Injectable Liquid Silicone (Siloxane) for Improvement of Nasolabial Folds

José Aparcana, MD; Enrique Hernández-Pérez, MD; Hassan Abbas Khawaja, MD

Improvement of facial wrinkles has been attempted through a number of modalities. For years we have used injectable liquid silicone (siloxane), with positive results. To confirm the effectiveness of siloxane, we injected it into the nasolabial folds of 50 patients and also performed a statistical analysis (Spearman rank correlation). Assessment was made by 3 observers. Our results were positive and statistically significant.

Improvement in nasolabial folds is the focus of many facial rejuvenation programs. Factors contributing to deepened nasolabial folds are cheek skin laxity, inferior shift of the malar fat pad, and undercutting by the lip tractus muscles.[1,2] Shallow nasolabial grooves and folds are signs of youth. With aging, the malar fat and skin descend. This descent cannot surpass attachments of the zygomaticus major and orbicularis oris muscles with the labial skin; this results in deepening of the nasolabial grooves and overhanging of the nasolabial folds.[2]

For years, injectable liquid silicone (siloxane) has been used for facial beautification. Siloxane comprises silicone, oxygen, and methane.[3] If used properly in small amounts and at the appropriate sites, siloxane usually produces pleasing results. When used in large amounts, at the wrong sites, or in an adulterated form, the results may be disastrous. We have injected siloxane for more than 25 years, following the indications we learned from Jay Barnett, MD, for its use. We have heard only anecdotal evidence of the advantages of siloxane from our colleagues; a clinical study with statistical support has not been published.

Dr. Aparcana is Dermatologist, Dr. Hernández-Pérez is Director, and Dr. Khawaja is Dermatologist, all at the Center for Dermatology and Cosmetic Surgery, San Salvador, El Salvador.

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This article assesses the improvement of nasolabial folds using siloxane.

MATERIALS AND METHODS

Fifty patients (46 females and 4 males, aged 28–60 years) were enrolled in the study. Thirty-six patients were Hispanic (Central American); 14 were Pakistani. All patients exhibited Fitzpatrick skin type III or IV and were healthy and had no systemic disease. Female patients were not pregnant and were not breast-feeding. Topical lidocaine 5% was applied 20 minutes before injection of siloxane into the nasolabial folds. Either 350 cc or 1000 cc of siloxane was used depending on the depth of the nasolabial folds; thick (heavy, 1000 cc) siloxane was used for deeper folds. The vial was inverted, and thick, viscous silicone was drawn into the syringe through an 18-gauge needle. The microdroplet technique, with a 25-gauge, 16-mm tuberculin syringe, was used for siloxane injection (Figure 1). Into the lower and mid nasolabial grooves, 0.2 cc was injected; into the upper groove and adjoining medial nasolabial triangle area, 0.4 cc was injected. The idea was not to eradicate the groove completely but to make it smooth and shallow. For this reason, only one session was performed. Preoperative photographs of all patients were taken, and all patients signed a consent form. Cold compresses were used for 15 minutes postinjection. Assessment was made by 3 observers: 2 physicians and the patient. One physician was the one who injected the siloxane; the other was blinded to the

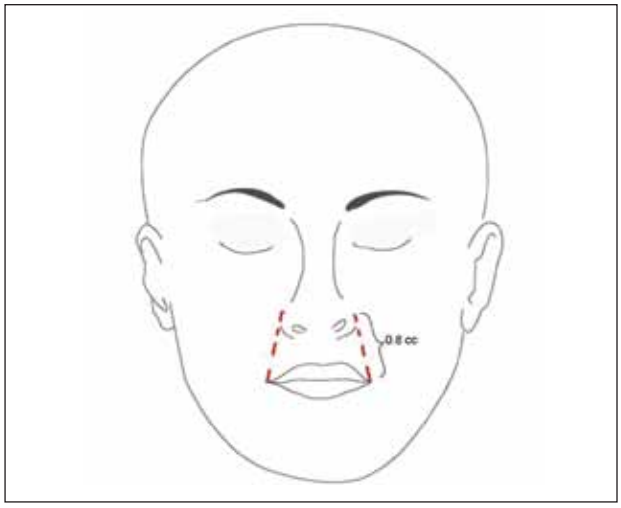

Figure 1. No more than 0.8-cc siloxane should be injected per side when correcting the nasolabial folds Use a little more than 0.8 cc with injections that are proximal to the nose. Generally, use 0.4 cc above (close to nose), 0.2 cc in the middle, and 0.2 cc distal to nose (close to mouth). The microdroplets should be injected near one another and never in the form of small nodules. To establish a smooth appearance, a gentle massage around the injection site must be performed postinjection. Illustration courtesy of José Enrique Hernández-Pérez, MD.

