

# New Silicone Technologies for Applications in Scar Therapy

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For consumers, scars and scar therapy are as much a cosmetic issue as they are a medical concern. Given the unique properties of silicones coupled with their long history in both the health care and personal care arenas, these materials are well positioned for application in new scar therapies. This manuscript describes the range of emerging applications for silicones in scar therapies, including sheeting, film forming, moisturizing, occlusion, adhesion and delivery of active ingredients.

## Abnormal Scarring

Hypertrophic scars and keloids are fibrotic conditions that result in an over-deposition of collagen in the skin. They can be caused by minor cutaneous perturbations such as ear piercing or acne, or by traumatic injuries such as burns. Visually, these scars are raised, reddish nodules that can cause pruritus, pain, restricted movement and cosmetic disfigurement. The principal difference distinguishing keloid from hypertrophic scarring is that a keloid progressively invades surrounding healthy tissue. In contrast, a hypertrophic scar only increases in dimension by pushing out its margins; there is no expansion into the surrounding tissue. Whether the scar is hypertrophic or keloid, the scar tissue rarely extends deep into the dermis.

It is well documented in the published literature that various factors including ethnic background, hormonal status and injury location can contribute to a heightened incidence of scarring. Keloids are more prevalent in individuals with darker skin pigmentation, with an incidence of 4.5 to 16% in African and Hispanic populations.<sup>1-2</sup> Of note, data from the National University of Singapore indicate that keloids are three times more common in Chinese patients than among Caucasian patients (<http://www.med.nus.edu.sg/sur/keloid.html>). Another study suggests that Chinese are slightly more prone to keloids than the darker-skinned Indians and Malays.<sup>3</sup> Hypertrophic scars are more common and occur with equal frequency in all racial groups.

The average age of onset for keloids has been estimated to be approximately 22 years for both men and women.<sup>4</sup> Others report a higher incidence in young women relative to age-matched males, which may reflect a higher frequency of earlobe piercing among women. Specific body sites that are more prone to scarring are areas with oil-secreting sebaceous glands or areas of increased skin tension. They include the shoulders, upper back, upper arms, chest, ears, cheeks and neck. Hypertrophic scars can regress over time, whereas spontaneous regression of keloids is rare.

## Treatment Modalities

A variety of techniques have been utilized to prevent, as well as treat, abnormal scars. Examples include topical or intralesional steroid applications, ultrasound, cryotherapy, compression therapy, radiotherapy and laser therapy. However, few of these treatment modalities have been supported by controlled clinical studies. Surgical excision is not indicated as the new surgical wound is prone to the same mechanical, immunological and biochemical forces as the original scar.

The standards for preventing and treating abnormal scars are therapies using silicone gel sheeting and intralesional corticosteroids.<sup>5</sup> Clinical studies have proven that silicone gel sheeting is safe and is superior to polyethylene, polyurethane and other occlusive dressings.<sup>6</sup> An international panel of scientists with expertise with scarring already have determined that silicone gel sheeting and intralesional corticosteroids are considered to be the current standards of care for preventing new scars and treating pre-existing abnormal scars. Results from a meta-study of 27 separate trials indicate that silicone is more effective than other occlusive dressings such as polyethylene or polyurethane. Importantly, no significant adverse effects were noted with the silicone gel dressing.

Although less studied, formulations of silicone fluids have also demonstrated efficacy on minor hypertrophic scars.<sup>7,8</sup> Whether this beneficial response is due in part to silicone-induced skin hydration is at present unknown. In general, hypertrophic scars appear to be more responsive to treatment than keloids.<sup>9</sup> In addition, dimethicone NF fluids conform to the National Formulary Monograph, and they have been classified as active drug ingredients for use in OTC formulations for skin protectancy claims.<sup>10</sup>

## Beyond Gel Sheeting

Other silicone ingredients can improve the aesthetics and modify the rheology of scar therapy products, while enhancing spreading and substantivity. For example, alkylmethylsiloxanes provide multifunctional benefits including increased occlusivity and lubricity. As in premium personal care products, these materials give ointments and lotions better substantivity on the skin, without greasiness or tackiness. Additional benefits derived through the use of silicones include moisturization (refer to Figure 1), humectancy, occlusivity, emolliency, formation of a water barrier, improved wash-off resistance and improved aesthetics.

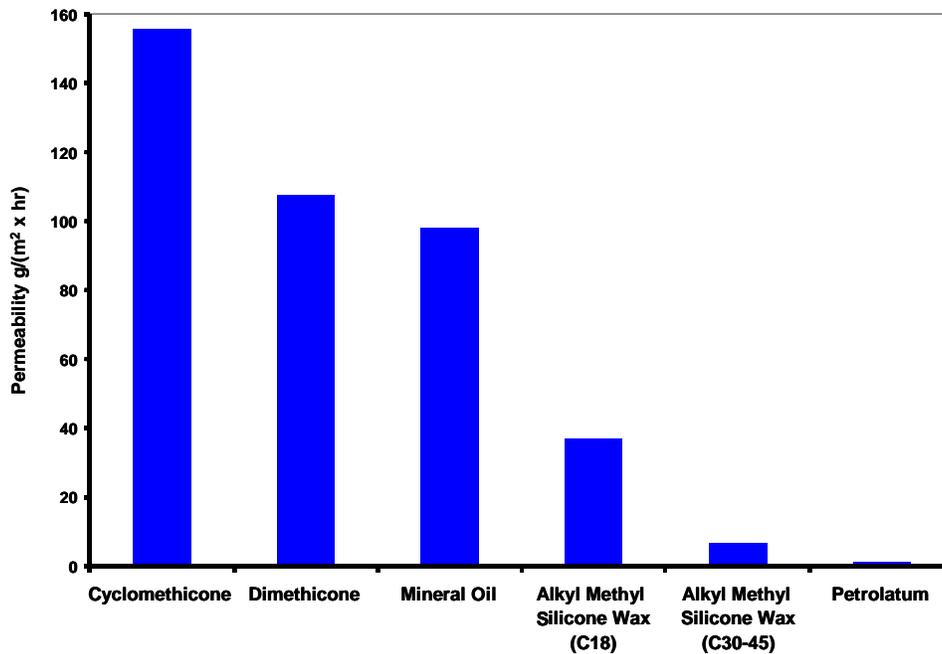


Figure 1. Moisture vapor permeability.

Silicone materials can also offer additional properties that can aid with scar management devices, which typically adhere to the skin with secondary dressings, films and nonwoven materials. Laboratory evaluations have shown that silicone adhesives designed for gentle skin adhesion can be repositioned and remain stable for extended periods, even under humid conditions.

New flexible film-forming technologies are being developed to allow treatment of scars with a nontacky, substantive semi-occlusive barrier on irregular areas such as the hands and elbows, which normally may be difficult to cover. These new technologies already have demonstrated utility in the laboratory for the topical delivery of pharmaceuticals and cosmetics. As such, silicone excipients qualified for use in topical pharmaceutical formulations can potentially serve as delivery vehicles for the controlled topical application of actives in emerging scar therapies (e.g., hyaluronic acid, interferon alpha-2b, imiquimod). Given the efficacy of silicone alone in the management of scars, the possibility of a synergistic response when coupled with additional scar modification active(s) becomes an intriguing prospect awaiting scientific investigation.

The treatment of abnormal scars is an emerging technology that can benefit from the versatility of silicones and their long use history in personal care and health care applications. Silicones bring multifunctional features to scar therapy applications, including superior aesthetics, demonstrated efficacy and the controlled delivery of active ingredients. We believe they offer a cost effective and technically innovative pathway for future product development.

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