
Lip Augmentation with Liquid Silicone

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BACKGROUND. Many fillers have been used to augment the lips. One of these that has provided long-term satisfactory results is liquid silicone.

OBJECTIVE. To demonstrate the efficacy and safety of lip augmentation with liquid silicone.

METHOD. Following a discussion of the benefits and risks of the procedure and the benefits and risks of alternatives and after answering all of the patients' questions, an informed consent form was signed. After obtaining anesthesia with a regional nerve block of the infraorbital and mental nerves, 0.25 to 0.5 cc of liquid silicone (1,000 centistokes) was injected using the microdroplet technique into the vermilion border of both the upper and lower lips. Depending on the desire of the patient, the procedure was repeated monthly. The augmentation of the lips was

documented with histology, micrometry, and digital photography.

RESULTS. Lip augmentation was achieved gradually during the months following liquid silicone injections into the vermilion border of the lips in the 608 patients studied. Most of the patients requested a second and third injection session. The results were most dramatic in the patients with type I and type II lips and less satisfactory in patients with type III lips. Bruising occurred in the majority of the patients. Eleven patients (2%) developed small palpable granulomas. These granulomas either required no treatment, responded to steroid injections, or were excised.

CONCLUSION. The use of liquid silicone remains an effective method of lip augmentation. It returns the adolescent vermilion curl to the lips.

JAMES E. FULTON JR, MD, PHD, SERBAN PORUMB, MD, JOHN C. CARUSO, MD, AND PAUL K. SHITABATA, MD, HAVE INDICATED NO SIGNIFICANT INTEREST WITH COMMERCIAL SUPPORTERS.

LIQUID SILICONE has been used for tissue augmentation for over 30 years. Multiple authors have reported on more than 17,000 facial treatments.¹⁻⁶ Lip augmentation with silicone has also been well documented.^{7,8} When correctly administered, the procedure produces satisfactory and often dramatic results. Unfortunately, the use of silicone for cosmetic purposes ceased in January 1992 when the US Food and Drug Administration (FDA) declared a moratorium on the use of this device. However, its use continued as a spray for the tips of needles and as a lubricant in plastic syringes.⁹ With FDA approval in 1994 as a medical device for intraocular injections to tamponade retinal detachments, silicone became available again. The FDA Modernization Act of 1997 allows for the off-label administration of silicone for soft tissue augmentation (Appendix 1).¹⁰ This article reviews our results of 608 cases that have undergone lip augmentation in the last 3 years. Recently, other authors have also outlined the safety and efficiency of lip augmentation with silicone^{11,12} and the treatment of the occasional silicone granuloma.¹³

Method

Informed Consent

After patients read the brochure *Silicone Micro-injections* (MJD Publications, Bethesda, MD) and discuss the risks and benefits of the procedure and the risks and benefits of alternatives and after all of their questions are answered, they sign the informed consent form (Appendix 2). Patients are informed that silicone (Silikon, Alcon Labs, Fort Worth, TX, USA) is approved by the FDA for injection into the eyes and that lip augmentation is an off-label use. This consent outlines for the patient the possible complications of bruising, swelling, and granuloma formation. It contains three signature lines indicating to the patient that repeat sessions are often necessary. To reduce bruising, patients are reminded not to take any salicylates, ibuprofens, or vitamin E for 2 weeks before a therapeutic session. They are allowed to use acetaminophen. Patients are advised that their own collagen will form around the silicone microdroplets and further augment the vermilion border of the lips over the next few weeks. We also inform patients that the prognosis is best in those with type I and type II lips and limited in those with type III lips (Figure 1). The latter patients are asked to consider additional therapies, such as lip advancement or lip tattooing. The patients are told to return in 1 month for follow-up and possible reinjection.

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Nerve Blocks

Anesthesia of the lips is obtained with intraoral regional nerve blocks of the infraorbital and mental nerves using 2% lidocaine with epinephrine (1:200,000) buffered with sodium bicarbonate. If the patient is sensitive to epinephrine, the 2% lidocaine is diluted with plain 1% lidocaine (50:50). Approximately 0.5 cc of anesthetic is injected through the gingival lining directly above both incisor teeth on the upper jaw bilaterally and below both incisor teeth on the lower jaw bilaterally using a half-inch 30-gauge needle (Figure 2). A small additional injection of 0.25 cc is placed adjacent to the frenulum of the upper lip to complete the process. This results in lip anesthesia within 5 minutes. An occasional repeat injection is sometimes needed for a particularly resistant quadrant of the lip.

