Case Report

American Academy of Cosmetic Surgery

The American Journal of Cosmetic Surgery
2018, Vol. 35(2) 59–63

DOI: 10.1177/0748806817751940
journals.sagepub.com/home/acs
SAGE

Acute Inflammatory Reaction Following Removal of Hydrophilic Polyacrylamide Gel

Victoria Karlinsky, MD, FACS, FAACS[1] and Judson Boisvert, MD[1]

Abstract

Hydrophilic polyacrylamide gel (PAAG), although not approved for use in the United States, has been used throughout the world as a permanent filler for aesthetic applications since the 1980s. Numerous articles and case reports have been published highlighting complications arising from its use. In this case report, we present a 54-year-old woman who presented for surgical consultation, requesting removal of previously injected polyacrylamide gel with subsequent silicone implant breast augmentation who experienced an acute reaction following attempted removal of the gel. This report reviews the current use, complications, and management of complications in patient's previously injected with PAAG.

Keywords

Cosmetic surgery, dermatologic fillers, filler complications, PAAG

Introduction

Polyacrylamide hydrogel (PAAG) has been available for medical use for more than 30 years, with its first documented use as a "filler" in 1987.[1] Although not approved by the US Food and Drug Administration (FDA) for sale or use in the United States, the product has been widely used throughout Europe and Asia since its inception. Documents report the gel was first used for breast augmentation in the Ukraine in the 1990s, with subsequent introduction in the Chinese market following approval by the Chinese State Drug Administration in 1997.[2,3] From 1996 to 2015, more than 200 000 women underwent breast augmentation through the injection of PAAG.[4] The gel itself is a combination of 2.5% to 5% polyacrylamide, a synthetic polymer, suspended in 95% to 97.5% apyrogenic water. It is considered nontoxic, nonallergenic, nonbiodegradable, and nonabsorbable.[5] Once injected into the body, the aqueous component is absorbed leaving the polyacrylamide behind which is eventually encapsulated, leading to permanent integration of the PAAG and augmentation of the soft tissues. Cellular-level pathologic changes caused by PAAG include fibrosis, foreign body reaction, and inflammation when the hydrogel is injected in medium or large quantities. Fibrosis was found to be caused by invasion by macrophages and giant cells, which following vascularization were replaced with collagen-producing fibroblasts. Inflammation reactions were characterized by increased number of giant cells, infiltration lymphocytes, plasma cells, and a small number of eosinophils.[5-7]

Over its 3 decades of use in breast augmentation, numerous articles and case reports have been published about the gel and its side effects. Reported complications range from mild and self-limiting, to severe, requiring extensive surgical interventions, and in some cases leaving patients permanently disfigured. A 2012 study reported the overall complication rate following PAAG injection to be 6.74%.[8]

Because the gel is placed throughout the breast, it is impossible to remove completely once injected. Large collections may be removed via minimally invasive aspiration techniques or via surgical excision with imaging studies allowing for better localization and targeting of these collections; however, those patients who fail to experience relief from symptoms may ultimately require mastectomy as a last resort.

The most common long-term reported complications include migration of the product, breast lumps, swelling, pain, infection, firmness, asymmetry, and disfigurement of the breasts.[4,9,10]

[1]New Look New Life Surgical Arts, New York, NY, USA

Corresponding Author:
Judson Boisvert, Cosmetic Surgery Fellow, New Look New Life Surgical Arts, 551 5th Avenue, Suite 525, New York, NY 10176, USA.
Email: judsonboisvertmd@aol.com

Figure 1. Raw hydrophilic polyacrylamide gel material.

Figure 2. Additional gel removed from left breast.

