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# Comparison of a novel wound dressing vs current clinical practice after laser resurfacing

Lindsey C. Yeh MD[1] | Noelani Gonzalez MD[2] | David J. Goldberg MD[1,2]

[1]Skin Laser & Surgery Specialists of NY and NJ, Hackensack, New Jersey

[2]Icahn School of Medicine at Mount Sinai, New York, New York

**Correspondence**
Lindsey Yeh, Skin Laser & Surgery Specialists of NY and NJ, Hackensack, NJ.
Email: dryeh@skinandlasers.com

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## Abstract

**Background:** There are many postprocedure skin care options, but no consensus on the best formulation to optimize healing. Silicone gels have only been used to treat keloids and hypertrophic scars and typically applied after the wound has healed. This study compared the healing response after fractional ablative erbium laser resurfacing with a petrolatum-based ointment and a silicone gel.

**Methods:** A randomized, open-label, split-face study was performed. Ten subjects underwent Erbium:YAG (Sciton) fractional laser resurfacing. Patients were randomized to apply a petrolatum-based gel or a silicone gel (Stratacel®; Stratpharma) on either the right or left side of the face. Subjects applied the products twice a day for 7 days and were evaluated in person 7, 30, and 60 days postprocedure. Subjects reported on the overall general aesthetic outcome, perceived pain, itch, and tightness via questionnaires using the Global Aesthetic Improvement Scale and the Wrinkle Severity Rating Scale (WSRS).

**Results:** All subjects healed without complications. By day 60, there was no difference in signs and symptoms of healing between the two different dressing approaches. However, patients treated with the silicone gel had less post-treatment erythema and hyperpigmentation.

**Conclusions:** A novel silicone gel resulted in reduced signs of erythema and hyperpigmentation postprocedure, without an increase in adverse events. Additionally, the silicone gel dries to form a thin, full contact film and can be covered with sunscreen or cosmetics once dry. This new silicone gel presents a good option for postprocedure care after ablative fractional laser resurfacing.

KEYWORDS

cosmetic procedure, fractional ablative laser, silicone, topical treatment

## 1 | INTRODUCTION

Optimizing wound healing whether from traumatic injuries or surgical scars has been an area of significant interest and research for many years. The initial insult that caused the wound can influence the healing process. Now that there are treatments that intentionally injure the skin for cosmetic purposes, focus on postprocedure care is increasingly necessary. An ideal postprocedure topical formulation would optimize wound healing, minimize the downtime, and expedite the recovery process, while also potentially enhancing the final cosmetic outcome of the procedure itself.

Ablative fractional laser procedures have gained popularity as part of advanced skin rejuvenating strategies. Ablative fractional laser techniques allow for a partial, variable depth, thermally induced multiple micro-channel skin ablation able to stimulate all subsequent

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steps of wound healing without involving the full surface of the skin.[1] Healing time is faster than full beam ablative laser procedures, but clinical results are less dramatic. Common concerns after laser use include postoperative erythema, pigment changes, prolonged healing time, infection, and scarring.

Topical silicone has been used for over 30 years as a treatment to improve the overall appearance of scars. It has been shown to soften, flatten, and improve the overall pigment of scars as well as reduce associated pruritus, erythema, and pain.[2-5] Petroleum-based ointments are commonly recommended for its occlusive properties and low irritant potential. We compare the use of an innovative novel silicone-based gel with a popular petroleum-based ointment postablative fractional laser treatment on the face.

## 2 | METHODS

### 2.1 | Design

We performed a randomized, open-label, split-face study comparing a commonly used petroleum-based ointment and a proprietary silicone-based gel specifically developed for postlaser care (Stratacel®; Stratapharma). The study was performed in accordance with the Declaration of Helsinki, and consent was obtained from all participants.

### 2.2 | Patients

Ten subjects who were 18 years or older and received treatment with Erbium:YAG (Sciton) fractional laser resurfacing were enrolled in the study. Only Fitzpatrick skin types I-III were eligible for the study. Participants were randomized into either Group 1 or Group 2, which dictated which side the silicone gel or petroleum ointment was applied to.

Full face treatment with the Erbium:YAG (Sciton) fractional resurfacing at fluences ranging from 12 to 50 J/cm$^2$, 50-200 micron depth (depending on anatomic area treated), and 11.5% density was performed. Immediately after treatment, the silicone gel or petroleum-based ointment was applied to the assigned side of the face. Patients were given instructions to apply the products two times a day for 7 days after treatment and sent home with stickers to place on the bathroom mirror to remind them of the assigned side of the face. Subjects were evaluated in person on day 7, day 30, and day 60 postprocedure. This was not a blinded study, so the tubes of ointment and gel were provided to the patient in their original packaging. Tubes were weighed at the 7-day follow-up to ensure compliance.

