

Liquid Injectable Silicone: Should You Implement It in Your Practice?

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Many factors have contributed to the renewed interest in liquid injectable silicone (LIS) as a permanent filler. Its use currently remains at the discretion of each individual physician and his or her threshold of concern about permanent side effects. The product's contentious past and absence of prospective, controlled trials has prompted many practitioners to oppose its use in elective procedures. However, with new "medical-grade" silicones being produced and the belief that previously noted adverse effects are attributable to "dirty" silicone and irresponsible use, others contend that LIS is completely safe for use as a soft tissue augmentation agent, particularly for facial rejuvenation. This article addresses the controversial history of silicone and the existing debate about its dermatologic uses. This debate may soon reach a climax as more patients request information from their dermatologist about the "new microdroplet technique" that "permanently treats wrinkles."

There has been recent fervor regarding liquid injectable silicone (LIS) for facial rejuvenation. It is believed that an absence of scientific data linking silicone to systemic disease, the advent of a specific microdroplet technique, and widespread public pressure for a long-lasting soft tissue filler have fostered an environment of renewed interest in LIS for facial rejuvenation.¹ This product is not free of risks, though. Most reported complications from

LIS are inherent to the procedure or related to the technique of the injector. These problems include transient erythema, swelling, induration, pain, undercorrection or overcorrection, and asymmetry. Serious and permanent end results such as sclerosis, granulomas, infections, and migration can occur.

A dearth of scientific data regarding silicone's efficacy and adverse-event profile has stifled its potential therapeutic uses. In addition, its prior use is marred by improper technique and unethical behavior. Myriad complications have been reported, most of which appear to be anecdotal. Thus, to appreciate the potential dermatologic uses of silicone as a permanent filler, it is essential to understand its biochemical characteristics and contentious history. The use of silicone gel implants will not be discussed in this article.

BACKGROUND

The term *silicone* was coined by Frederick Stanley Kipping to describe the combination of a ketone and

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silicon.² During the rubber shortage that occurred in World War II, silicones were used as greases, liquid repellents, and rubbers. Later, the Dow Corning Corporation in Midland, Michigan, used them in paints, polishes, and insulation.² One of the first medical applications of silicone was to coat penicillin bottles and glassware used for the handling of blood to prevent liquid from adhering to the glass.³ Further investigation into this material led to its use in many fields of medicine—most commonly surgery,⁴ dermatology,⁵ and ophthalmology.⁶

Physicians find silicones useful because they have minimal biologic reactivity. Silicone comprises a repetitive core of oxygen and silicon; silicones are called *polyorganosiloxanes* when their backbone is combined with methane and other organic radicals. The viscosity and the heat stability of the material are each directly proportional to the length of the silicone-oxygen structure and the number of silicone-methyl bonds, respectively.⁷ The widespread functionality of silicone flows from its many forms (ie, solid, liquid, or gel). Its viscosity is measured in a unit called centistokes (cs), with 1 cs equivalent to the viscosity of water. Typically, the “medical-grade” silicone used today is 350 cs or greater.

Dimethyl polysiloxane is synonymous with LIS and is one of the few “medical-grade” silicones typically used by dermatologists for injection, though it is approved by the US Food and Drug Administration (FDA) for the treatment of retinal detachments. Silicone is injected into facial soft tissue contour deformities by a specific microdroplet technique that causes an immunologic and fibroblastic reaction that induces collagen deposition and capsular formation around each droplet several weeks after implantation. Silicone, unlike other commonly used soft tissue fillers, permanently leads to collagen deposition. Moreover, it is inexpensive, inert, easily stored, mechanically resilient, and noncarcinogenic.⁸

CONTROVERSY AND COMPLICATIONS

Silicone does, however, carry a long history of controversy and complications when used to treat cosmetic conditions. There were reports in the early 1960s of a baglike prosthesis filled with silicone being used for mammary augmentation,⁹ though there are earlier reports of such enhancement using “cooling fluid” during World War II. It is believed that Japanese prostitutes who desired a more Western appearance allowed American military officers to inject their breasts with a fluid containing silicone.¹⁰ American physicians only became aware of this unsanctioned procedure as Asian patients arrived in the United States after World War II and later as American women in the entertainment industry began receiving silicone injections.

