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Silicone-based Scar Cream for Post Upper Eyelid Blepharoplasty-associated Cicatricial and Hypertrophic Scarring

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ABSTRACT

Purpose: Silicone cream has been shown to improve the appearance of postoperative scars. Nevertheless, surgeons may incorporate intralesional wound modulators such as a triamcinolone and/or 5-fluorouracil (5-FU) for scars that do not completely heal well or those that do not completely respond to other treatment options such as silicone cream. This study sought to determine whether a silicone-based topical scar cream that incorporates selective growth factors can help reduce the incidence of postoperative cicatricial and hypertrophic changes in upper eyelid blepharoplasty incisions.

Methods: This is a single-surgeon, retrospective chart review of patients that underwent a cosmetic upper eyelid blepharoplasty. Subjects were divided into two cohorts depending on whether they received postoperative topical scar cream (SKN2017B) twice daily for 3 months versus no topical scar treatment. Using a modified Vancouver Scar Study Scale for treatment criteria, the incidence of focal intralesional injections of triamcinolone and 5-FU to targeted areas of cicatricial and hypertrophic changes was compared between the two groups.

Results: 272 eyelids were identified, of those, 132 eyelids received no treatment and 140 were treated with SKN2017B. 43.9% of eyelids that did not receive treatment underwent intralesional injections of triamcinolone and 5-FU, and 22.9% of eyelids treated with SKN2017B underwent intralesional injections of triamcinolone and 5-FU. The difference between the two groups was found to be statistically significant ($P<0.05$). No adverse reactions were reported from either group.

Conclusion: The use of a topical silicone-based scar cream has been shown to be safe and effective in decreasing the incidence of intralesional injections of triamcinolone and 5-FU for postoperative cicatricial and hypertrophic changes in upper eyelid blepharoplasty incisions.

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INTRODUCTION

Upper eyelid blepharoplasty, one of the most common plastic surgery procedures performed, involves surgically excising excess upper eyelid skin to provide an aesthetically rejuvenated appearance to the periorbital area.[1,2] In severe cases of excess upper eyelid skin, the procedure can also provide functional improvement to the patient's visual field. In a routine upper eyelid blepharoplasty procedure, the incision is strategically made along the natural eyelid crease to conceal visible scarring and create the best aesthetic outcome. Given the minimal tension and thin anatomy of the upper eyelid skin, upper eyelid incisions heal relatively well.[3,4] Despite this, there may be instances where some patients may be troubled by the appearance of unappealing cicatricial and hypertrophic changes that may arise postoperatively. They can present as either focal, raised areas or diffuse thickening of the entire scar. Although these changes are often minor and usually improve with time, they can be bothersome, especially for those that undergo an upper eyelid blepharoplasty for aesthetic reasons. Attempts have also been made to investigate whether the type of instrument used for the skin incision can improve the healing and appearance, but a recent prospective multicenter study found no difference between Colorado microdissection and a scalpel.[5] Furthermore, there is a paucity of literature supporting the optimal suture material and the type of wound closure for an upper eyelid blepharoplasty, and surgeons often rely on their formal training and personal experience for their choices in wound closure. However, one study of note showed the least incidence of complications and revisions for post upper eyelid blepharoplasty incisions with the use of a running suture along with two interrupted sutures (placed medial and laterally) in a large single-surgeon prospective study.[6]

Depending on certain scenarios and the surgeon's experience with scar management, postoperative cicatricial and hypertrophic scar tissue may necessitate treatments such as the application of a topical silicone-based cream and/or intralesional injections of triamcinolone with or without 5-fluorouracil (5-FU). Although an off-label use, 5-FU has been shown to be safe and effective in the dermatologic, ophthalmic plastic, facial plastic, and plastic surgery fields.[7-12] For over 20 years, intralesional injectable 5-FU has been used as a safe and effective adjunct treatment with triamcinolone or primary treatment for

hypertrophic scars, keloids, and various other wound healing abnormalities.[9] The combination of 5-FU and triamcinolone injections have been shown to be safe and effective with very little side effect profile.[7,9,13-15] Laser resurfacing, dermabrasion, or surgical revision are other options, but they are less common and are usually performed in the post-acute healing phase if the above mentioned options do not provide improvement.[16,17]

Glucocorticoid suspension injection remains a first-line treatment; however, this treatment has substantial side effects when glucocorticoid is applied alone, which limits its clinical utility. Because 5-FU inhibits cell proliferation, the combination of 5-FU with triamcinolone produces good results, and this combination has been used for clinical treatment.