Vermilion Border Injections

Liquid silicone (Silikon) (0.25–0.5 cc) is injected through a 27-gauge needle into the vermilion border or “white line” of the lip in a microdroplet fashion. The shaft of the needle is inserted into the vermilion border, and the liquid silicone is injected as the needle is withdrawn (Figure 3). The injections are repeated along the vermilion border until the procedure is complete. Approximately 0.25 cc is injected into the upper lip and 0.25 cc is injected into the lower lip to yield symmetry. In selected patients (with type III lips), additional injections are occasionally introduced into the lateral orbicularis oris muscle to attempt lip eversion. Finger compression of the angular artery and direct compression with cotton gauze are immediately applied to reduce bruising. Following hemostasis, the area is compressed with ice for 3 to 4 minutes to reduce swelling. Patients are warned not to drink hot tea or coffee until the anesthesia has worn off. Afterward, there are no special instructions, and the patient may return to work the next day. The desired augmentation is gradually attained with a series of treatments at monthly intervals.

Documentation

The results were documented with millimeter measurements of the lips using a micrometer. Lip thickness was measured in both quadrants of the upper lip. The results were averaged and charted (Figure 4). The results were also documented with digital photography using *Computer Imaging Software* (United Imaging, Inc., Winston-Salem, NC, USA).

Histologic Evaluation

Two-millimeter punch biopsies were obtained from the vermilion border of the upper lip in five patients 8 to 12

weeks following tissue augmentation. These were processed in formaldehyde and stained with hematoxylin and eosin. The slides were viewed microscopically at $\times 40$ and $\times 100$. The results were documented with digital photography. The extent of dermal fibrosis and inflammation was examined. The two granulomas that were excised were also examined microscopically.

Results

The restoration of the vermilion curl of the lips gradually developed as new collagen formed around the silicone microdroplets following repeat treatment sessions. This was documented with micrometer measurements (see Figure 4) and digital photography (Figures 5 to 7). Six hundred eight patients were followed (590 females, 18 males; average age 38 years) over 3 years. Seventy-three percent of the patients had two sessions, 51% had three sessions, and 31% had more than three sessions.

Patients with type I and type II lips were uniformly pleased with the results. Patients with type III lips were less satisfied and considered further therapy, such as permanent tattooing of the vermilion border or a lip-lift.¹⁴ Significantly, none of the augmentations that were attained were lost during the follow-up period.

The complications were minor, although the majority of patients developed minor bruising following the procedure. This was only a temporary inconvenience. Eleven patients (2%) developed palpable silicone granulomas (Figure 8). These were not treated (four cases), were improved with the therapeutic intervention with intralesional steroids (five cases), or were excised (2 cases). The lip biopsies demonstrated an increase in dermal fibrosis and areas of vacuolization that were surrounded by histiocytes (Figures 9 and 10). There was an occasional foreign body giant cell. The pathologist interpreted these biopsies as showing early stages of granuloma formation. The two nodules that were excised demonstrated the same findings except that the granulomas were more developed with larger vacuoles and more foreign body giant cells.

Discussion

The use of liquid silicone for lip augmentation has been a successful cosmetic procedure for over 30 years. It is a safe and effective method to achieve long-term lip augmentation. Orentreich and Orentreich reviewed the method in 1989.⁵ Duffy outlined his perspectives on injectable liquid silicone in 1998.⁶ Its effectiveness and safety surpass those of bovine collagen, which produces only temporary augmentation lasting a few weeks or months and has a significant incidence of allergic reactions.¹⁵ Other permanent implants, such as expanded polytetrafluoroethylene, produce augmentations that feel unnatural and may extrude