In the 1960s, many women received silicone injections, and physicians noted more side effects. Cystic lesions, mastitis, rock-hard breasts, and/or severe pain that occasionally required silicone removal were noted.^{11,12} Proponents of silicone argue that many of these sequelae were attributable to nonmedical-grade products, adulterants, and utilization of excessive injection loads.¹³ A climate of fear and distrust regarding medical use of silicone prompted Nevada legislators to criminalize its use in 1964. In 1965, the FDA maintained that only those physicians authorized to experiment with silicone were allowed to acquire or use the substance.

Silicone as a soft tissue augmentation agent has never received true FDA approval. Dow Corning developed a “medical-grade” silicone in 1974 but opted not to market it because the company “could not effectively prevent misuse of the product.”¹⁴ Clinical investigations of LIS have been conducted under FDA-approved and monitored protocol. One investigation lasted from 1978 to 1988. Study participants had severe facial deformities that were refractory to other forms of treatment. The study was terminated early, as one patient experienced massive facial necrosis. Some physicians believe that the study’s preliminary results were promising and that this complication was confounded by the patient’s Weber-Christian disease, rheumatoid arthritis, and another possible infection.¹⁵ Nevertheless, the FDA banned LIS for cosmetic use in 1992 when this information was discovered and there were reports that several American physicians were using LIS for facial rejuvenation.

In 1994, the FDA approved silicone oil for certain cases of retinal detachment to prevent blindness. Two forms of LIS are currently approved by the FDA for this indication: AdatoSil 5000™ and Silikon® 1000. As a provision to the federal Food, Drug, and Cosmetic Act, the Modernization Act of 1997 allows any legally marketed, FDA-approved device to be prescribed or administered for any condition within a doctor-patient relationship (“off-label use”).¹⁶ This provision has given dermatologists the ability to use silicone as a soft tissue augmentation agent.

Benedetto and Lewis¹⁷ have described a specific protocol that allows for easy, precise injection of LIS, thereby minimizing common adverse effects. Many variations of the actual technique exist; however, most dermatologists abide by the following protocol. After thoroughly cleansing and marking the areas to be injected and positioning the lights to properly illuminate the facial anatomy, needle punctures are made approximately 2 to 4 mm apart into the subdermal tissues. No more than 0.01 mL should be injected at each needle insertion. Finger pressure should also be applied immediately after injection to reduce patient bruising. A topical anesthetic

administered 45 minutes prior to injection can also be added to this microdroplet technique for patient comfort. Follow-up injections are spaced at approximately 1-month intervals.

The controversy surrounding LIS will likely continue as more patients begin to seek permanent methods of slowing the aging process, and as more dermatologists become comfortable with the microdroplet technique. Rohrich and Potter¹ advise caution regarding this movement toward widespread elective use of silicone, as many studies supporting LIS are retrospective and uncontrolled. Furthermore, Rapaport et al¹⁸ documented 54 patients treated during a 20-year period for complications arising from injection of LIS into the facial soft tissues. Chronic cellulitis, nodules, foreign body reactions, and migration were common. More shocking, however, was the assertion that “unadulterated sterile silicone was used in the overwhelming majority” of these cases.¹⁸ Dermatologists must now ask themselves if eliminating their patients’ facial wrinkles is worth the possible risk of such complications. Additionally, with safe alternatives such as an autologous hyaluronic acid filler available, is using a non-FDA-approved filler worth the potential risks?

The newer “medical-grade” silicones do present fewer problems than older silicone preparations, particularly if injection guidelines (ie, not injecting lips or breasts) are followed and limited quantities of silicone are used.¹⁵ LIS is best used in the nasolabial and glabellar furrows, as well as the perioral lines.¹⁹ HIV-associated facial lipoatrophy also can be treated with LIS.²⁰ Purified silicone injected with 28-gauge or smaller-bore needles minimizes pain and may prevent migration of the injected liquid and granuloma formation.¹⁷

Hexsel et al¹⁹ addressed the history and controversial issues regarding silicone and contend that LIS is a highly useful filler for a number of indications. However, these experts state that because the literature is riddled with anecdotal reports of horrific adverse events,²¹ many physicians are hesitant to use silicone in their practices. Rohrich and Potter¹ believe that the adage “permanent fillers such as injectable silicone portend permanent problems long-term” holds true.

COMMENT

In an attempt to rid silicone of its long-carried stigma and understand its actual side-effect profile, 2 trials are

under way to obtain FDA-approval of silicone for soft tissue augmentation. These trials will likely demonstrate the safety and efficacy of LIS. Until then, the use of LIS as a permanent filler remains at the discretion of each physician and his or her threshold of concern regarding permanent negative side effects.

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