



Injectable Silicone for Soft Tissue Augmentation

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The modern era of soft tissue augmentation has generated several materials for use, but no material is as controversial as injectable silicone. The study of the compounds called *silicones*, which are polydimethylsiloxanes, dates back to the 1800s,¹ but the first medical application of silicone was credited to a urologist in 1950 for using a silicone rubber prosthesis to replace the urethra of a patient who could not urinate due to gonococcal disease with stricture. Also in 1950, Barondes et al² published an article on the various uses of liquid silicone in medicine and Brown et al³ published an article on the use of liquid silicone in plastic surgery in 1953. The first injections of liquid silicone were performed in Japan in the early 1960s as Uchida⁴ reported. He used silicone injections to correct breast and cheek deformities. In 1963, Conway and Goulian⁵ reported on the use of silicone injections for facial hemiatrophy and breast enlargement. When silicone injections were first tested in animals, the material disappeared and left no correction and no side effects; however, after several months, follow-up showed siliconomas and silicone in lymph nodes of animals that had been injected with silicone.⁶ The US Food and Drug Administration (FDA) became involved in studies of silicone injection materials from the mid-1960s until the early 1980s without a true conclusion being reached regarding the safety and long-term efficacy of injectable liquid silicone.

Injectable Silicone Leaders

As clinical trials were being conducted, silicone injections using different types of silicone from various sources were being used outside of these trials. There were some

delayed reactions to the materials under investigation (eg, foreign particles, granulomas), but several problems began to surface from using silicones that were not approved for investigational use. Some of the reactions were very severe, such as marked lip distortions years after injection.⁷ The use of injectable liquid silicone was pioneered by Orentreich⁸ in the 1980s. He introduced the microdroplet technique (placing extremely small amounts of silicone into the dermal/subcutaneous junction). Orentreich,⁸ who manufactured his own silicone, reported 1400 patients under continuous study who had no severe side effects.

David M. Duffy, MD, and Jay Barnett, MD, also were leaders and proponents of injectable liquid silicone. Duffy¹ reported on a large series of patients injected with liquid silicone; these patients experienced minimal side effects, but the nature of the silicone used was unknown.

FDA Regulation

In the 1980s and early 1990s, the FDA interjected and discontinued investigations of approved silicone materials. The FDA also declared that using injectable silicone outside of an approved investigational protocol was illegal. Obviously, this led to a great deal of controversy and dispute among the dermatologic and cosmetic surgery communities. Some leading dermatologists were required to sign documents stating they would not use injectable silicone, and the FDA threatened to incarcerate them if they used silicone injections.⁹ The subject of injectable silicone even was banned from discussion at scientific meetings, thereby eliminating a forum for physicians to report side effects or their experience with this material.

Problems With Silicone Injections

Beyond the FDA regulation of injectable silicone, other problems with silicone injections included the uncertainty of the nature of the material, as well as the lack of information on where it came from, how it was injected, and what was involved with follow-up. At one point,

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A FRESH LOOK AT FILLERS

injectable silicone was ordered through a post office box in Miami, Florida, and delivered to the consignee who wrote a blank check without ever knowing the manufacturer, the nature of the material, or its purity.¹⁰

A short review of the problems associated with injectable liquid silicone is in order at this point. Medical grade silicone is sterile and pure, containing only the siloxane moiety. Silicone used in metallurgy and manufacturing as a lubricant that has found its way into medical practices in the past is not sterile and may contain solvents or foreign particles such as dust. The formation of granulomas (siliconomas) can occur even with medical grade silicone because silicone acts like a foreign body and induces granuloma formation. Although migration should not be a significant problem with the microdroplet technique, not every physician uses this technique, and migration can certainly occur when larger amounts of liquid silicone are injected.

Off-Label Use of Liquid Silicone

In more recent years, the FDA has approved liquid silicone for ophthalmic use. For example, Adatosil® 5000 silicone oil (5000 centistokes viscosity) is used to treat patients with retinal detachments when other treatments are not appropriate.^{11,12} Since this product was introduced and approved for ophthalmic use by the FDA, some physicians have started using it off label to treat lines and wrinkles in the skin. Although it is not uncommon for a drug or device to be used by physicians off label, because of the controversial history of injectable silicone and its use for nonapproved purposes, as well as the number of recently-approved longer-lasting products

for soft tissue augmentation, I think physicians should consider applying the reverse of the famous Nike advertising slogan—just don't do it.

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