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# Ten-Year Experience Using Injectable Silicone Oil for Soft Tissue Augmentation in the Philippines

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**BACKGROUND.** No ideal, permanent filler is approved by the US Food and Drug Administration. Repeated injections of new temporary fillers make this cosmetic procedure expensive.

**OBJECTIVE.** To show that silicone oil is effective, safe, economical, and permanent.

**MATERIALS AND METHOD.** The age, sex, number, indications, sites, adverse reactions, total amounts injected, and clinical cosmetic results of 206 cases were tallied.

**RESULTS.** Females (82%) outnumbered males (18%). The majority were in the 21- to 30-year age group. Fifty-five percent had acne scars, 42% nasolabial grooves, 13.5% marionette lines, 12.6% glabellar lines, 9.8% postvaricella scars, 9.3% inframalar depressions, 1.8% post-traumatic scars, 1.4% lipodystrophy, 1%

lip augmentation, 0.9% sleep lines, and 0.4% contour defect. Fifty-one percent had  $\leq 0.5$  cc, 22% 1 cc, 7%  $\leq 1.5$  cc, 7%  $\leq 2$  cc, and 12%  $> 2$  cc. Clinical improvement was graded excellent (76–100%), good (50–75%), fair (26–50%), and poor ( $< 25\%$ ). Seventy-two percent had excellent results, 18% good, 2% fair, and 0.5% poor. Seven percent were lost to follow-up. Two percent ( $n = 5$ ) had transient erythematous papules lasting 2 to 6 weeks, with the exception of two patients.

**CONCLUSION.** Silicone oil injected with the correct indications and techniques and with microdroplet injections is a safe, economical, and permanent dermal and subcutaneous filler. Rare permanent erythematous papules and transient ecchymoses appear on deep dermal injections.

SYLVIA S. JACINTO, MD, HAS INDICATED NO SIGNIFICANT INTEREST WITH COMMERCIAL SUPPORTERS.

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LIQUID SILICONE oil (polydimethylsiloxane) has been used for soft tissue facial dermal and lipodystrophic augmentation by investigators, notably Dr. Norman Orentreich, since the 1960s.<sup>1</sup> It has never been available commercially, and the manufacturer, Dow Corning, has not applied for its approval for commercial purposes.

However, through a friend, Dr. Jay Barnett, who has used it over 25 years, I was able to start using it beginning in 1993. I use the 350-centistoke (cSt) silicone, which is much less viscous and easier to administer than the intraocular silicone preparation, which is 1,000 cSt and is recommended for retinal detachment (Silikon 1000, Alcon Laboratories, Fort Worth, TX, USA), which is now being used off-label for soft tissue augmentation.

Many reports of adverse reactions,<sup>2–10</sup> such as granulomas<sup>6–8</sup> (one delayed up to 7 years), surface deformities, infections, necrosis, rosacea-like reactions, migration (high volumes), lymph vessel blockage, embolism, blindness, asymmetry, distortion, allergies, lipoatrophy, recurrent edema with or without erythema or idiosyncrasy, and sensorial changes with large volumes,<sup>10</sup> showed that these were caused by adulterated silicone, used in areas not indicated, using incorrect techniques and injecting large volumes.

To be absolutely certain that there would be no immediate and medium-term adverse side effects, I still injected this silicone on the lumbar area of a volunteer (with

informed consent) and biopsied sequentially after 2 weeks and 1, 2, and 3 months. There was neither granuloma nor foreign body reaction. Each microdroplet of silicone was surrounded by collagen.

By using the correct multiple serial puncture, microdroplet technique as advised by Drs. Norman Orentreich, Selmanowitz, and Barnett, I have observed in the past 11 years that this silicone oil is safe, economical, and permanent and has few, temporary adverse side effects. Even after 11 years, the injected sites remain soft to the touch, like normal skin.

## Material and Methods

Over the years, I had been collating all of the data on 206 patients injected with silicone. The silicone oil used is 350 cSt and is sourced from a private commercial company.

