CHAPTER **39**

SILICONE INJECTION COMPLICATIONS IN THE LOWER EXTREMITY: Migration, Local Reaction, and Autoimmune Response

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INTRODUCTION

Silicone is the name used to describe condensation polymers of dimethylsilicone joined by oxygen linkages. The term was coined by F.S. Kippling of England during the early 1900s. Depending on the degree of polymerization, silicone may appear in a liquid, gelatinous, or solid form.[1] Silicone is a permanent filler that after injection is dispersed into surrounding tissue in the form of millions of microdroplets.[2] Medical grade silicone is approved by the US Food and Drug Administration for intraocular injection in select cases of prevention and treatment of retinal detachment. Medical grade silicone injections is used off-label as a soft tissue filler.[3,4]

In the field of podiatric medicine, injectable silicone has been used to manage fat pad atrophy, and to reduce the plantar pressures beneath metatarsal heads that may lead to pressure ulcerations in the insensate or diabetic patient.[5-7] Medical grade silicone is considered chemically immobile, noncarcinogenic, thermally stable, and produces no known allergic reaction.[4,7,8] Despite these characteristics, injectable silicone has shown to have acute and chronic complications including multi-system organ failure.[9] These complications include: migration, local inflammatory reactions, and autoimmune responses.

The literature suggests that when large volume silicone injections are performed versus the microdroplet technique, there is an increased risk of serious complications by increasing the antigenic burden.[4,10] In the face, small amounts are used in the microdroplet technique described as the use of tiny droplets of silicone (0.01 to 0.03 cc) deposited subcuticular by a series of injections spaced approximately 2 to 10 mm apart.[4] Large volumes of 10 to 15 ccs were used in the case described below. This case demonstrates the acute and chronic complications as well as the surgical management of large volume, questionable grade silicone injection into the bilateral calves.

CASE REPORT

A 37-year old Hispanic female relates having silicone injected into her bilateral calves. The patient stated she had clubfoot and had reconstructive surgery at a very young age in Mexico. To compensate for the appearance of atrophy in the left calf, and to enhance the appearance of the right calf, the patient states at the age of 14 years silicone was injected into her bilateral lower extremity, the procedure was done in Mexico. The patient is uncertain of the medical grade, type of injectable silicone, and the exact amount used.

Over the years, the patient began to notice firm palpable nodules develop around the injection sites, as well as their migration distally in the bilateral lower extremities. The patient experiences a metallic taste in her mouth, electrical sensations throughout the body, muscle fatigue, weakness, joint pain, and electrical neuropathy. Over the years, the patient admits that she was able to identify when a reaction would take place. Acutely, she experienced a red rash, indurations, vapor, and a dizziness that would last several weeks. The local reaction was directly related to the location of migration of the silicone. The chronic sequlae includes indurated and fibrosed soft tissue patches and limited musculo-tendinous activity. The patient's daily activities have been significantly limited due to pain. Over the last 10 years, the patient admits increased anxiety, depression and inability to sleep. The patient's past medical history is unremarkable with no co-morbidities. The patient's current medications include: OxyContin, Dilaudid, Flexaril, and Diazapam.

The initial clinical presentation showed acute reaction around the right medial malleolus, and mottled erythema to the right distal one-third of the leg that extended to the dorsum of the foot. Multiple, firm, non-fluctuant nodules were noted to the right medial ankle. Pain on palpation was noted to the bilateral ankles. Surgical scars were noted on the left lower extremity and exhibited chronic indurated soft

tissue with multiple fibrous granulomas. Magnetic resonance imaging results of both the foot and ankle revealed abnormal signal and small ovoid collections within the medial soft tissues, which given with the history could represent silicone or other reactive chemical responses, cellulites, and panniculitis (Figure 1).

A lazy S-incision was made over the distal medial right ankle and carried down to the subcutaneous tissue (Figure 2). The soft tissue was then reflected for maximum exposure. At this level, multiple beads of silicone globules that formed a fibrotic mass were visualized and then excised (Figures 3). The superficial silicone globules appeared well-circumscribed, clear, and fluid-filled (Figure 4). The deep fascia of the medial ankle was then opened, and more globules of silicone were visualized (Figure 5). The foreign bodies were removed and sent for pathological examination. Copious amounts of irrigation were given to the surgical incision site and the skin was reapproximated with absorbable suture (Figure 10). A posterior splint was then applied to the right lower extremity.

Pathological results revealed fibroadipose tissue with cysts and a diffuse infiltrate of foamy histiocytes that suggest the presence of an oily foreign body. The patient returned for postoperative follow up 3 days following the surgery expressing minimal pain. The patient states the pressure to the right lower extremity feels as if it has been relieved.