Silicone cream has been shown to improve the appearance of postoperative scars in various studies.[18-20] Silicone cream's generally accepted mechanism of action is twofold: wound hydration and occlusion during the maturation phase of wound healing.[18-20] We believe that the use of a silicone-based topical scar cream may reduce the incidence of postoperative cicatricial and hypertrophic changes in post blepharoplasty incisions, and as a result, reduce the incidence of postoperative intralesional wound modulation. We are not aware of any study that evaluates the use of a topical scar cream and the incidence of postoperative cicatricial and hypertrophic changes requiring intralesional wound modulation post blepharoplasty.

In our study, we utilized SKN2017B, a recently developed silicone-based scar cream, as our post blepharoplasty scar cream. SKN2017B has been shown to be safe and effective for cutaneous scars in areas such as the eyelids, breasts, and abdomen. In addition to silicone cream, SKN2017B also contains synthetic recombinant human transforming growth factor beta-3 (TGF-β3), hyaluronic acid (HA), and Vitamin C as key ingredients. Both TGF-β3 and HA are implicated in fetal scarless healing.[18,21] The cream also contains several other synthetic recombinant human growth factors, Aloe vera extract, and Centella asiatica extract, all of which have been individually shown to positively influence wound healing and/or scarring.[22-25] A large, randomized, multicenter, double-blinded clinical trial comparing SKN2017B to silicone cream showed that SKN2017B demonstrated a 73% improvement in the appearance of scars on the eyelids, face, breasts, and abdomen when compared to silicone cream.[26]

This current study compares the incidence of post upper eyelid blepharoplasty cicatricial and hypertrophic scarring in subjects that used a topical silicone-based cream beginning 2 weeks post procedure to those that did not receive topical scar therapy (no treatment).

METHODS

This is a retrospective, single-surgeon case series study of patients that underwent a cosmetic upper eyelid blepharoplasty between January 2015 and December 2017. During this time period, postoperative upper blepharoplasty incisions were either treated with a silicone-based topical scar cream (SKN2017B) twice daily for 3 months or received no treatment. SKN2017B was clinically developed for patient use by November 2016, and patients that received blepharoplasty surgery after November 2016 were instructed to use SKN2017B on their eyelid incisions. The study was approved by an institutional review board (Solutions IRB, Little Rock, AZ). The study was conducted in accordance with the provisions of the Declaration of Helsinki and was in compliance with the Health Portability and Accountability Act. SKN2017B is manufactured by MD Medical Designs, Los Angeles, CA.

Patients were excluded from the study if they underwent a concomitant ptosis repair, eyelid surgery that required supratarsal fixation, or prior upper eyelid surgery. Those that had a combined endoscopic brow lift and/or lower eyelid blepharoplasty were included in the study. For both groups, a chart review spanning January 2015 to December 2017 was performed, and the incidence of combined intralesional injections of triamcinolone and 5-FU for cicatricial and hypertrophic areas along the upper eyelid incisions within the first 6 months post blepharoplasty was recorded. A T-test was performed for statistical analysis.

All patients underwent an upper eyelid blepharoplasty by the senior author (C.I.Z.), a right-handed surgeon. Excess skin was marked for removal prior to surgery and removed using a 15 blade to incise the skin, followed by removal of the skin flap using Westcott scissors, sparing the underlying orbicularis muscle. Prolapsed medial fat was debulked in those cases that had prominent nasal fat pads using monopolar cautery. Gentle cautery was applied for hemostasis using a monopolar cautery. At the end of the case, the wounds were closed with a running suture in addition to approximately four interrupted sutures along the wound using a 6-0 polypropylene suture, one located medially, two centrally, and one laterally. All patients were instructed to use erythromycin ophthalmic ointment for seven days postoperatively. Sutures were removed on either postoperative day six or seven, and patients were next seen at their routine postoperative visits at: postoperative month 1, month 3, and an optional month 6 depending on their healing. Patients that were instructed to use SKN2017B began to apply the cream to their upper eyelid incisions at postoperative week 2, twice daily, for 3 months. Patients within the SKN2017B group had been using the cream topically for 2 weeks at their week 4 postoperative visit. Patients were first evaluated for cicatricial

