Complications from Injectable Polyacrylamide Gel, a New Nonbiodegradable Soft Tissue Filler

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BACKGROUND. **Polyacrylamide gels, containing a hydrogel composed of polyacrylamide and water, are used for soft tissue augmentation and contour correction. There are no reports of significant complications after injection of this material into the face.**

OBJECTIVE. **We report an inflammatory reaction after injection of polyacrylamide gels for zygomatic facial augmentation.**

METHODS. **A retrospective chart review of single case is presented.**

RESULTS. **An inflammatory reaction at the sites of polyacrylamide gels injection was noted at 1 month after initial injection. Despite two ensuing courses of broad-spectrum antibiotics, the patient presented to us with persistent draining nodules. Intralesional steroid injections resulted in prompt resolution and no recurrence.**

CONCLUSION. **Inflammatory reactions have been noted in patients receiving polyacrylamide gels for breast augmentation. Facial polyacrylamide gels injections may also be associated with an inflammatory reaction that responds to intralesional steroids. With increasing availability of a variety of soft tissue fillers, dermatologists should be aware of this delayed complication from polyacrylamide gels.**

SNEHAL P. AMIN, ELLEN S. MARMUR, AND DAVID J. GOLDBERG HAVE INDICATED NO SIGNIFICANT INTEREST WITH COMMERCIAL SUPPORTERS.

NUMEROUS BIOMATERIALS have been developed for the augmentation and correction of soft tissue contours on the face. Various materials are available for sculpting the angle of the lips, filling in the melolabial folds, or even correcting scars. The ideal material varies by indication. A permanent and immobile substance may be appropriate for an iatrogenic scar. A soft, resorbable and noninflammatory substance might be more appropriate for rhytids that change with age.

Semipermanent substances available as microspheres or small particles in a gel, such as polymethylmethacrylate microspheres, have been widely used in Europe. Resorbable materials such as collagen or hyaluronic acid have been approved for use in the United States. Logic suggests that the ideal filler substance for contour correction of the face should be a nonparticulate gel that is immobile and long-lasting. The gel should be completely synthetic, nonimmunogenic, and noninflammatory. This stable formulation should be easy to administer and cosmetically pleasing.

A 5% polyacrylamide polymer with 97.5% water (Aquamid, Ferrosan NS, Copenhagen, Denmark) is one of the newest materials marketed for facial contouring in Europe. Is not yet approved for use in the United States. This polyacrylamide gel has been used in Europe for more than 10 years and has been widely used in industry and biomedical research. In the cosmetic aena polyacrylamide gel has been used for breast and other soft tissue augmentation.[1] The polymer is considered to be nontoxic, nonbiodegradable, and nonteratogenic.[2] Although the polymer does not appreciably degrade into single molecules, the acrylamide monomer has been shown to be a neurotoxin and teratogen.[3–6]

The Aquamid gel form of polyacrylamide gel is available only in Europe in prefilled 1-mL syringes that can be stored at room temperature and injected as a viscous gel via a 27-gauge needle. There is a theoretically decreased risk of postinjection lumpiness because the materials do not contain spherical particles, lead to minimal inflammatory reaction, and promote avid binding of water. The gel remains soft after injection with the development of a postinjection thin membrane forming around the material.[7] Three recent studies describes infrequent post-polyacrylamide gel injection adverse events limited to edema, transient erythema (within 1 week), ecchymosis, and pain.[1,7,8] Although bacteria can be seen histologically after polyacrylamide gel injection, wound cultures are generally negative. Two histologic studies have described

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minimal capsular formation and foreign body reaction to the injected material.[1,8] There are no reports of a significant skin inflammatory reaction to injected polyacrylamide gel for soft tissue contouring.

In this case report, we present a patient who received polyacrylamide gel and later developed an inflammatory reaction at the injection sites that did not respond to antibiotics. The patient's persistent inflammatory nodules did respond to intralesional steroid injections.

Case Report

A 64-year-old female US citizen with no significant past medical history presented with an 8-week history of asymptomatic erythematous facial nodules at the sites of previous polyacrylamide gel injections. The patient sought dermal injections of polyacrylamide gel in France approximately 2 months before her presentation to our office. Within a few days of her first injection, she developed urticarial plaques at the injection sites which spontaneously resolved. Approximately 10 days after the initial injections, she was retreated in the same cheek locations. She again developed erythematous plaques at the injection sites a few days after treatment. Upon her return to the United States, a right cheek nodule drained a small amount of clear to yellow fluid and then subsequently crusted. An infection was suspected by her internist who started empiric amoxicillin and clavulanate.

Two months after the initial injection, and after two more unsuccessful courses of oral antibiotics, the patient presented to our office (Figures 1 and 2) with erythematous nodules on her cheeks. She had no significant past medical history. She denied any cough, fevers, weight loss, or joint pains. Wound cultures and Gram stains were negative. The patient refused a biopsy request. Intralesional triamcinalone acetonide (5 mg/mL, 0.2 mL total) was administered to only the right cheek lesion. The patient returned in 1 week with improvement on the right side but worsened lesions on the left side. There was no drainage or crusting on either side. The left cheek was injected on this visit with triamcinalone (5 mg/mL, 0.2 mL total). The symptoms resolved within 2 weeks and have not recurred 3 months after steroid injections.