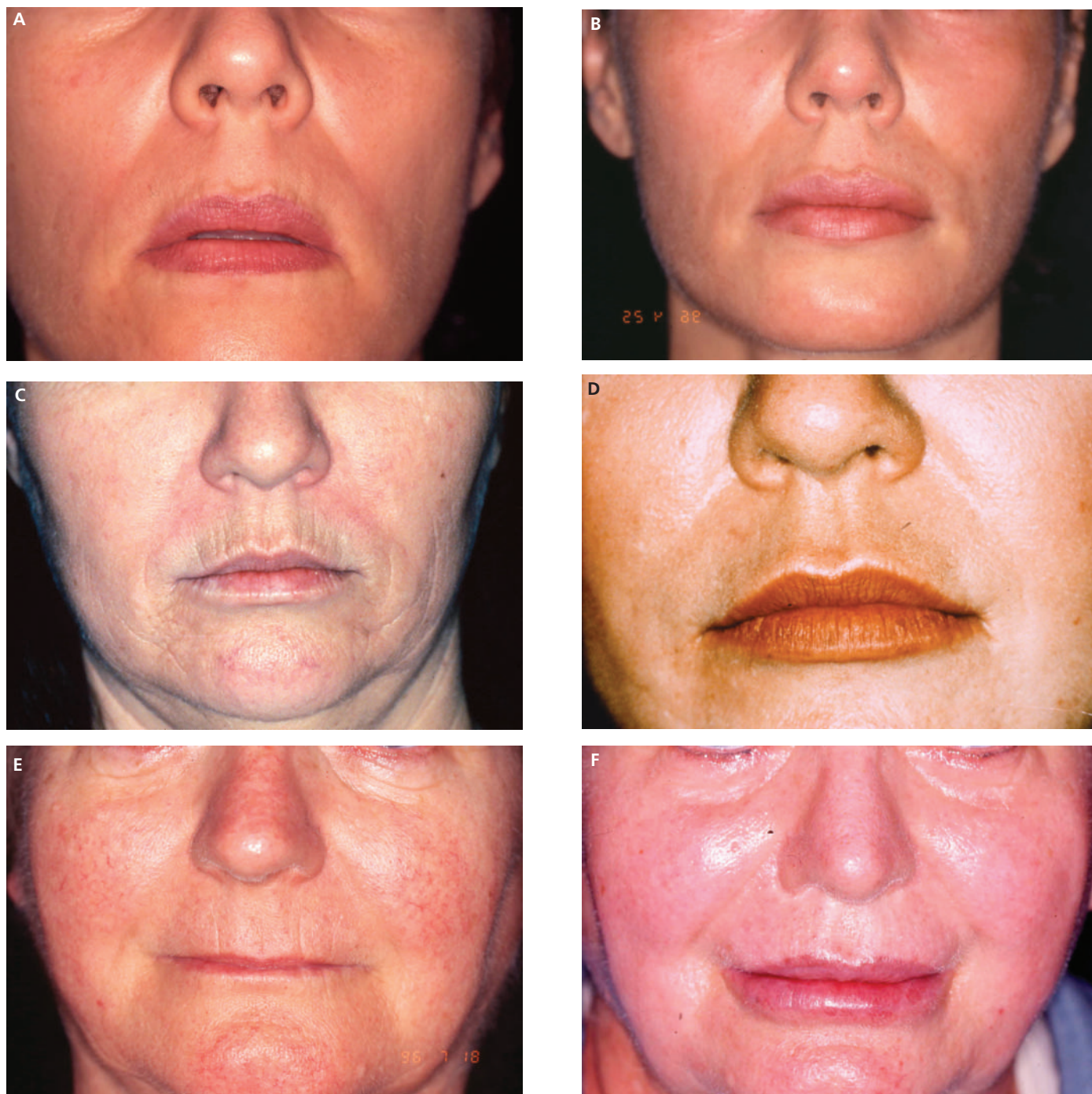


Figure 1. Types of lips. (A) Type I. This patient had a full lip with a vermilion curl that was lost with aging. (B) The curl was easily restored with microdroplet silicone injections. (C) Type II. This patient had a full lip that developed excessive vertical lines from smoking and/or ultraviolet light damage. (D) Rejuvenation of this lip required resurfacing in addition to filling. (E) Type III. This patient never had a full lip. It could not be generated by simple filling. (F) A lip-lift and lip tattooing produced a satisfactory result. Reproduced with permission from Fulton JE Jr et al.¹⁴

or buckle. They may also produce a foreign body granuloma.¹⁶ Fat transfer for lip augmentation requires more volume (9–12 mL). This results in temporary lip distortion and ends up as a disappointment because the volume is lost, only to be distorted again during the second or third

refill.¹⁷ Injectable silicone is far more predictable and reproducible for lip augmentation. The Soft Tissue Augmentation Task Force Report on Liquid Injectable Silicone for the American Academy of Dermatology concluded in December 1993 that “there is a wealth of clinical experi-