and hypertrophic changes in their eyelids at their postoperative week 4 visit. If they required intralesional wound modulation, an intradermal injection of approximately 0.1-0.2ml of combined 5-FU (50mg/ml, Fresenius Kabi, Lake Zurich, IL) and triamcinolone (10mg/ml, Bristol-Myers Squibb Company, Princeton, NJ) mixed with 1% lidocaine (Hospira Inc, Lake Forest, IL) was injected to targeted areas along the upper eyelids. The pain of the injection can be substantially reduced by adding 1% lidocaine (1:1:1 of 5-FU: triamcinolone: 1% lidocaine) in the same syringe along with the use of topical anesthetics. Patients who received 5-FU and triamcinolone injections were informed of the off-label use, and each signed a separate informed consent for the injection. If they required an intralesional injection at their visits, they were seen one month later in lieu of their planned postoperative visits. When indicated, repeat intralesional injections were performed monthly.

The indication for intralesional injection was determined by the scar characteristics using a modified Vancouver Scar Scale (Table 1), which has been previously published.[26] The parameters assessed by the scale include: vascularity, height, pigmentation, and pliability. A 4-point scale was used to assess vascularity and height of scars. A 6-point scale was used to assess scar pigmentation and pliability. In each case, a higher score denoted a worse outcome. Inclusion criteria for intralesional injection included: Pliability grade that was "yielding" or worse (Grade 2 or higher) and a Height grade that was "moderate" or worse (Grade 2 or higher).

RESULTS

A total of 272 eyelids (136 patients) were identified that underwent upper eyelid blepharoplasty, mean age, 52.1 (+/- 12.7) years; 30 males and 106 females. Of these, 140 eyelids (70 patients) underwent upper eyelid blepharoplasty and were treated with SKN2017B twice a day for 3 months beginning 2 weeks post procedure; mean age, 51.7 (+/- 11.5) years; 17 males and 53 females. The remaining 132 eyelids (66 patients) did not receive any postsurgical topical scar treatment; mean age, 53.7 (+/- 14.4) years; 13 males and 53 females.

The cohort was followed for an average of 6.4 (+/- 4.0) months. Those treated with SKN2017B post blepharoplasty were followed for an average of 6.2 (+/- 3.6) months. Those that received no topical scar treatment post blepharoplasty were followed for an average of 6.6 (+/- 4.5) months. Within the follow-up period, of those treated with SKN2017B post blepharoplasty, 22.9% received at least one round of intralesional injection postoperatively; 32 eyelids of 21 patients (17 right eyelids, 15 left eyelids). In contrast, of those that received no topical scar treatment, 43.9% received at least one round of intralesional injections postoperatively; 58 eyelids of 35 patients (27 right eyelids, 31 left eyelids). The difference in the number of eyelids that received combined intralesional injections of triamcinolone and 5-FU was found to be statistically significant between the two groups; $P<0.05$.

Within the SKN2017B group, the number of injections each eyelid received per treatment ranged from 1 to 3, with an average of 1.31 injections per treatment. Within the group that received no treatment, the number of injections each eyelid received ranged from 1 to 3, with an average of 1.40 injections per treatment. The average number of injections per treatment for the cohort as a whole was 1.37. The difference between the number of injections administered per treatment between the two groups was not found to be statistically significant.

Within the SKN2017B group, 6.4% of those eyelids that received intralesional injections received more than 1 treatment session; 2 eyelids of 2 patients (2 left eyelids). Within the no treatment group, 27.6% of eyelids that received intralesional injections received more than 1 treatment session; 16 eyelids of 11 patients (8 right eyelids, 8 left eyelids); Figure 1. There was a statistically significant reduction in the need for repeat injections in the group that received SKN2017B [2 eyelids (6.4%)] when compared to those that received no treatment [16 eyelids (27.6%)]; $P<0.05$. There was no significant difference between the groups or cohort as a whole in the injection frequency between the left and right eyelids.

TABLE 1.

Modified Vancouver Scar Scale. The indication for intralesional wound modulation was determined by the scar characteristics using a modified Vancouver Scar Scale. The parameters assessed by the scale include: vascularity, height, pigmentation, and pliability. Inclusion criteria for intralesional wound modulation included: Pliability grade that was "yielding" or worse (Grade 2 or higher) and/or a Height grade that was "moderate" or worse (Grade 2 or higher). Vascularity and Pigmentation were not considered inclusion criteria parameters for this study.