patient's treatment. Assessment was made in the form of crosses from + to +++, with +++ showing maximum improvement. Photographs were taken at 1, 2, and 6 months postinjection. The nasolabial groove was divided into 3 zones: (1) upper nasolabial triangle bounded by the alar crease, upper nasolabial groove, and lines drawn obliquely from the ends of the alar crease toward the nasolabial groove; (2) mid zone below the upper nasolabial triangle up to the lip margin; and (3) lower zone below the mid zone until the end of the groove. As with nasolabial grooves, nasolabial folds were divided into 3 zones: upper, mid, and lower. Zonal improvement was assessed. Results were subjected to statistical analysis; the assessment made by the 3 observers was compared with the preinjection and postinjection clinical observations and photographs.

For statistical purposes, we used the Spearman rank correlation, which is appropriate for small samples and assesses qualitative variables, and the scale of + to +++ previously described.

RESULTS

Improvement was seen in all patients after only one injection. Nasolabial folds became less prominent; nasolabial grooves became shallower. The 3 observers assessed improvement in the lower and mid zones as 76% for ++ and 24% for +++. Improvement in the upper zone (nasolabial triangle) was assessed as 83% for +++ and 17% for ++. Follow-up showed that the same improvements persisted in all patients after 6 months (Figures 2 and 3).

Statistical analysis was as follows: the correlation coefficients were determined and their values were compared with the limit or critical value for the 0.05 level of statistical significance that is standard for this test. Correlations were as follows: among patient and first physician, 0.5169; among patient and second physician, 0.5544; and among first and second physicians, 0.6287. Taking into account the Spearman table of significance, using 1-tailed test and for the 0.05 level of statistical significance, the critical value (limit) was 0.3059; this study proved to be statistically significant.

No complications, such as persistent edema, foreign body granuloma, or skin necrosis, were noted. Pain was mild and tolerable during the injection. Minor bruising was noted in one patient (with thin skin) at one side of the nasolabial triangle area. The bruising disappeared spontaneously in a few days.

COMMENT

A variety of techniques and materials have been used to obliterate nasolabial folds. These include face-lift procedures, insertion of Gore-Tex threads and patches, and use of fat, collagen, autologous dermis, polymethylmethacrylate, and botulinum toxin type A, with variable results.[4,5] Fat and collagen are short-lived in the nasolabial folds and usually disappear in a few weeks. Infection, extrusion, and granuloma formation are possible complications of Gore-Tex implants.[4,5] Botulinum toxin type A is used by some practitioners, with variable results, to relax the muscles and the nasolabial folds.[5] Subperiosteal and other surgical face-lifts that lead to extensive dissection beyond the nasolabial folds are aggressive procedures.[6] Regular face-lifts by themselves cannot completely eliminate the folds, especially in the upper zone (nasolabial triangle). As the superficial muscular aponeurotic system thins out over the zygomaticus muscles along the nasolabial folds, plicating it in the upper portion may cause a bunching effect with more prominence of the nasolabial triangle.

A number of fibers of facial-expression muscles insert into the dermis of the nasolabial folds. Incomplete resection of these slips at the nasolabial folds may cause dimples and depressions along the folds that become prominent with smiling and other facial expressions.[7] However, complete removal of these dermal attachments may improve the nasolabial folds. Lightoller[7] described such attachments extending from the quadratus labii superioris muscle; Zufferey[8] described them extending from the zygomaticus major muscle. Pessa[9] noted improvement in the medial nasolabial folds by selectively resecting the levator alae facial muscle. Duchenne[10]

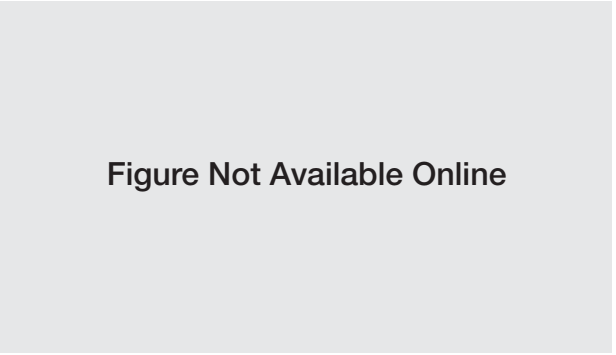

Figure 2. A patient in her late 30s before (A) and 6 months after (B) treatment with 0.8 cc siloxane in the nasolabial grooves.