Figure 2. Intraoral anesthesia. Lidocaine (2%) with epinephrine (1:200,000) is injected as regional nerve block anesthesia before a therapeutic session of lip augmentation. Approximately 0.5 cc is injected directly above both incisor teeth of the upper jaw and below both incisor teeth of the lower jaw. To complete the anesthesia, an additional injection (0.25 cc) is placed next to the frenulum of the upper lip.



Figure 3. Microdroplet silicone injection. Silicone is injected slowly in a retrograde fashion as the 27-gauge needle is withdrawn. The thick viscosity (1,000 centistokes) allows only droplets (0.02 mL) to be deposited as the needle is withdrawn. Approximately 0.25 cc is used in the upper lip and 0.25 cc is used in the lower lip during each session. Compression of the angular artery during a therapeutic session reduces bruising.

ence in dermatology with the use of liquid injectable silicone by the microdroplet technique which shows its efficacy and safety in many individuals over many years."¹⁸ Many newer fillers, such as hyaluronic acid, polylactic acid, and polyacrylamide, are becoming available. Their efficacy and economy should be compared with silicone for lip augmentation.

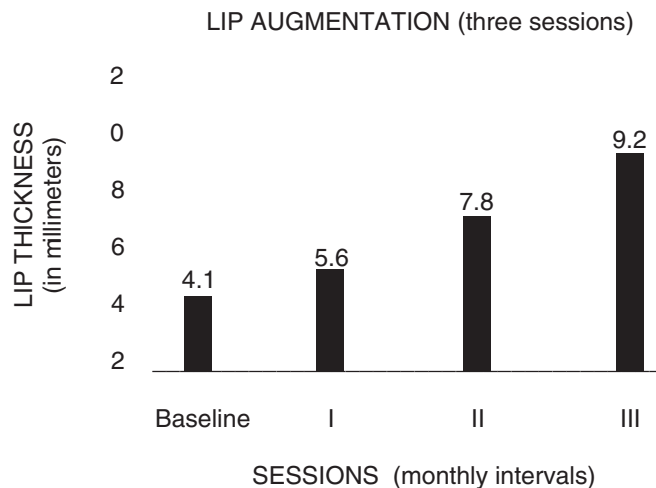


Figure 4. Lip augmentation (three sessions). The thickness of the upper lip was measured in both quadrants of 25 patients and averaged. The results were plotted at baseline and 30 days after one, two, and three therapeutic sessions. Note the gradual increase in lip thickness. This level of augmentation was not lost during the 1-year follow-up period.

The vermilion border of the lip is an area resistant to excessive silicone granuloma formation.⁸

All of the biopsies taken demonstrated reactive granulomas with histocytes and new collagen surrounding the droplets of silicone (see Figure 11). This is how the tissue reacts to the injection of some foreign bodies—similar to the tissue reactions seen with polylactic acid.¹⁹ Some individuals have a more dramatic reaction, producing a small visible nodule as the silicone droplets pool and produce larger vacuoles surrounded by a histocyte inflammatory response. We have never been able to correlate this reaction with an infectious process, poor dental hygiene, trauma, or herpes flare-ups.²⁰ Perhaps the extent of the inflammatory reaction is genetic. The visible reactive granulomas are more common when silicone is injected into the fine lines of the face, such as the vertical lip lines or crow's feet, especially in thin-skinned individuals.¹⁰ Caution should be used in areas off the vermilion border of the lips because new collagen formation may become apparent as a nodule. New collagen formation may be pleasing in the vermilion border of the lips but troublesome in the thin skin of the face. The 2% incidence of visible silicone granulomas is higher than that induced by hyaluronic acid²¹ but lower than the reactions produced by expanded polytetrafluoroethylene.¹⁶ The report indicating that silicone foreign body reactions may be treated with imiquimod 5% is exciting.¹³ We hope to try this therapeutic possibility.