Excluded from treatment with silicone oil were patients who had previous injections of other fillers in the same sites within 9 months and those on anticoagulants, antiplatelet therapy, vitamin E, and aspirin. A wash-out period of 2 weeks of all of these medicines was required before injections were done.

I had earlier reported in 1995 my experience with this silicone oil, so I updated the data.<sup>11</sup> Sex ratio, age, indications, amount injected, clinical improvement, techniques of injections, adverse reactions, and the number of injections were all tallied.

From the beginning, I followed the microdroplet technique of Dr. Orentreich taught to me by Dr. Barnett using

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multiple, serial punctures using 0.01 to 0.03 cc per injection<sup>1</sup> and 30-gauge half-inch disposable Becton, Dickinson needles (Becton, Dickinson, Franklin Lakes, NJ, USA) and glass and later plastic tuberculin syringes with Luer-Lock (Becton, Dickinson). Five percent EMLA gel (eutectic mixture of lignocaine 25 mg and prilocaine 25 mg) was applied under Tegaderm occlusion for 1 hour prior to injections. Two patients preferred getting the injections without topical anesthesia, one because of erythema and edema and the other because she did not want to wait for 1 hour.

Undercorrection was preferred because the microdroplets of silicone injected continue to be coated with the patient's collagen for up to 3 months. Therefore, reinjections were done in 2 to 3 months if still needed.

Different techniques of injection were done: intradermal for acne and postvaricella scars and deep dermal for nasolabial grooves, glabellar frown lines, inframalar creases and depressions, marionette lines, and sleep lines. An angle of 30 degrees with the needle bevel down was followed for intradermal injections. Linear intradermal injections on withdrawal of the needle were done on linear atrophic post-traumatic scars. For the nasolabial grooves, glabellar frown lines, and sleep and marionette lines, about 4 mm-deep injections at an angle of 45 to 90 degrees are followed also injecting microdroplets. Subcutaneous injections, about 5 mm deep, on a 90-degree angle were done for lipodystrophy.

Clinical improvement was graded as excellent (76–100% improvement), good (50–75%), fair (26–50%), or poor (1–25%). Adverse reactions were noted.

## Results

Two hundred six patients were treated in an 11-year period. Patients were Filipinos and Chinese. They had not received any previous dermal fillers except for one patient, whose atrophic defect was adjacent to the previous "collagen" injections 10 years before.

**Table 1.** Demographic and Clinical Characteristics (N = 206 Patients)

Variable	Number (%)
Sex	
Male	42 (20)
Female	164 (80)
Age, yr	
11–20	10 (5)
21–30	65 (32)
31–40	47 (23)
41–50	42 (20)
51–60	30 (15)
61–70	12 (6)

Table 1 shows the sex distribution and age groupings of 206 patients. The sex ratio was 4.5:1. There were 82% females ( $n = 168$ ) and 18% males ( $n = 38$ ).

Table 1 also shows the age distribution. The majority (32%; 65) of the patients belonged to the 21- to 30-year group, 23% (47) were in the 31- to 40-year group, 20% (42) were between 41 and 50 years, 15% (30) were 51–60 years old, 6% (12) were 61 to 70 years old, and 5% (10) were 11 to 20 years old. The youngest was 15 years old, and the oldest was 69 years old.

Most of the patients had simultaneously treated multiple indications for soft tissue augmentation. Table 2 shows the multiple indications for silicone injections.

Table 3 shows the amount of silicone injected. The majority of patients (51.5%; 106) had  $\leq 0.5$  cc of medical-grade liquid silicone injected, 22% (46) had about 1 cc, 14.6% (30) had  $\leq 2.0$  cc, and 11.6% (24) had more than 2.0 cc.

More than half (72%; 149) had excellent results, 18% (37) good, 2% (4) fair, and 0.5% (1) poor. Seven percent (15) did not come back for follow-up.