Assessment	Score					
	0	1	2	3	4	5
Vascularity	Normal	Pink	Red	Purple	--	--
Pigmentation	Normal	Hypo	Mixed	Hyper (mild)	Hyper (moderate)	Hyper (severe)
Pliability	Normal	Supple	Yielding	Firm	Ropes	Contracture
Height	Flat	Minimal	Moderate	Extreme	--	--

FIGURE 1. Frequency of intralesional injections that were required in both SKN2017B treatment and no treatment groups. Majority of eyelids in both groups required one injection treatment session. There was a statistically significant reduction in the need for repeat injections in the group that received SKN2017B (2 eyelids [6.4%]) when compared to those that received no treatment; $P<0.05$.

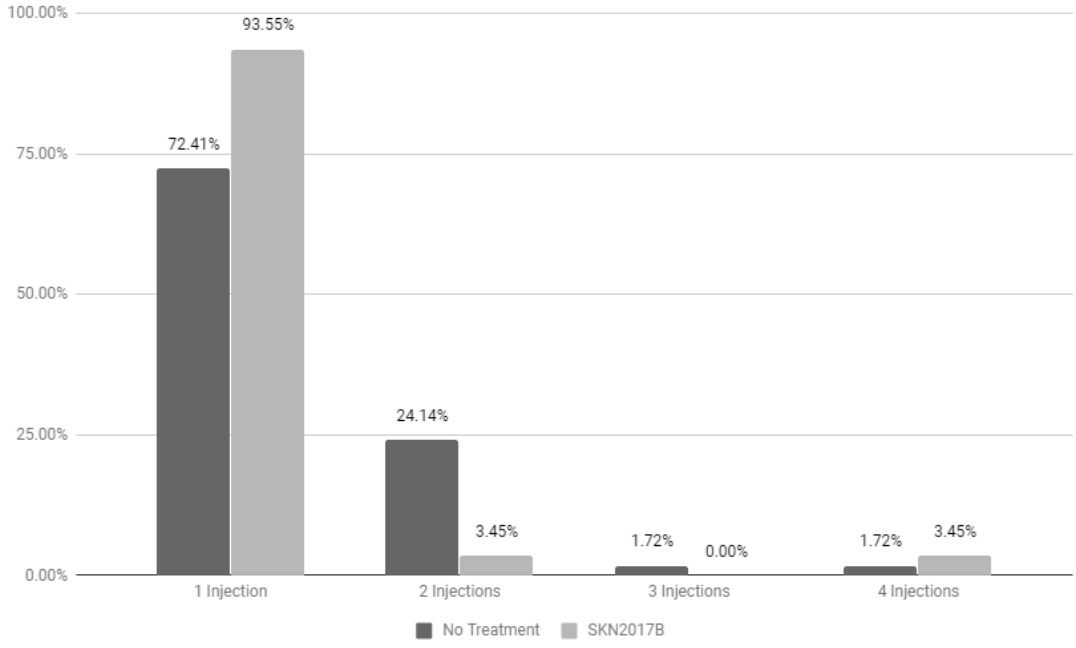

FIGURE 2. Distribution of intralesional injections at postoperative visits for both SKN2017B treatment and no treatment groups. Majority of injections were performed at the one-month postoperative visit in both groups.