Although there have been medical and legal ramifications from using silicone in the past, Shiffman reviewed the current legal status of silicone injections in cosmetic sur-

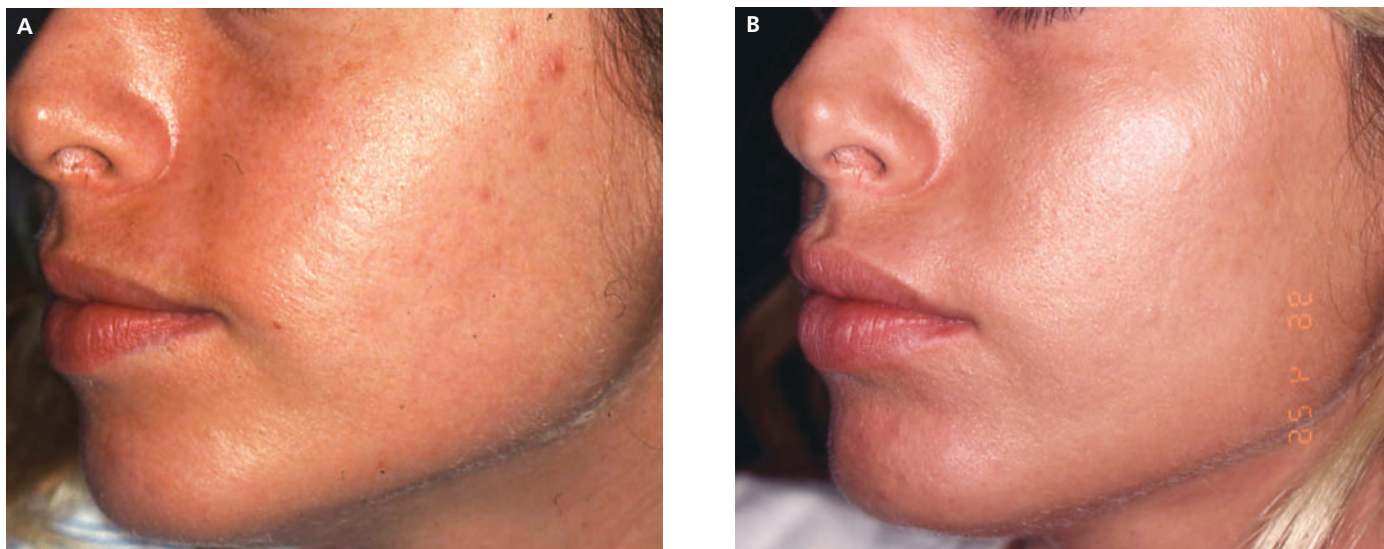


Figure 5. Lip augmentation (type I). (A) This patient demonstrates a type I lip with loss of natural lip curl owing to aging. (B) The original fullness was restored with silicone augmentation over three sessions.