Two-dimensional digital photographs and three-dimensional digital photographs (Antera 3D) were taken immediately after the procedure, before any product was applied, and at each follow-up visit. Patient-reported level of pain, pruritus, tightness, oozing, and crusting of the right and left face were documented at each follow-up visit.

### 2.3 | Primary and secondary endpoints

The primary objective was to evaluate the overall general aesthetic outcome with the novel proprietary silicone gel compared with a petroleum-based ointment through assessment with the Global Aesthetic Improvement Scale (GAIS) and Wrinkle Severity Rating Scale (WSRS). Secondary objectives evaluated erythema based on digital photographs obtained at each follow-up visit perceived pain as measured by the visual analogue scale (VAS), perceived pruritus, tightness of skin, and crusting both measured by the ordinal scale (0 None, 1 Light, 2 Moderate, 3 Heavy). Lastly, the overall perceived improvement was also assessed on day 60 on a scale of 1-10 (0 No Improvement, 5 Moderate Improvement, 10 Maximum Improvement).

### 2.4 | Data analysis

The overall general aesthetic outcome (GAIS and WSRS) was assessed and analyzed by two-tailed t test as well as the perceived tightness of the skin, oozing, crusting, perceived pain, and pruritus. A blinded physician investigator assessed erythema based on digital photographs taken at each follow-up visit.

## 3 | RESULTS

Data were obtained from 10 patients, ages ranging from 36 to 68 years of age. All participants were female, and all patients were compliant with application of the studied products. Only one participant did not return for the final visit on postprocedure day 60. There were no significant differences between the petroleum ointment and the silicone gel in perceived tightness of the skin, oozing, perceived pain, or pruritus on days 7, 30, or 60 postprocedure ($P > 0.05$; Table 1). By day 30, only two patients reported any pain. One patient reported a pain score of 1 on both sides of her face and another reported a pain level of 4 on the side treated with petroleum ointment and 0 on the silicone gel side. Three patients complained of pruritus on day 30. Two of which were equal on both sides, and one reported greater pruritus on the side treated with petroleum ointment. Participants no longer experienced oozing or crusting at their 30-day visit or any pain and pruritus by day 60. Patients reported the exact same overall perceived outcome between the two sides on day 60. None of the participants reported a difference in the GAIS and WSRS 60 days after treatment.

All participants showed less erythema and post-treatment hyperpigmentation on the side treated exclusively with the silicone gel at the follow-up visit 7 days postprocedure (Figures 1 and 2). Although hyperpigmentation was not initially studied, it was clinically noted that there was less hyperpigmentation in patients treated with the silicone gel. There were no differences in the level of erythema after 30 and 60 days. There were no infections or signs of increased irritation or allergic contact dermatitis from either of the products.

**TABLE 1** Patient reported pain as measured by the visual analogue scale (VAS), perceived pruritus, and tightness of skin both measured by the ordinal scale (0 None, 1 Light, 2 Moderate, 3 Heavy) on postprocedure days 7, 30, and 60

| Postprocedure day | Silicone gel Mean (SD) | Petroleum ointment Mean (SD) | *P*-value |
|---|---|---|---|
| Pain | | | |
| 7 | 3.9 (3.0) | 3.5 (2.9) | 0.77 |
| 30 | 0.1 (0.3) | 0.5 (1.3) | 0.35 |
| 60 | 0 | 0 | 0 |
| Pruritus | | | |
| 7 | 5.2 (3.2) | 4.5 (3.1) | 0.62 |
| 30 | 0.4 (1.0) | 0.7 (1.3) | 0.56 |
| 60 | 0 | 0 | 0 |
| Skin tightness | | | |
| 7 | 2.3 (0.7) | 1.8 (0.8) | 0.18 |
| 30 | 0.3 (0.5) | 0.4 (0.5) | 0.6 |
| 60 | 0.4 (0.9) | 0.4 (0.9) | 1.0 |
| Oozing | | | |
| 7 | 0.6 (0.8) | 0.7 (1.2) | 0.83 |
| 30 | 0 | 0 | 0 |
| 60 | 0 | 0 | 0 |