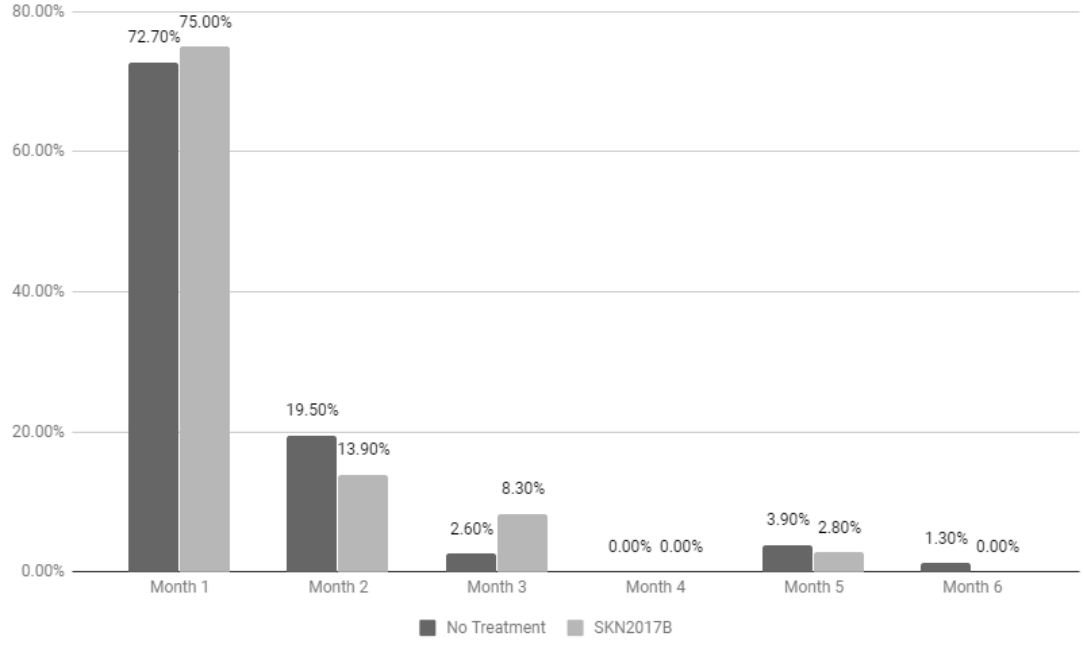

FIGURE 3. (A) 35-year-old Caucasian female, presenting with minimal scarring in her upper eyelids 4 weeks post blepharoplasty. Modified Vancouver Scar Study Scale (MVSSS) for Pliability: supple (1), Height: minimal (1) in both upper eyelids. **(B)** 6-month postoperative photograph, no injections were required, MVSSS for Pliability: normal (0), Height: flat (0) in both upper eyelids.

(A) **(B)**

FIGURE 4. (A) 62-year-old male, presenting with minimal scarring in his upper eyelids 4 weeks post blepharoplasty, Modified Vancouver Scar Study Scale (MVSSS) for Pliability: supple (1), Height: minimal (1) in the right upper eyelid; MVSSS for Pliability: supple (1), Height: moderate (2) in the left upper eyelid. **(B)** 3-month postoperative photograph, no injections were required, MVSSS for Pliability: normal (0), Height: flat (0) in the right upper eyelid; MVSS for Pliability: flat (0), Height: mild (1) in the left upper eyelid.

(A) **(B)**

FIGURE 5. (A) 64-year-old African American female, presenting with raised focal cicatricial areas in her upper eyelids 4 weeks post blepharoplasty. Areas of intralesional injections of triamcinolone and 5-FU are designated by asterisk(s), Modified Vancouver Scar Study Scale (MVSSS) for Pliability: yielding (2), Height: moderate (2) in the right upper eyelid; MVSSS for Pliability: firm (3), Height: extreme (3) in the left upper eyelid. **(B)** 2-month postoperative photograph, one injection was required to left upper eyelid, MVSSS for Pliability: supple (1), Height: minimal (1) for right upper eyelid; MVSSS for Pliability: yielding (2), Height: moderate (2) for left upper eyelid. **(C)** 3-month postoperative photograph, no injections were required, MVSSS for Pliability: normal (0), Height: flat (0) in the right upper eyelid; MVSSS for Pliability: supple (1), Height: minimal (1) for left upper eyelid.

(A) **(B)**

(C)

FIGURE 6. (A) 62-year-old Hispanic female, presenting with minimally raised areas in her upper eyelids 4 weeks post blepharoplasty which required treatment in the right upper eyelid, designated by asterisk, Modified Vancouver Scar Study Scale (MVSSS) Pliability: yielding (2), Height: moderate (2) in right upper eyelid; MVSSS for Pliability: supple (1), Height: minimal (1) in the left eyelid. **(B)** 3-month postoperative photograph, where no injections were required, MVSSS for Pliability: normal (0), Height: minimal (1) for right upper eyelid and MVSSS for Pliability: normal (0), Height: minimal (1) for left upper eyelid.

(A) **(B)**

FIGURE 7. (A) 34-year-old Hispanic female, presenting with raised focal cicatricial areas in her upper eyelids 4 weeks post blepharoplasty. Areas of intralesional injections of triamcinolone and 5-FU are designated by asterisk(s), Modified Vancouver Scar Study Scale (MVSSS) for Pliability: firm (3), Height: moderate (2) in both upper eyelids. **(B)** 3-month postoperative photograph, no injections were required, MVSSS Pliability: supple (1), Height: flat (0).

(A) **(B)**

More specifically, a total of 113 intralesional injections were performed over the course of 6 months follow-up in both groups. Among the injection treatments performed, 73.5% (83 treatments) were performed at 1 month, 17.7% (20 treatments) at 2 months, 4.4% (5 treatments) at 3 months, 3.5% (4 treatments) at 5 months, and 0.9% (1 treatment) at 6 months. A similar distribution of injection treatments was observed between the two groups with the majority occurring 4 weeks after undergoing blepharoplasty; see Figure 2.