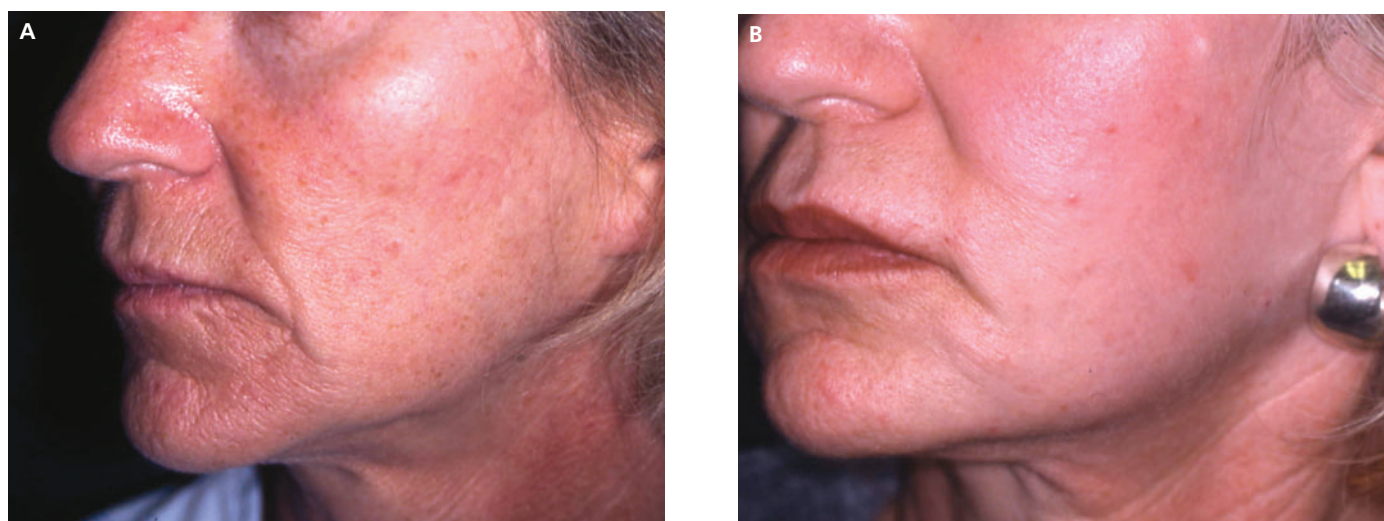


Figure 6. Lip augmentation (type II). (A) The lips of this patient were augmented with liquid silicone. (B) This patient also underwent skin resurfacing with the CO₂ Ultrapulse (Lumenis, Santa Clara, CA, USA) laser to further improve her facial lines.

gery.²² The FDA considered the use of liquid silicone in cosmetic surgery illegal until 1994 when silicone, as AdatoSil (Micromedex, Inc., Greenwood Village, CO, USA), was approved for use in the eye for the tamponade of retinal detachments. Currently, silicone for cosmetic use is considered an “off-label” use of a medical device. This is legal except, as outlined by Shiffman, the practice cannot be advertised directly to the public, and the special needs of the patient must be documented in the chart (see Appendix 1).

The currently available choice of silicone (Silikon) has a higher viscosity (1,000 centistokes) than the previously

available medical-grade silicone (350 centistokes). The viscosity of the initially approved silicone (AdatoSil) is too high (5,000 centistokes) for easy use. These higher viscosities have the disadvantage of requiring a 27-gauge needle for injection instead of the previous 30-gauge needle. There is more bleeding and bruising following the use of this larger needle. However, the 1,000-centistoke silicone migrates less, is more predictable, and may produce fewer silicone granulomas than the former, less viscous silicone.⁴ With this continual stimulation from the microdroplets of silicone, the degree of lip augmentation attained is not lost.

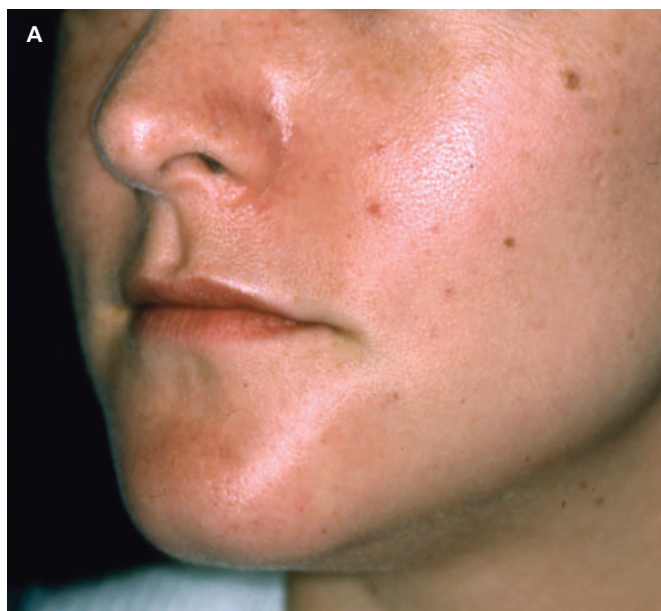


Figure 7. Lip augmentation (type III). (A) In this type of patient, the inadequate lip cannot be successfully augmented with filler material alone. It often looks more like a duck bill after augmentation. (B) In addition, the procedures of a lip-lift and permanent lip tattooing added to her appearance.



Figure 8. Silicone granuloma. A few cases (2%) developed small nodules in the lip after augmentation. These were either not treated or responded to steroid injections or excision.

