CASE REPORT

Successful Management of Delayed-Onset Complications From a Dermal Filler of Unknown Provenance

Drew Munro, MD; Michael Ehrlich, MD; Julie Woodward, MD

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Introduction: *A 52 year-old woman presented with delayed-onset nodules in the malar and glabellar regions approximately 16 months after undergoing facial augmentation via injection of an unknown substance in China. Medical records for the procedure were not available. The authors performed an investigative review of fillers used abroad to determine possible treatment options for the patient. After discussion with general plastic surgeons in China, a treatment plan was initiated.*

Materials and Methods: *Computed tomography (CT) of the head with 3-dimensional reformatting was performed to characterize the nature and extent of the interventions performed. The study revealed significant amounts of a subdermal substance in the malar and glabellar regions.*

Results: *A cycle of treatment was performed involving the injection of lidocaine, triamcinolone, and fluorouracil into the affected areas accompanied by interspersed daily massage. The regimen proved effective, and there was clear reduction in the size and inflammation of the nodules.*

Conclusions: *The modern age of facial rejuvenation features an increasing array of soft tissue fillers available to physicians performing facial augmentation. The expansion of available filling agents and the rising costs of domestic health care have resulted in an increase in the number of patients seeking elective cosmetic procedures abroad, and patients presenting with complications from cosmetic tourism are increasingly a part of the modern aesthetic practice. Maintaining a solid awareness of current usage trends of injectable filling agents and a thorough understanding of the management options for delayed-onset nodules are essential for mitigating complications from soft tissue fillers of unknown provenance.*

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From Duke University Medical Center, Durham, NC (Dr Munro and Dr Woodward), and Danbury Eye Physicians & Surgeons, Danbury, Conn (Dr Ehrlich).

Corresponding author: Drew Munro, MD, Duke Eye Center, Box 3802, Durham, NC 27710 (e-mail: andrew.munro@duke.edu).

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The modern age of facial rejuvenation features an increasing array of soft tissue fillers available to physicians performing facial augmentation. The expansion of available filling agents and the rising costs of domestic health care have resulted in an increase in the number of patients seeking elective cosmetic procedures abroad.[1] Keckley and Underwood[2] report that in 2009 there were an estimated 648,000 outbound medical tourists, approximately 11% of whom were seeking cosmetic procedures, and they projected an annual growth rate of 35% in medical tourism. According to the most recent survey of plastic surgeons by the International Society of Aesthetic Plastic Surgery, more than 5.5 million cosmetic injections were performed in 2009 by the worldwide plastic surgeon community alone, and millions of additional injections were performed by dermasurgeons, oculoplastic surgeons, and other medical providers (Table).[3]

The percentage of these injections taking place abroad will continue to grow, as many countries outside the United States are actively courting patients for cosmetic and elective procedures. The endeavors of these countries to attract medical tourists include efforts coordinated at the national government level.[4] Additionally, many entities inside the United States are establishing relationships with counterparts in Asia and South America.[5] Among these entities are such prestigious institutions as Harvard and Johns Hopkins, whose involvement is expanding and legitimizing the concept of traveling abroad for medical care.[6]

As a result, physicians may increasingly find themselves handling complications resulting from soft tissue fillers of unknown and possibly unorthodox composition. This is particularly true for delayed-onset complications, which likely will manifest themselves long after the patient has returned to his or her country of residence. The questions facing the treating physician are numerous, including the identity and quality

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Table 1. Annual Worldwide Injectable Procedures by Plastic Surgeons*

Botulinum (Botox/Dysport)	2 860 238
Hyaluronic acid	1 762 700
Autologous fat	514 118
Polymethyl methacrylate	113 129
Collagen	104 226
Calcium hydroxylapatite	101 872
Other fillers	60 080
Poly-L-latic acid	44 753
Total	5 561 116

*Source: International Society of Aesthetic Plastic Surgery, ISAPS Biennial Global Survey, 2009.

of the injected substance, the extent of the intervention, and the nature of the lesion (eg, purulent, granulomatous). Furthermore, procedures performed in other countries are not necessarily subject to the same degree of regulation and scrutiny as in the United States. Consequently, opportunities exist for unscrupulous or incompetent practitioners to use substances that are not approved by the US Food and Drug Administration (FDA), are contaminated or adulterated, are of poor manufacture, or are frankly not meant for medical use. This has important implications for immunogenic reactivity, infection, and implant migration, all of which may require management by the treating physician.

