

# Silicone Granulomas, a Growing Problem?

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## ABSTRACT

The formation of granulomas is known to be a possible adverse effect of liquid silicone administration, used for soft tissue augmentation. Its plumping effects provide enhancement of certain body parts, such as the lips, hips, and buttocks. The desire for enhancement, perhaps influenced by popular culture and an unrealistic standard of beauty, leads individuals to seek silicone injections. There is a growing population of women and men receiving injections by unlicensed, unskilled “practitioners” not related to the healthcare profession. Complications under such circumstances are not uncommon, particularly the emergence of silicone granulomas, and the authors’ medical center has seen an increase in such cases. In this case report, the authors illustrate a young patient with significant complications from her silicone injections, review current therapies for silicone granulomas, and discuss this growing medical problem.

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Liquid injectable silicone (LIS) has been used for decades as a permanent filler for soft tissue augmentation, and its use has been documented in the face, lips, eyelids, buttocks, legs, and penis. It is noncarcinogenic, nondegradable, stable at room temperature, and resistant to bacterial growth, making it a seemingly ideal option for such use.<sup>1</sup> LIS remains controversial, however, due to reports of potentially devastating short, intermediate, and long-term adverse effects.<sup>2</sup> One notable adverse effect that can lead to disfigurement is the development of granulomas. Silicone itself is hydrophobic and, when injected, will disperse in the dermis as droplets that tend to attract macrophages and giant cells that surround the silicone in a foreign body reaction.<sup>3</sup> The onset of appearance of these granulomas can be anywhere from months to many years after injection and distinctly follows a waxing and waning course of exacerbation and remission.

## CASE

A 19-year-old woman with no significant past medical history presented to our County Medical Center with the chief complaint of fevers and chills, in addition to painful skin lesions on the hips and buttocks. Nine months prior, in October, 2012, she underwent cosmetic enhancement of the hips and buttocks via silicone injections. The procedure was performed in a local hotel room by

nonmedical personnel. Within a few weeks, she subsequently began to notice discomfort in the area and went to the emergency room at a local hospital. A skin biopsy performed at that time was consistent with silicone granulomas. In addition, cultures for bacteria, acid fast bacilli, and fungi were performed, all of which showed no growth. She received a week of broad-spectrum antibiotics and was ultimately discharged on 5mg of prednisone, which gave her mild relief.

When the patient presented to the authors’ emergency department, the dermatology service was consulted, and a full work up was again started to rule out infection, as the patient was spiking fevers to 103°F and was having significant chills and malaise. Physical exam revealed considerably firm, edematous, hyperpigmented plaques on bilateral hips and buttocks. All areas affected were tender to the touch (Figures 1 and 2). Again, a skin biopsy was performed, with results consistent with silicone granulomas. Culture for bacterial, fungi, and atypical mycobacterium were again all negative. She received broad-spectrum antibiotics for one week, along with minocycline, due to its anti-inflammatory properties as well as atypical mycobacterial coverage. Computed tomography scan was performed, which revealed hundreds of microdroplets of silicone in the pelvis. Once all cultures were negative, she was discharged on 30mg of prednisone. After six weeks, she noted improvement in

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her pain, swelling, and intermittent fevers. However, since her admission, the skin overlying the injection sites had become even more thickened and hyperpigmented. She wears 2 to 3 pairs of compression shorts underneath her pants due to her embarrassment of the texture of her skin. She is currently seeking surgical intervention for the removal of the silicone.

A diverse spectrum of therapies has been utilized to treat silicone granulomas and some may resolve spontaneously, but most are excised surgically or given pharmacological therapy with varying success. Surgical excision may be employed, but silicone is a permanent filler and is known to migrate to other areas of the body,<sup>4</sup> making complete removal of the injected material impossible. This may lead to even more disfigurement, making it an unlikely treatment option particularly for facial granulomas. Success with oral and intralesional corticosteroids has been documented, but the literature suggests that relapse is seen upon corticosteroid taper. Moreover, many studies and case studies fail to report long-term follow-up. Intralesional triamcinolone injected weekly can improve silicone granulomas, but treatment must be monitored for atrophy.<sup>5</sup> If there is no improvement following triamcinolone injections, 5-fluorouracil may be added.<sup>6</sup> One study used low-dose isotretinoin (20mg daily), chosen for its anti-inflammatory properties, for the treatment of facial silicone granulomas over six months and resulted in complete resolution.<sup>7</sup> Another study found evident improvement and partial improvement in two separate cases following the use of isotretinoin.<sup>8</sup>

Minocycline has been reported to be successful in the treatment of silicone granulomas due to its anti-inflammatory, immunomodulating, and anti-granulomatous effects.<sup>9-11</sup> Reports demonstrate that aside from its use alone, it can also be used effectively in combination with either prednisone or celecoxib.<sup>9,10</sup>