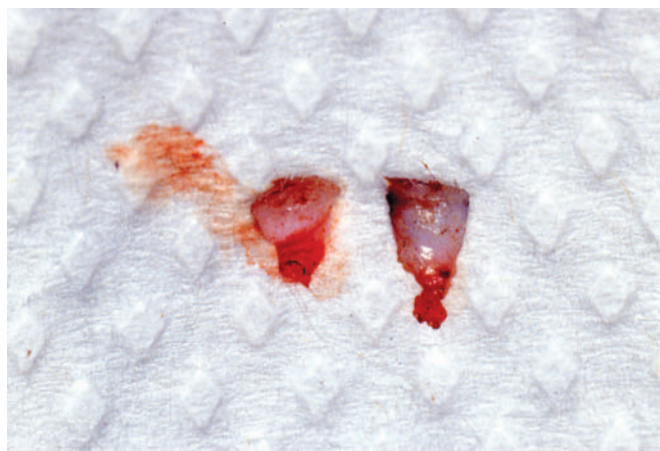


Figure 9. Gross anatomy. Biopsies demonstrated the development of dermal sclerosis after augmentation with silicone. Note the thickness of the treated dermis on the right compared with the control specimen on the left.

In conclusion, the ease of injection, the predictability of the results, and the relative lack of side effects using silicone may outweigh the results obtained with some other filler materials.²³ However, some patients may only want temporary fillers, such as hyaluronic acid, and some patients prefer to use their own fat. These options should remain available. We were able to confirm that the major problem with enlarging an individual's lips was weaning them off their requests for more repeat injections.⁷ Once patients are aware that their lips are becoming fuller, they want more. The main

caution is not to overdo it. The adage, "Beauty is a matter of a few millimeters" is especially true for lips.⁸ Esthetic skill must be employed to give a subtle, tasteful lip enhancement.

We have reviewed the many advantages and potential pitfalls of lip augmentation with silicone. It is nevertheless imperative for cosmetic dermatologists to do a preceptorship with an "injecting physician" before adding this procedure to their "menu of services" and to review their coverage for this procedure with their malpractice carrier because coverage may vary from state to state.

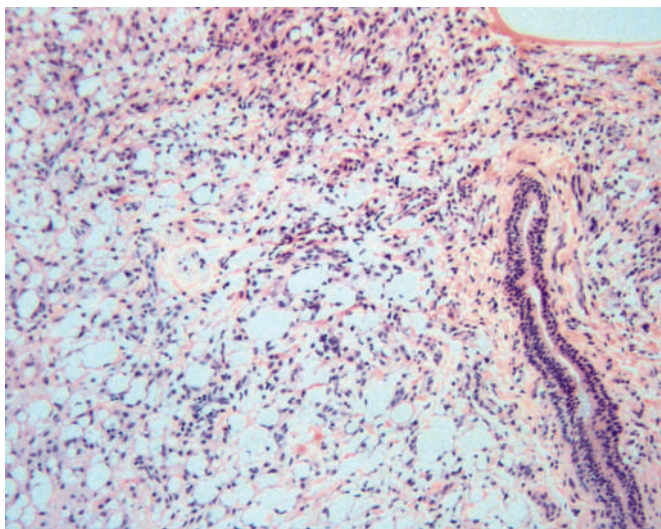


Figure 10. Microscopic anatomy ($\times 100$ original magnification). Note the vacuoles, the increase in dermal collagen, and the presence of histiocytes.

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Appendix 1. Legality of the Use of Silicone Injections

Dear Editor:

The use of liquid silicone in cosmetic surgery had been considered illegal by the Food and Drug Administration (FDA) until 1994 when silicone, as AdatoSil, was approved by the FDA for use in the eye for retinal detachment. As such, silicone may now be used in an "off-label" use as a medical device. There are, however, restrictions which include no advertisement of the product's use in this manner and the decision as to whether to use the device has to be an individual physician's decision based on the unique needs of the patient. The physician should record in the medical record the reasons for the decision to use silicone for each individual patient. In California, there is a specific statute which states that "the prescribing, dispensing, administering, or furnishing of liquid silicone for the purpose of injecting such substance into a human breast or mammary constitutes unprofessional conduct."¹

The following letter was received from the FDA by a member of the American Academy of Cosmetic Surgery detailing the FDA's position:

"Dear Dr. _____,

This letter replies to your facsimile transmission of February 10, 1999, regarding the off-label use of a

product, which is cleared for commercial marketing by the Food and Drug Administration (FDA). In particular, you used AdatoSil, an ophthalmic product, to fill a defect in a patient's nose. You state you have never advertised the product, and it was an individual physician's decision based on the unique needs of one of your patients.