Case Report

A 52-year-old woman presented with delayed-onset nodules in the malar and glabellar regions approximately 16 months after undergoing facial augmentation via injection of an unknown substance in China. Medical records for the procedure were not available, and the provider could not be contacted. Computed tomography (CT) of the head with 3-dimensional reformatting was performed to better characterize the nature and extent of the interventions performed (Figures 1 and 2). The CT images revealed significant amounts of a subdermal substance in the malar and glabellar regions as well as a stent overlying the nasal bridge from a previous procedure (also performed in China). An experienced plastic surgeon in China was consulted, who postulated that the filling agent was likely silicone based on historical practice patterns in the region where the procedure had been performed. Other possibilities that were less likely were polyacrylamide 4% gel or polymethylmethacrylate.

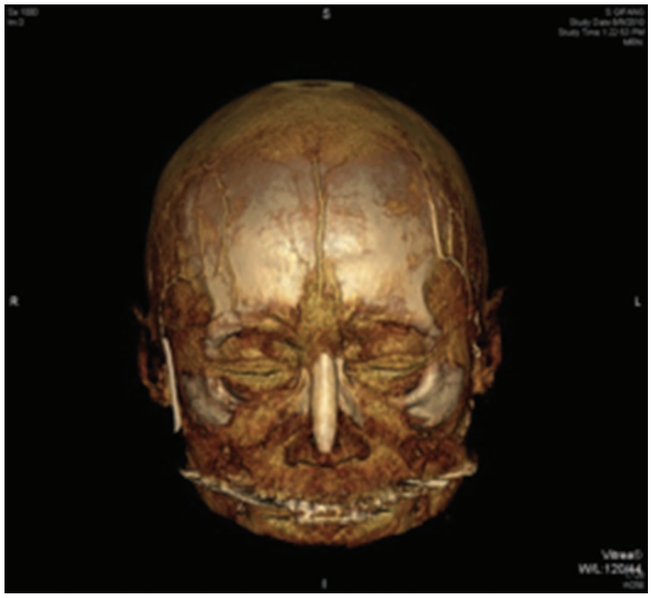

Figure 1. *Computed tomography of the head with 3-dimensional reformatting: Delayed-onset nodules in the malar and glabellar regions with stent overlying nasal bridge.*

Given this input, surgical intervention was deferred in favor of a cycle of treatment involving the injection of lidocaine, triamcinolone, and fluorouracil into the affected areas, along with daily massage interspersed between the injections. The initial injection consisted of 1.0 mL fluorouracil with 1.0 mL triamcinolone and 0.8 mL lidocaine 2%. One month later, a second injection

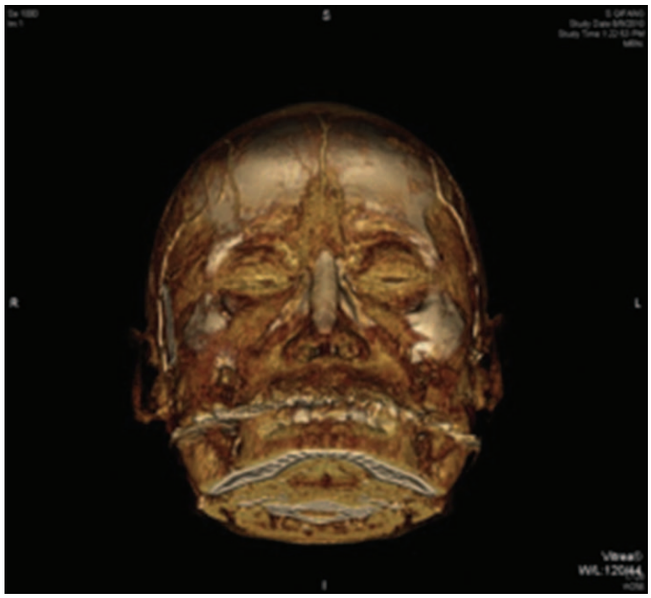

Figure 2. *Computed tomography of the head with 3-dimensional reformatting, inferior view.*

was administered, which consisted of 2.5 mL fluorouracil with 2.5 mL triamcinolone and 0.5 mL lidocaine 2%. The regimen proved effective, and there was a clear reduction in the size and inflammation of the nodular areas.