DISCUSSION

The local and systemic complications of silicone include skin color changes, tissue induration, granulomas, inflammation, deformities, lymph enlargement, myalgias, arthralgias, rashes, lymphadenopathy, pulmonary disease, hepatic disease, and renal disease.[7,8,11] Silicone travels to the lymph

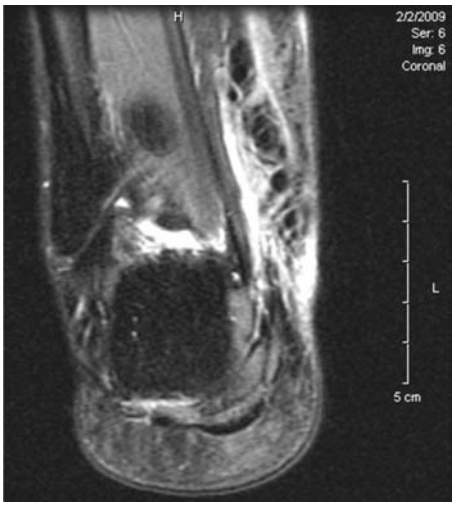

Figure 1. MRI right ankle shows multiple silicone nodules and extensive soft tissue inflammation.

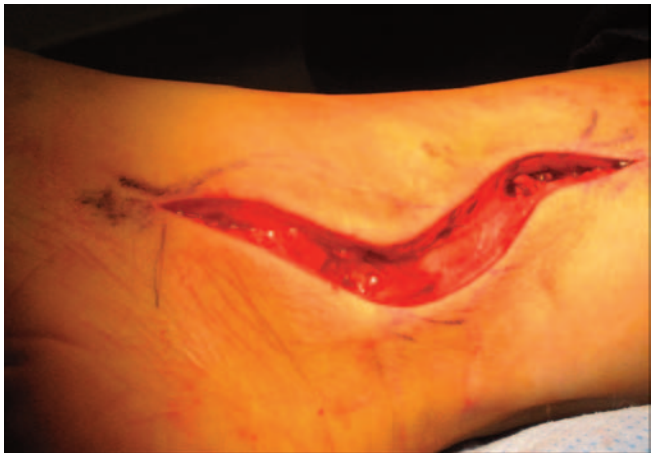

Figure 2. Lazy S-incision made over the distal medial right ankle.

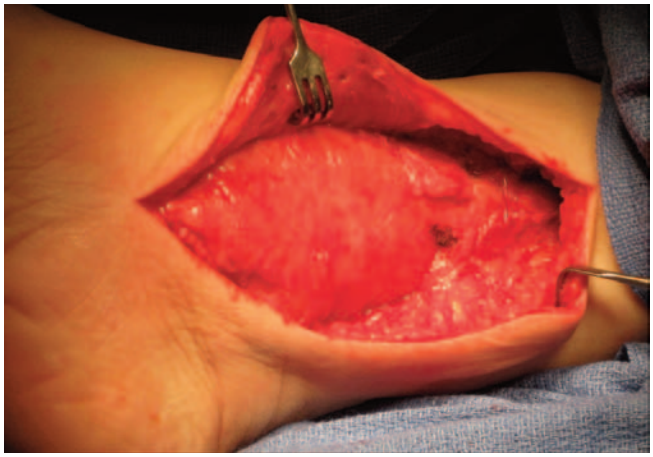

Figure 3. Superficial fascia retraction shows elongated mass posterior to the ankle and a bulging mass within the deep fascia.

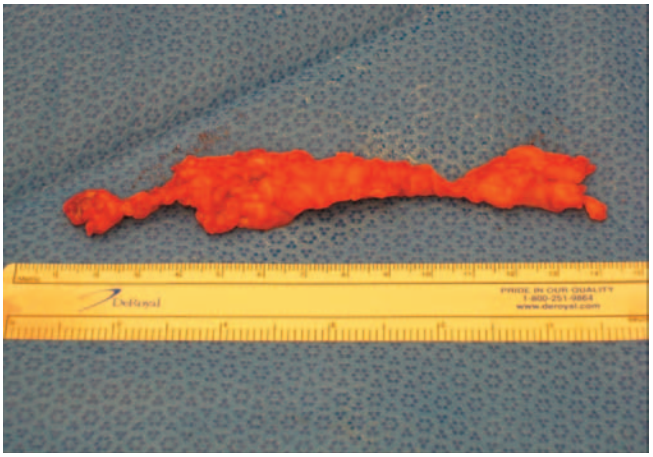

Figure 4. Excision of fibrotic mass of silicone visualized in superficial fascia.

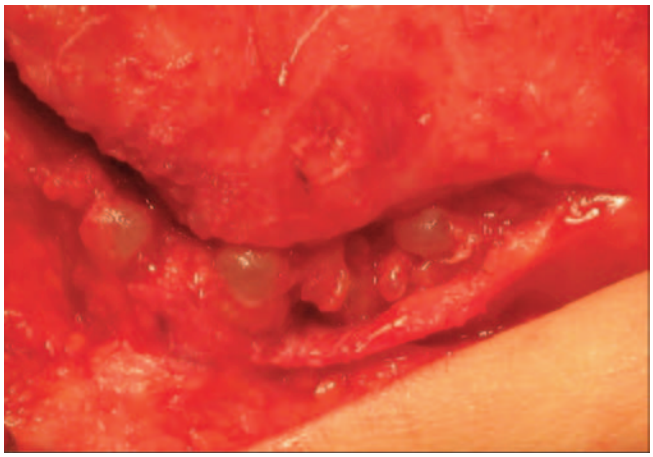

Figure 5. Excision of medial right ankle globules in the tarsal tunnel deep to the deep fascia.