The situation you describe has always been viewed by the FDA as "the practice of medicine," and therefore, this off-labeled use is considered legal.

Sincerely yours,
Mr. Eric Latish, Chief
Dental, ENT, and Ophthalmic Devices Branch
Division of Enforcement II
Office of Compliance
Center for Devices and Radiologic Health
Food and Drug Administration"

Reproduced with permission from Shiffman MA. Legality of the use of silicone injections. *Int J Cosmet Surg Aesthetic Dermatol* 2000;2:6.

Reference

1. Annotated California Codes, Business and Professions, §2251 (West), 1980.

Appendix 2. Informed Consent for Tissue Augmentation

Patient Name: _____

Age: _____

To the Patient: You have the right to be fully informed about your skin condition, the risks, benefits and complications of treatment and any alternatives to treatment of your condition prior to deciding whether or not to undergo the proposed procedure. This disclosure is not meant to scare or alarm you; it is simply an effort to better inform you so that you may give or withhold your consent for the treatment program.

Silikon® (liquid silicone) was approved in 1997 by the FDA (Food and Drug Administration) for use in the eyes of patients with certain conditions. As a result, liquid silicone may now be used as an "off-label" filler material for cosmetic improvement of certain tissue defects and/or for cosmetic enhancement in select individuals for specific purposes. I hereby authorize Dr. _____, M.D., or whomever he/she may designate as his/her assistant, to perform the following procedure: _____.

Initial if you understand and agree _____

I have been informed that the practice of medicine is not an exact science and that no guarantees can or have been made concerning the expected results in my case. I have read and understand the brochure titled "**SILICONE MICRO-INJECTIONS.**"

Initial if you understand and agree _____

The most frequent complications are bruising, swelling or the development of small lumps at the injection site. I have been advised of the risks of this treatment, which could include darkening of the pigment, inflammation, asymmetry, infection, allergic reaction, silicone migration or scarring. There may be a need for surgical removal of the silicone.

Initial if you understand and agree _____

I have also been advised of the expected benefits of this treatment and alternative treatments for my condition, including no treatment at all. I have been advised that several treatment sessions may be necessary to obtain satisfactory results and that results may not be permanent.

Initial if you understand and agree _____

I certify that the above consent has been read and fully understood by me and that I have been given ample opportunity for discussion and to ask questions. I have received no medication prior to signing this consent. I hereby consent to treatment. This constitutes full disclosure and supersedes any previous verbal or written disclosures.

Session I	_____	_____	_____	_____
	Staff Signature	Date	Patient Signature	Date
Session II	_____	_____	_____	_____
	Staff Signature	Date	Patient Signature	Date
Session III	_____	_____	_____	_____
	Staff Signature	Date	Patient Signature	Date

Commentary

Although the authors' favorable results using liquid silicone to augment lips are reassuring and to some degree mirror the experience of other authorities in the field, there are some issues worth discussing. First, fashions change. Today's full lips may be tomorrow's social embarrassment. Second, granulomas occurring in the lips have been reported with a wide variety of tissue augmenting agents.^{1,2} This may be due to the lips' proximity to a vast oral reservoir of bacteria or their susceptibility to cutaneous trauma and infectious processes, which may trigger the development of granulomas.³ Indeed, the incidence of granuloma formation in this study is substantially higher than that reported in other large-scale studies.^{4,5} Third, although the type of liquid silicone Fulton and colleagues employ is legal to use, practitioners who experience complications may be unfairly penalized for its use by juries subjected to media demonization of silicone.⁶ Fourth, complications following liquid silicone may occur years after treatment, whereas the use of permanent agents creates a de facto long-term relationship with patients who receive it. Initiat-

ing treatments with less permanent agents gives the practitioner the chance to assess both therapeutic efficacy and patient psychological suitability for permanent implantation.

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