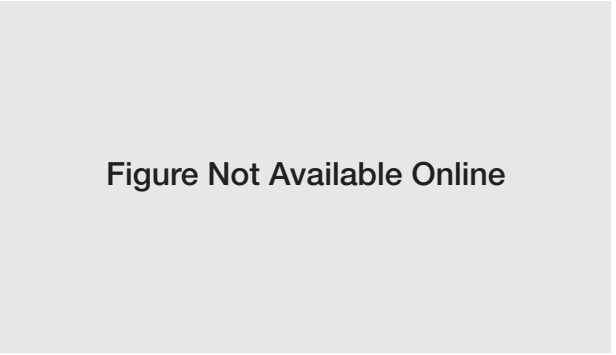

Figure 3. A patient in her early 40s before (A) and 6 months after (B) treatment with 0.8 cc siloxane in the nasolabial grooves.

showed that through electrostimulation, individual facial muscles could be made to contract independently of each other. Rubin[11] described the anatomy of the smile. Barton[12] classified nasolabial folds into 3 functional zones for rhytidectomy, each zone having a separate area of cutaneous wrinkling accentuated by the action of underlying mimetic muscles.

Siloxane is inert and usually does not react antigenically and lead to complications if injected properly into the lower dermis or upper subcutaneous tissue using the microdroplet technique.[13] Since it is classified as a permanent filler, a new siloxane injection must never be repeated at the same place until 4 to 6 weeks postinjection.[14] Complications with siloxane occurred in many women when massive amounts were injected into the breasts for augmentation. Sakurai repeatedly injected more than 100,000 patients; Kagan, who introduced the procedure in the United States, stated that he had injected more than 100 women over a 1½-year period.[14] Amounts varied from 750 to 2000 cc per breast. This led to serious problems, including partial or total mastectomy, skin necrosis, and a few deaths after intravascular injections.[14,15] One incident involved patients who were injected with massive amounts of a material alleged to be mineral oil or silicone. Up to 8 L of the material was used per patient (average, 4.5 L); at least 6 of the patients were injected by nonphysicians. Information was never given about the formula, the brand, or the degree of quality or purity, and the results were catastrophic.[15] To improve the results, the patients were subjected to mutilating surgeries. Silicone embolism may occur when massive volumes are used, leading to asphyxia and death.[16] However, when silicone or another filler is used around the orbit of the eye, the injection should never be directed toward the eye but always centrifugally.[16,17] Blindness may occur if the injection is made centripetally.[16,17]

Siloxane has been a source of conceptual and legal confusion. By concept, a drug or medication is a substance with therapeutic benefits that is prepared to serve, through its pharmacologic properties, as a remedy. On the contrary, a medical device is a product used for therapeutic purposes but that does not act chemically (eg, intraocular implants).[18] In short, siloxane has never been a drug but a medical device, so it must be subject to different legislation than a drug. The enactment of the US Food and Drug Administration (FDA) Modernization Act of 1997 allowed any legally marketed FDA-approved device to be prescribed or administered for any condition or disease within a physician-patient relationship.[19,20] Siloxane is now considered to be an off-label medical device, a view that the FDA has always considered to be the practice of medicine; therefore, off-label use of siloxane is considered legal.[19,20]

Because siloxane is known as a permanent filler, it should be used with caution. But is this not true, medically speaking, when using any other facial or body implant? Although siloxane has been classified as a permanent filler, as a result of muscle action such as smiling and crying and from gravity, facial tissues may experience some form of displacement, and in some cases the injection must be repeated after a variable period from 6 months to a year.[21] It may be combined effectively with peels, sunscreens, topical tretinoin, oral isotretinoin, botulinum toxin injections, transcutaneous face-lift, percutaneous eyebrow-lift, delta or S lift, or blepharoplasty as part of a facial rejuvenation program.[22,23]

CONCLUSION

Injectable siloxane is a simple, safe option for improving the nasolabial folds using the microdroplet technique. The results may be pleasing if siloxane is used in the correct amounts and at the correct sites and not injected at the same site within 4 to 6 weeks of the last injection. Extrapolating our results, we believe that similar improvement may be obtained by injecting siloxane into other parts of the face. Clinical studies should be made to confirm this hypothesis.

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