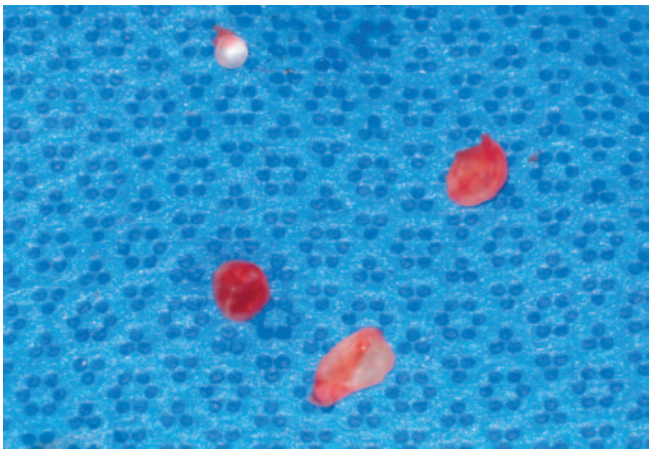

Figure 6. Intact and broken oily silicone capsules.

nodes via macrophages usually forming granulomas or subcutaneous soft tissue.[3,7] If these granulomas become large enough, clinically a painful lymphadenopathy may occur.[7,11] Another common complication of liquid silicone injection is fibrosis that usually becomes evident around 14 months after the initial injection, which was seen in the described case above. It has been reported that fibrosis in the foot from silicone injections is well-organized whereas in the breast or other locations requiring larger amounts of injectable silicone demonstrate more of a diffuse and irregular distribution.[7] Silicone migration, which was seen in the above case is also a complication that ultimately may impinge surrounding structures resulting in pain.[12] It is not conclusive that our patient was experiencing pain from nerve entrapment however; she was most symptomatic around the tarsal tunnel region of her right ankle.

Histological complications of liquid silicone reveal a noninflammatory histiocytic silicone engulfment and fibrous deposition with giant cells.[7,13] Fibrous tissue with numerous silicone vacuoles forming a Swiss-cheese like appearance is noted.[1,7,14] This is consistent with what was found in the case presented above.

Clinical manifestations of liquid silicone injections may require treatment intervention. Silicone is a permanent entity; therefore treatment of its side effects may be difficult.[8] Some treatments include long term antibiotics, oral and interlesional steroids such as prednisone, immunomodulating agents, and surgical excision.[8,15] Due to the effects of continued use of some of the conservative treatments, any widespread lesions or any failure in conservative modalities will require surgical excision.[15] All injected silicone can not be removed, so surgical intervention should be limited to symptomatic silicone nodules that are well-circumscribed.[8,15] This technique was utilized in the above case where surgical excision of the silicone nodules were only used on those most symptomatic to the patient.

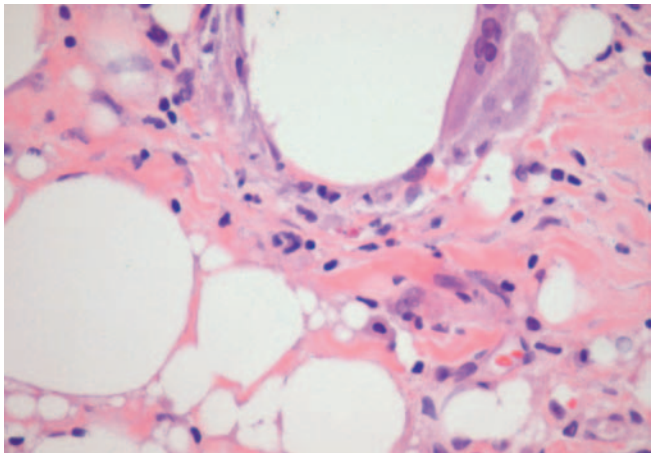

Figure 7. Microscopic view of silicone capsules, fibrous cell reaction and foamy histiocytes.

Many studies have been done to prove the efficacy and safety of injectable liquid silicone. In a study done by van Schie, smaller amounts of injectable liquid silicone had a less likely chance for migration when used in the foot as an artificial cushioning agent.[6,7] In fact when used as a soft tissue prosthesis in the foot, no complications where found.[5] Other studies using standardized small amounts of silicone are underway to show the outcomes of medical grade liquid silicone. Liquid injectable silicone has been found to have different effects at different anatomical locations. When injected in the face, granulomas have been known to be a side effect whereas in the foot granulomas have not been found.[4]

SUMMARY

We presented a case of a patient who suffered 3 complications due to injectable silicone in bilateral calves: local response (i.e., inflammation, red rash, edema, induration), migration, and autoimmune response (i.e., dizziness, headache, muscle weakness and fatigue). The patient is 6 months after surgical excision of the silicone in the right extremity and is pain free with full range of motion, no erythema, and no edema.

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