**Table 2.** Indications for Silicone Treatment (N = 206 Patients)

Variable	Number
Soft-contoured acne scars	117
Nasolabial grooves	77
Marionette lines	42
Glabellar frown lines	29
Postvaricella scars	18
Post-traumatic atrophic scars	14
Inframalar depressions/creases	4
Lip augmentation	1
Lipodystrophy, postliposuction	1
Sleep lines	1
Contour defect post-"collagen" injection	1
Atrophic temples	1

**Table 3.** Total Amount of Silicone Injected (N = 206 Patients)

Total Volume Injected, mL	Number (%)
$\leq 0.5$	106 (51.5)
0.6–1	46 (22)
1.1–1.5	15 (7)
1.6–2	15 (7)
2.1–2.5	5 (2.5)
2.6–3	5 (2.5)
3.1–3.5	3 (1.5)
3.6–4	2 (1)
4.1–4.5	2 (1)
$\geq 4.6$	7 (3)

Figure 1 shows a female patient with soft-contoured acne scars with excellent results after 4 injections of silicone at 0.5 mL per session done in four sessions totaling 2 mL.

Figure 2 shows a female patient with multiple soft-contoured acne scars with good results injected in two sessions using 0.5 mL per session, totaling 1 mL of silicone.

Figure 3 shows a male patient with nasolabial grooves, marionette lines, glabellar frown lines, sleep lines, and soft-contoured acne scars with one session of silicone injections to all defects, totaling 2 mL.

Table 4 shows the number of injections done on the patients. More than half of the patients (54%; 111) had the injections done once, 25% (51) twice, 7% (15) three times, 4% (9) four times, 2% (4) 5 times, and 8% (16) more than five times.

Adverse reactions<sup>2,6-8,10</sup> that have been noted in the literature with injections of huge amounts or silicone of questionable purity or injected using the incorrect technique were not seen. Only 2% (5) had erythematous

papules that lasted from 2 to 6 weeks and spontaneously disappeared, with the exception of two patients.

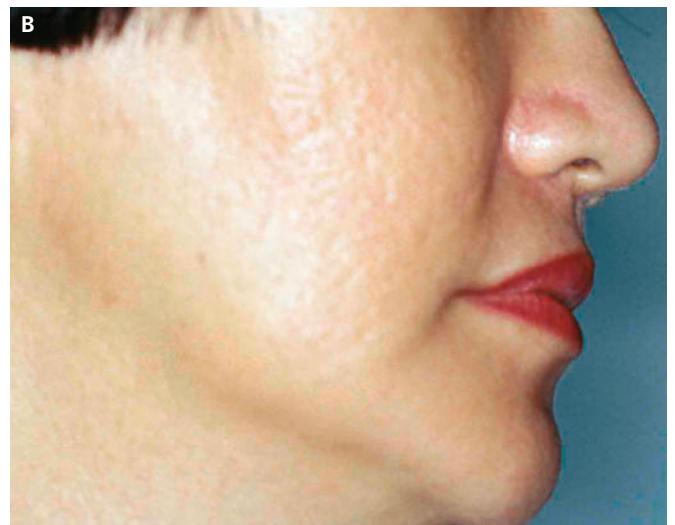
Figure 4 shows a patient with erythematous papulonodules that disappeared after 4 weeks. One patient had her one papule injected with triamcinolone acetonide (5 mg/cc) after it had not disappeared for 3 months; it then subsequently disappeared. Another patient had recurrence after 3 years of one papule with her severe bouts of aller-

**Table 4.** Number of Silicone Injections (*N* = 206 Patients, 390 Injections)

Number of Injections	Number (%)
1	111 (54)
2	51 (25)
3	15 (7)
4	9 (4)
5	4 (2)
> 5	16 (8)



**Figure 1.** Patient 1 with acne scars before (A) and after (B) treatment. Four treatments totalled 2 mL.



**Figure 2.** Patient with soft-contoured acne scars (A) with two sessions of silicone injections (B); total amount 1 mL.

gic rhinitis despite two intralesional triamcinolone injections. There were no other adverse symptoms.

Other rare local reactions were transient ecchymoses after deep dermal injections for nasolabial grooves and injections into the inframalar areas and sleep lines. These, however, disappeared after 1 to 2 weeks. Ice-cold water compresses were advised if any appeared.