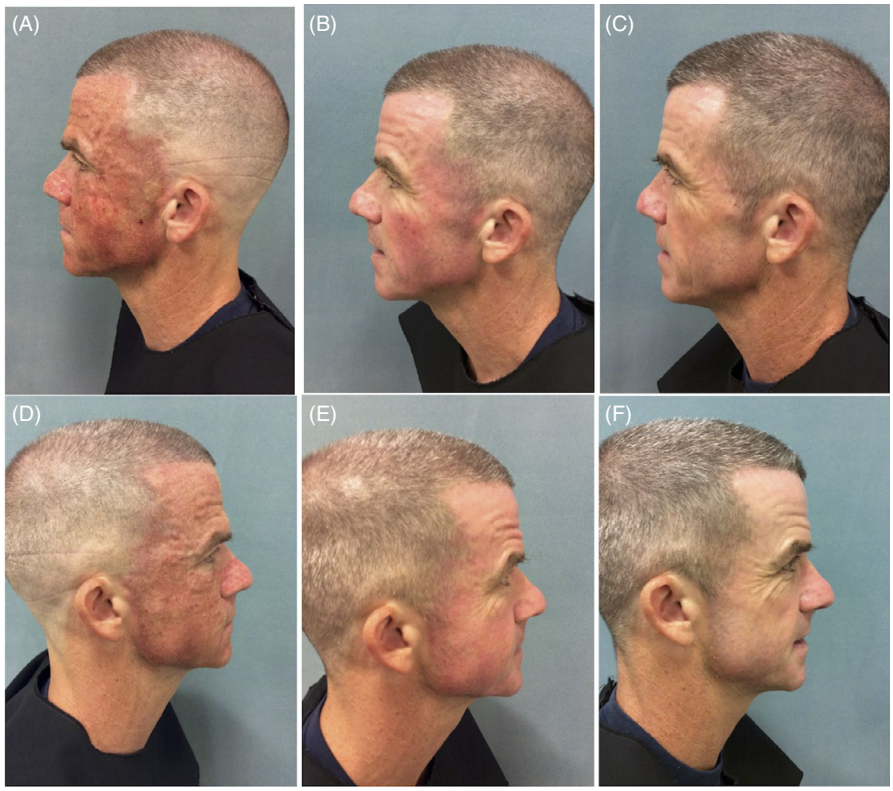


**FIGURE 1** The left side of the subject's face was treated with the novel silicone gel (A-C). The right side of the subject's face was treated with the petroleum-based ointment (D-F). A, D, Day 0, immediately postprocedure. B, E, Day 7 postprocedure. C, F, Day 60 postprocedure

## 4 | DISCUSSION

Silicone sheeting/gels have been well established as first-line therapy for the management and treatment of scars once the wound is re-epithelialized or healed. The majority of data on silicone products for scar treatment has been evaluated for its benefits in treating or preventing hypertrophic and keloid scars; however, the mechanism of action is still unclear. One proposed mechanism of action is that the semi-occlusive nature of silicone-based products improves healing outcomes by decreasing transepidermal water loss, which normalizes the hydration.[2]

Silicone sheets have been shown to help prevent hypertrophic scars and keloids and improve their appearance of existing ones.[3-6] Rhee et al[7] applied a silicone sheet immediately after surgical procedures and found that there were significantly less hypertrophic scars that developed in the group treated with silicone gel than