There is also suggestion for treatment utilizing immunomodulating agents. Anti-tumor necrosis factor agents, particularly etanercept, are now documented in several reports to be used in the treatment of silicone granulomas with varying success.<sup>12-14</sup> The rationale for this treatment is that T cells activated by the presence of silicone lead to the release of tumor necrosis factor-alpha, which is an essential component of granuloma formation. In addition, topical imiquimod 5%, which increases interferon levels, has been reported to improve lip silicone granulomas.<sup>15</sup>

Ablative and nonablative lasers have both been used in the treatment of silicone granulomas. Reports and opinion on the use of lasers are mixed. Although some claim that lasers cannot be safely used in patients previously treated with silicone, Chui and Fong<sup>16</sup> reported that carbon dioxide lasers were able to vaporize small globules of silicone that resulted in successful treatment of facial silicone granulomas. Duffy<sup>17</sup> published personal experience suggesting that the use of fractionated lasers could reduce the size and firmness of patients' nodules.



**Figure 2.** Hyperpigmented plaques on right hip and buttock

One interesting study suggests that the combination of ablative CO<sub>2</sub> fractional laser and nonablative Erbium-glass lasers can be an effective method for heating silicone, leading to its evaporation or elimination and inducing remodeling of dermal collagen.<sup>18</sup> No studies or reports have been published on the use of lasers in large silicone granulomas.

It is impossible to distinguish the cause of silicone granulomas, and may not result from one single cause.

Possible theories for the cause of granulomas include the use of impure industrial grade silicone (there are only two types of LIS that have been approved by the United States Food and Drug Administration for medical use: AdatoSil and Silikon), improper technique, (i.e., not the recommended “microdroplet” technique), too much silicone injected at one time, or the fact that some people naturally react this way to silicone. No matter the reason, it is important to realize that although the use of silicone implants has been approved for cosmetic breast augmentation, the practice of using liquid injectable silicone is rarely used by licensed physicians due to the associated health and safety risks.<sup>19</sup> In addition to the outcome that the authors’ patient unfortunately experienced, victims are left with infections, hypersensitivity reactions, permanent disfigurement, or even worse, death. Multiple cases have been reported of individuals presenting to emergency departments after these procedures with shortness of breath and neurologic symptoms. These clinical symptoms are the dreaded, but not uncommon, consequence of intra-arterial injection of LIS and subsequent travel of the foreign material to the heart and lungs. This causes respiratory distress, which can lead to respiratory and cardiac failure and death.

Despite this, there is a growing trend of illicit cosmetic surgery being performed with nonmedical grade injectable silicone in the United States and abroad. There are no established studies or statistics of the number of cases of silicone granulomas resulting from illicit silicone use, which is not surprising given the likely difficulty in surveillance and unlikely reporting of cases by patients. However, an increase in cases in the authors’ department prompted them to acknowledge the increase of unlicensed and unskilled “practitioners” administering LIS with little knowledge or regard for the risks associated with these injections. It is being administered at best in quasi-sterile environments, hotel rooms, and homes, where unknowing victims are hoping to augment everything from their lips to their buttocks. An ever-increasing number of patients are presenting to the hospital with silicone granulomas after having silicone injections performed by the hands of unskilled and unlicensed nonmedical practitioners. Although no formal studies have been conducted on the incidence of this condition, the numerous case reports and news reports acknowledge that this is a growing trend and a serious problem that must be addressed.

As physicians search for answers to best treat these adverse outcomes, this question remains: Why do people continue to place themselves at considerable risk with these procedures? The answer to this is multi-factorial, but at the core is society’s unrealistic definition of beauty. Magazine and television images and cultural ideals encourage the desire for perfectly shaped lips, buttocks, and breasts, particularly in the young and impressionable who often will go to great lengths to attain these ideals, regardless of the associated risks.

A significant contributing factor, at least in the authors’ experience, to individuals seeking out these illegal services

is the low relative cost. With unlicensed “practitioners” charging hundreds to several thousands of dollars, it still remains a less expensive option when compared with similar procedures done by a licensed professional in a medical environment. Additionally, some of these procedures are often unsafe and would not be carried out by a licensed physician at any price. Therefore, these victims look to nonmedical persons who will provide these services, believing this to be their best and only option.

Another critical factor is the lack of information and knowledge in the community about the reality of the risks associated with these procedures. False advertising and idealized outcomes often lull victims into a sense of safety. As true informed consent is lacking, people are unaware of associated risks both short and long term. Therefore, it is critical that medical professionals educate the general public on the dangers of such injectable cosmetic products.

In the medical community, it is quite concerning that despite these horrific cases, people continue to undergo such detrimental procedures. Society’s continued fixation on the current definition of “beauty” continues to push patients, especially women and transgenders, to risk their health in the pursuit of perfection. The medical community should understand this serious issue that does not appear to be waning, recognize the potential adverse outcomes, and seek appropriate opportunities to educate patients that may fall prey to these illicit medical procedures.

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