The data for 18 patients with a minimum of 5 years of follow-up are as follows: 13 years (the longest follow-up), 1; 11 years, 1; 10 years, 1; 9 years, 1; 7 years, 3; 6 years, 5; and 5 years, 6. The median age was 47.5 years (range 26–70 years). There were 16 females and 2 males. The areas injected were the temples and cheeks for acne scars for 5 patients and the nasolabial grooves, marionette lines, glabellar frown lines, and cheeks for 14 patients. The total median amount injected was 4.4 cc. The median number of times injected was 7.5. Adverse reactions were erythematous papules that lasted for 1 week (1) and disappeared spontaneously and a single erythematous papule (among about 68 injected acne scar sites) that recurs with the patient's bouts of allergic rhinitis despite intralesional triamcinolone acetonide injections.

## Discussion

Silicone oil has been used for over 40 years by a few dermatologists for augmentation of various facial defects. However, it has never been approved for these indications by the US Food and Drug Administration (FDA) because the company that had originally produced it for investigational studies in the 1960s did not request its approval for commercial purposes.

Some dermatologists continued to use it until a few years ago, when the FDA banned its use for patients. When Silikon 1000 was approved by the FDA for use in retinal detachment, many dermatologists started using it off-label for soft tissue augmentation.<sup>9,12,13</sup> The 1,000 cSt silicone oil seems to be as safe as the 350 cSt silicone oil, which I am using, except for its viscosity. It has been harder to administer, so the Becton, Dickinson and Company<sup>3/10</sup> insulin U-100 has been recommended for its use.<sup>9</sup> The latter has also been found to be equally safe, economical, permanent, and easy to administer. Adverse reactions were few (2%) and transient, except for two patients. The two females in their twenties needed intralesional triamcinolone acetonide 5 mg/mL injections. One of them still had a recurrence of one papule (of 68 injected acne scars) with her bouts of allergic rhinitis. All of the injection sites remained soft to the touch.

If injected with the correct technique of serial punctures using microdroplets of silicone oil, no systemic, serious, and permanent side effects are noted.



**Figure 3.** Before (A) and 1 month after (B) number 1 injection (2 mL) to the nasolabial grooves, glabellar frown lines, sleep lines, acne scars, and marionette lines.



**Figure 4.** Adverse reaction of erythematous papules that disappeared spontaneously after 4 weeks.

## Conclusion

Silicone is an excellent dermal and subcutaneous filler for soft tissue augmentation if pure and done with the right technique and indications.<sup>1,10,12</sup> It is economical and permanent and remains soft to the touch, like normal skin. It has been reported being used now off-label with Silikon 1000 approved by the FDA for retinal detachment and human immunodeficiency virus (HIV) lipodystrophy.<sup>9,12-14</sup> The adverse reactions of transient and occasionally permanent erythematous papules in intradermal injections and transient ecchymoses with deep dermal injections are uncommon, and patients should be informed before treatment. However, owing to its simplicity and ease of injections, silicone may lend itself to misuse and abuse by untrained doctors and nondoctors.

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## Commentary

Physicians experienced in the use of liquid silicone for soft tissue augmentation have been impressed by its permanence and the relative rarity of serious complications. There are, however, some problems having to do with long-term risks, both to the physician and the patient that should be addressed:

1. Not all adverse reactions are caused by impure silicone or poor technique.<sup>1,2</sup> Although severe complications of pure liquid silicone are rare, they do occur, often in association with allergies and infectious processes, and may be triggered by certain classes of drugs.
2. Not all complications are easily treated.<sup>3</sup>
3. Liquid silicone is extremely technique sensitive and unforgiving. When things go wrong, permanence is definitely not a virtue.
4. The risk of litigation from ill-conceived or baseless lawsuits is very high in the United States. Accordingly, the

medicolegal risks to physicians who use liquid silicone may be measurably greater than the medical risks for patients who receive it.<sup>4</sup>

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