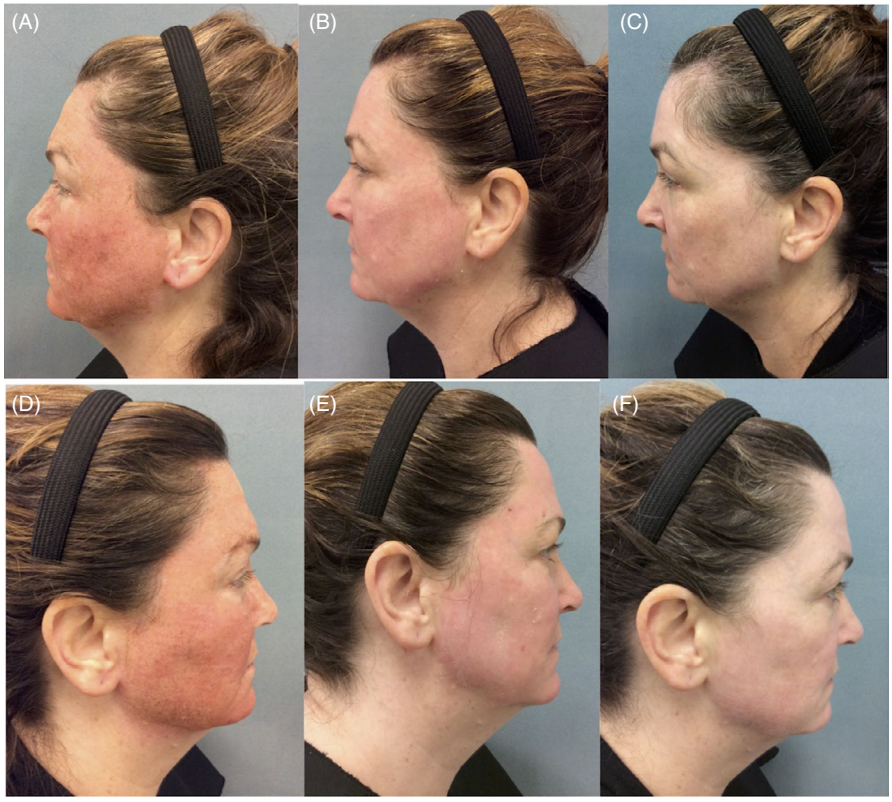


**FIGURE 2** The left side of the subject's face was treated with the novel silicone gel (A-C). The right side of the subject's face was treated with the petroleum-based ointment (D-F). A, D, Day 0, immediately postprocedure. B, E, Day 7 postprocedure. C, F, Day 60 postprocedure

those who were not. Khamthara et al treated 19 patients with ablative Er:YAG for acne scarring on the face for three sessions at 1-month intervals.[7] Patients applied a white petroleum jelly for the first five days and were subsequently randomized to apply either a silicone gel or hydrophilic cream to each side of the face. Patients experience significantly less roughness on the side treated with silicone gel compared with a placebo cream at weeks 4 and 12 ($P < 0.05$).[8]

The silicone gel used in this study has been FDA cleared for use on de-epithelialized or compromised skin and open wounds. It forms a uniform protective layer creating a moist environment to enhance healing. A prior study of this semi-permeable silicone gel used compared the silicone gel to spring water and petroleum jelly after ablative fractional $CO_2$ laser resurfacing in a split-face study. The side of the face treated with the silicone gel demonstrated a reduction in superficial melanin content, skin porphyrins, and superficial hemoglobin, which serves as marker of inflammation. Participants also preferred the ease with which the gel could be applied and removed and the comfort of the silicone gel compared with petroleum jelly.[9]

There are many other topical products available that are specifically marketed and designed for postprocedure care. Currently, there is no universal consensus on what could be considered the best postoperative wound-care strategy after undergoing an ablative procedure; however, general goals of acute wound healing include maintaining a moist wound environment, nonadherent dressings to minimize additional trauma to the skin, preventing and minimizing symptoms such as pain and pruritus, and preventing infections and scarring, while maximizing outcomes and patient compliance.

Petroleum products are commonly recommended after fractional ablative and fully ablative treatments. The highly occlusive nature of petroleum products can increase the risk of acneiform eruptions and the development of milia. The silicone gel is less occlusive and can minimize this risk. Use of petroleum products may be beneficial during the first 5 days after a fully ablative laser treatment, as was described by Khamthra et al,[7] but can be replaced with a silicone gel afterwards for easier application, which may encourage improved patient compliance and outcomes.

The silicone gel was designed specifically for use after ablative and nonablative laser treatments that can be applied immediately after treatment. A small amount of the gel easily covers the entire treatment area and quickly dries into an inert, full contact nonsticky thin film that is gas permeable and waterproof. It fulfills the above-mentioned criteria in treating a new wound without greasiness and mess that can make petroleum products difficult to use. The gel film is ideal for creating a moist environment that rinses off easily without disrupting the epidermal layer. There were no cases of infection or abnormal scarring with the silicone gel, and patients reported the same final cosmetic outcome after treatment when compared to a petroleum ointment. It is unclear whether there could be additional benefit with continued application of the silicone gel beyond the first 7 days of treatment.

The silicone gel was equally effective in controlling pruritus, pain, perceived skin tightness, oozing, and crusting. Erythema and post-treatment hyperpigmentation improved more quickly when treated with the silicone gel. Erythema is the most common complication after ablative lasers treatments. It can last up to months after treatment.[10] The ability to reduce downtime is crucial advantage to the

use of this novel silicone gel, which can provide a superior, uniform, protective layer without any additional irritation or side effects. This new silicone gel presents a good option for postprocedure care after ablative laser resurfacing.

## ORCID

*Lindsey C. Yeh* https://orcid.org/0000-0002-2248-7038

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