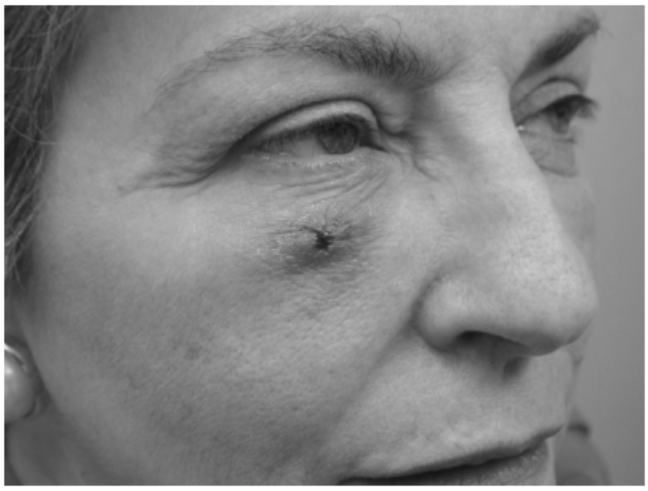

Figure 1. Right cheek nodule 8 weeks after polyacrylamide gel injection.

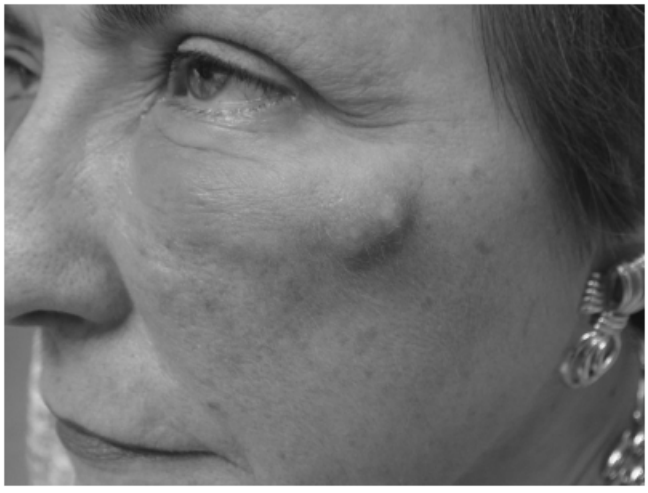

Figure 2. Left cheek nodule 8 weeks after polyacrylamide gel injection.

Discussion

Although polyacrylamide gel has not yet been FDA cleared in the United States, an increasing number of persons from the United States are traveling to Europe to receive injections of this material. With an increasing number of available filler agents, cosmetic dermatologists must become increasingly knowledgeable of the various injectable soft tissue fillers and their possible complications.

Post-filler agent complications can be divided into acute and delayed reactions. Acute complications are usually minor and transient. They can be caused by the injection procedure itself or the material that is injected. Erythema, pain, edema, pruritus, and bleeding at injection are possible and relatively common with all injectable materials. Infections can also occur after any injection. Delayed complications are fortunately rare and include migration of the injected material, degradation into toxic or immunogenic substances, inflammatory or granulomatous reactions, keloid formation, dyspigmentation, embolization, extrusion, dysaesthesia, disfigurement, and scarring.

The manufacturer of the Aquamid brand of polyacrylamide gel states that there may be 1 in 1500

patients with transient swelling and tenderness.[7] One small study evaluated histologic specimens from patients experiencing tenderness after injection of this polyacrylamide gel.[8] The authors noted bacteria on stained histologic specimens of injected polyacrylamide gel even when tissue cultures were negative. They suggested that bacterial infections must be initially considered in patients experiencing symptoms after injection of polyacrylamide gel.

Another case study evaluated complications seen after breast augmentation with polyacrylamide gel.[9] Although the material used in this study was not produced by the same manufacturer as the polyacrylamide gel injected into our patient, the authors did conclude that polyacrylamide gel itself can cause inflammatory and granulomatous reactions—albeit very rarely.

Another retrospective study examined breast tissue specimens collected from patients experiencing complications after augmentation with polyacrylamide gel.[1] Histologic specimens showed macrophages and granulomas in patients experiencing symptomatic delayed reactions.

Our patient showed no clinical signs of infection, had more than one negative wound culture, and did not respond to broad-spectrum antibiotics, yet showed a positive response to localized steroid injections.

Polyacrylamide gel is a potentially promising synthetic soft tissue filler. In the United States, experience with polyacrylamide gel as a facial contouring agent is extremely limited. With the increasing interest and availability of newer filler agents, however, it can be expected that polyacrylamide gel and its potential complications will also be seen in the United States. We have now presented the first case report describing a delayed reaction to polyacrylamide gel injected into the face for soft tissue augmentation.

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