Materials and Methods

Determining the nature of the implant involved with the presenting lesion is the first step in mitigating its effects. Documentation relevant to the procedure is obviously useful but is often not available. Practice patterns for the time and region of the procedure can provide insights when records are not available; the Joint Commission International and International Society of Aesthetic Plastic Surgery are excellent resources for locating reputable providers abroad. Fine-needle or excisional biopsy are often required to provide a definitive diagnosis, although the patient may not consent to invasive options. Lloret et al[7] describe the successful use of a reflexion electron microscopy probe and electron dispersing x-ray to determine the identity of a given implant as silicone. Although such methods require advanced equipment, they may allow for a successful diagnosis with minimal invasiveness.

Once the nature of the implant is determined or estimated, the scope of its involvement should be ascertained. The extent of a given lesion has important implications for the choice of intervention (surgical, local, systemic) and the particulars of the approach. Beyond observation and palpation, modern imaging can be invaluable in providing details of the location of the implant, including an awareness of any occult migration that may have occurred. CT, particularly with 3-dimensional reformatting, is an excellent means of elucidating such details when the implant remains relatively cohesive and has minimal dispersion.

Discussion

In the case of our patient, the 3-dimensional CT scan was useful for determining the relation of the filler to the patient's arterial vascular supply. Of note, she had only 1 glabellar artery to supply her central forehead; therefore, great care was taken when treating this area with the therapeutic steroid injections so as to minimize any further risk of vascular occlusion in this area.

Regarding the present case, our execution of the aforementioned methodology led us to suspect that the implant in question was likely some form of silicone. Silicone oil, commonly used as a dermal filler outside the United States, is a substance that has been reported to cause complications in a variety of circumstances. Silicone has a long history of use in aesthetic procedures, and it was used in the United States for cosmetic injections from the 1960s through the 1980s, when the FDA revoked its approval for as a cosmetic injectable, citing an unacceptable incidence of complications such as granulomas, delayed hypersensitivity reactions, and implant migration, among others.[8] Silicone oil remains available for ophthalmic use in the United States as Silikon 1000 (Alcon, Fort Worth, TX) and Adaptosil 5000 (Bausch & Lomb, Rochester, NY), and it is occasionally still used off-label for cosmetic injections. Many other countries still allow the use of silicone oil as a cosmetic injectable, and some foreign practitioners actively promote its safety and efficacy through reports in the literature.[9]

Beyond academic and regulatory differences regarding medical-grade silicone oil is the more troubling phenomenon of practitioners using substandard medical-grade or industrial-grade silicone for injections. The presence of impurities in injected silicone, whether from shoddy manufacturing or improper handling, can increase the likelihood or severity of an immunogenic reaction. Similarly, contamination of the injected material with microbes can cause long-term chronic infections as a result of biofilm formation, which some researchers believe is an important component of delayed-onset nodule formation.[10,11]

Fillers may hold the potential for future issues, even in patients who had no complications when they present for additional cosmetic procedures. Alijotas-Reig et al[12] note that injection with filling agents of different compositions seems to increase the odds of an immunogenic event, and delayed-onset complications may subsequently arise with either the new implant or previous ones. Although such events are not common, the treating provider may reap complications sown by a distant practitioner. Additionally, caution is warranted when contemplating laser resurfacing in patients who have potentially undergone dermal injections with silicone oil, as thermal injury and scarring have been reported when CO2 laser is used on skin that contains silicone oil.[13] A thorough history of any and all cosmetic interventions, especially those occurring abroad or under suspicious circumstances, is clearly prudent in this era of burgeoning cosmetic tourism.

Conclusions

As the globalization of elective medical services continues to expand, patients presenting with complications from cosmetic tourism are increasingly a part of the modern aesthetic practice. Maintaining a solid awareness of current usage trends of injectable filling agents and a thorough understanding of the management options for delayed-onset nodules are essential for mitigating complications from soft tissue fillers of unknown provenance.

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