicone’s benefits in the treatment of burns

was lauded. Submersion of severely burned trunks and limbs in baths of silicone fluid, or wrapping of the injured extremity in silicone soaked fabric, was credited as a life-saving treatment (Investigational New Drug application [IND] 243 and 3101). The stage at which treatment of the burn commences can be important (van der Wal, 2010). While the general perception is that earlier treatment is better, current recommendations are treatment with silicone should begin once the epithelium is intact and stable. Once applied to healed partial-thickness burns, the area with hypertrophy potential will be evident well before the usual six to eight weeks healing time (Perkins, 1982). Silicone treatment of the burn can lessen scar itching (van der Wal, 2010). Less pronounced surface roughness and restoration of flexion are also observed with silicone gel treatment (Perkins, 1982).

Stretch Marks

While generally associated with pregnancy, skin striations, commonly known as stretch marks, can result from any significant rapid weight change, and even the use of glucocorticoids (which result in skin becoming thinner and less flexible). Even normal skin becomes less elastic at higher elongations; fast expansion due to rapid weight gain causes tearing of the dermis and epidermis, as well as loss of normal random collagen distribution. Although the pathogenesis is not completely understood, it is believed this dysfunction of the extracellular matrix and dermal cells, specifically fibroblasts—elements of which may be reversible—results in the formation of stretch marks. The histology of SD (*striae distensae*, the generic medical term for stretch marks) shows the tissue is similar to that of a scar, and consequently, development has been compared to typical wound healing or abnormal scar formation. In general, stretch marks can appear as slightly raised pink/purple bands called *striae rubrae*; these mature into pale, atrophic scars with fine, white wrinkled lines called *striae albae*.

Stretch marks are common. Statistics indicate 70% of females and 40% of males will develop stretch marks during their formative adolescence years. 80% of women during pregnancy develop *striae gravidarum* or SG, a type of atrophic (flat) scarring (UK NHS, 2014). SG most frequently appears on all four quadrants of the abdomen, and less frequently, the breasts, buttocks, hips, arms and thighs.

Given the high prevalence of stretch marks throughout the population, the market for effective treatments is diverse and abundant; and due to biological similarities between striae and scars, previously discussed scar treatment products can be repurposed for those afflicted with stretch marks. One such product form, a film-forming gel of self-drying silicone, creates a gas permeable, waterproof and durable membrane that protects and hydrates skin’s surface. An example of this type of product is Stratamark® gel (Málková, 2014). The film which results from this treatment reportedly provides physical protection and hydration, helping to restore the extracellular matrix and correct fibroblast regulation. Other stretchmark treatment options include: phototherapies such as fractional laser therapy, CO₂ or pulsed dye laser, pulsed light therapy;

and topical preparations such as cocoa butter, topical tretinoin (Vitamin A) and various other hydrating creams, massage oil, and herbal remedies.

Conclusion

Disfiguring scars and marks, associated with patient suffering and mental anguish, affect the vast majority of the population; irrespective of geography, demographic class and wound type or severity. This situation provides a setting for products that, with early and frequent use, provide preventative and corrective treatment of the physical condition, helping to improve patient quality of life. Silicones, with their excellent biocompatibility, durability, versatility and ideal permeability, enable the formulation of safe and effective scar treatment products to address this tremendous market opportunity.

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