There were no adverse reactions reported from either group, nor were there any reported incidence of post injection thinning of skin, pigmentary changes, nor irritation. All patients tolerated SKN2017B well. All patients were able to reach an end point of Grade 1 or better in the Pliability and Height parameters of the Vancouver Scar Study Scale at the conclusion of their treatment. No patient required post procedure dermabrasion, laser resurfacing, or surgical revision.

DISCUSSION

Undesirable scarring following a surgical procedure can result in emotional distress for the patient, as well as the surgeon. Therefore, it is of great importance to help prevent abnormal scarring, and appropriately manage scars to improve patient

care. Maximal scar contraction begins to occur roughly 10-14 days after the incision is made, which is approximately the time when we began to apply SKN2017B in our treatment group.[27] Our rationale was to begin applying the topical cream at the point when maximal scar tissue develops. Our study provides support for the early use of a topical scar cream, since we observed a reduction in the need for intralesional wound modulation at the 1-month postoperative visit in those treated with SKN2017B.

Additionally, subjects treated with SKN2017B were less likely to develop postoperative cicatricial and hypertrophic scarring, which subsequently reduced the need for intralesional injection of triamcinolone and 5-FU by nearly 50% in the patients. Furthermore, there was a decreased need for repeated intralesional wound modulation for the SKN2017B group (only 6.4% of eyelids) in comparison to the no treatment group, in which nearly 27.6% of eyelids required at least 2 injection treatments. Therefore, surgeons that pay particular attention to the quality of scars may benefit from using a silicone-cream based scar cream that has proven effective in wound healing. Furthermore, patients that are not able to follow-up as frequently as desired due to various situations (long-distance travel, employment reasons) may benefit from a topical scar cream that can reduce the likelihood of post incisional cicatricial or hypertrophic changes.

Despite a large assortment of topical scar creams on the market, few have demonstrated the capacity to effectively reduce scarring. Silicone cream, the foundational matrix of SKN2017B, has a reliable history as a safe method for reducing scars.[19,28] A recent double-blinded, multi-center clinical trial demonstrated SKN2017B to be superior to silicone cream for improving the appearance of various scars that were evaluated, including eyelids.[26] Nevertheless, in this particular study, we cannot determine which particular ingredient (i.e., silicone cream or growth factors) played a dominant role in wound healing. We suspect that it was a combination of the growth factors and other ingredients synergistically working together within a silicone cream matrix to allow for the results seen in this study.

Although there is a reduction in post-operative hypertrophic and cicatricial changes with topical application of SKN2017B, undesirable scars can still occur. Of those that were treated with SKN2017B, there was still a need for intralesional wound modulation in 22.9% of the eyelids based on our Vancouver Scar Study Scale inclusion criteria. In cases where eyelid scars do not heal well despite intralesional wound modulation, ablative resurfacing, microneedling, and even scar revision in severe cases may need to be considered.[16,17,30-32]

There are several limitations to this study. The incidence of intralesional wound modulation varies among surgeons, whereas some may inject incisions more often than others, and that the reader should not generalize the incidence of intralesional injections of triamcinolone and 5-FU performed in this study to the general population of surgeons performing eyelid surgery. We attempted to rid as many biases in our study by performing chart review from a single-surgeon case series of patients that underwent a similar surgical technique and type of wound closure by the same individual, thus establishing an ideal internal consistency. This greatly reduces the possibility of a confounding variable (i.e., surgical technique, mastery, etc.) influencing the results. Furthermore, the senior author objectively evaluated the quality of the scar using the modified Vancouver Scar Study Scale, and an intralesional injection was performed to selected areas of the scars in areas that were Grade 2 or higher in "Pliability" and "Height." In our study, we did not evaluate for other issues that can result from scarring, such as hyperpigmentation, prolonged vascularity, milia, and standing cone deformities. These should be evaluated in future studies. Future studies should also evaluate the optimal suture type and wound closure technique through a well-designed, prospective studies.

DISCLOSURES

Christopher I. Zoumalan MD FACS is a consultant for Allergan, Irvine, CA and owns stock and is the scientific advisor for MD Medical Designs, Inc., Los Angeles, CA, manufacturer of the scar creams studied in this trial.

Brandon D. Kalasho BA and Robin Kikuchi have nothing to disclose.

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