Case Report

A 54-year-old Chinese woman presented to the cosmetic surgery practice for consultation in late January 2017. She reported that she had undergone injection of hydrophilic polyacrylamide for breast augmentation in Chinatown, New York, in 2000, and had subsequently undergone removal of some of the material in 2006. She requested removal of the remaining polyacrylamide as well as reaugmentation with silicone implants. Her chief complaint at the time of presentation was asymmetry, as well as palpable and visual irregularities throughout the breasts and over the sternum. At the time of initial consultation, a thorough breast examination was performed and numerous discrete masses were noted. Clinical exam findings were concordant with those made via mammogram and ultrasound. Following initial imaging and examination, the procedure was carried out in the office setting; 1% lidocaine was used for local anesthesia. The skin was then prepped with iodine. Aspirations were performed with a 16-gauge needle and syringes. Removal of the material was completed during 2 separate appointments, with removal of 4 to 5 mL of material from the lower inner quadrant of the left breast during the first appointment (see Figure 1), and 12 mL of material from the medial edge of the left breast, superficial to the sternum, and from the upper outer quadrant of the left breast during a subsequent visit (see Figure 2). On both initial and subsequent aspirations, the areas targeted were chosen based on presumed volume (based on clinical and imaging findings) of material at that location. Following the initial aspiration, a sample was sent for laboratory analysis which described as "Amorphous foreign material and a fragment of benign bone"; a culture was not performed on the initial sample. The aspirations were performed over multiple visits, as after the initial removal of material, the attending surgeon felt it prudent to positively identify the substance prior to performing additional aspirations. Preoperative labs and urinalysis were collected per practice standard, and the patient was subsequently prescribed ciprofloxacin for a presumed subclinical urinary tract infection.

Her remaining lab work was unremarkable. The patient was seen and medically cleared for the proposed breast augmentation by her primary care physician. She contacted our practice 3 days after the second round of PAAG aspiration reporting that for the last few days she was "not feeling well" and had now developed significant left breast pain. She presented for evaluation later that day. On examination, there was significant swelling and tenderness to palpation noted throughout the left breast. In addition, there was a large area of ecchymosis over the sternum which extended onto the medial aspect of the left breast. At the time of exam, the patient was afebrile and without other signs or symptoms of systemic infection; however, given the acute swelling and tenderness of the breast, the patient was started on a course of Augmentin for possible local infection and/or upper respiratory infection (URI) and follow-up labs and imaging were ordered.

Ultrasound of the left breast was completed the following day. The findings are as follows: "1. Extensive heterogeneous hypoechogenicity throughout left breast, some areas slightly more prominent since the previous study. This is suggestive of superimposed serosanguineous fluid within gel material. 2. Probably development of granulation tissue within midline chest as described above." ("In the midline of the chest between the right and left breasts, there is a large heterogeneous hypoechoic area measuring at least 6.9 × 2.1 × 5.2 cm. This demonstrates a few small areas of minimal Doppler flow. The Doppler flow is suggestive of development of granulation tissue.") At the next follow-up visit, the patient reported decreased pain in the left breast but reported new onset of pain in the right breast. Examination showed no further tenderness on the left but confirmed new onset tenderness to palpation of the right breast, localized to the upper quadrants. The following weekend, the patient was seen by her primary care physician (PCP) and received "several days of IV antibiotics." At her subsequent follow-up at our practice, a significant collection of fluid was suspected over the sternum. A 5-mm incision was made under local anesthesia, and approximately 500 mL of serosanguineous fluid with small white flecks suspected to be additional polyacrylamide was drained (see Figure 3). The patient reported an immediate improvement in discomfort following the drainage, and there was a significant reduction in the

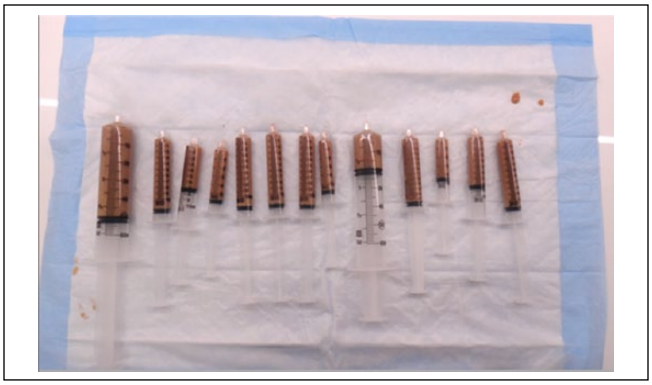

Figure 3. Material removed during incision and drainage.

size of the breasts. The wound was packed to allow for continued drainage. A fluid culture was sent for culture, with findings of "few WBC but no organisms." Over the next week, the amount of drainage tapered off with amounts decreasing from 150 to 30 mL. A chest computed tomography (CT) scan was performed which noted "Diffuse anterior chest wall swelling with numerous fluid collections and air bubbles, especially posteriorly in the region of the pectoralis muscles and associated with presternal soft tissue mass with fluid and air compatible with infection or previous surgical procedure. Necrotizing infection cannot be excluded." (See Figures 4-6).

She returned for frequent follow-up visits for wound care and packing changes. This continued until the previous incision and drainage (I&D) site was noted to have closed. A week later, she was seen again and reported increased presternal swelling and pressure, which was localized over the distal portion of the sternum; 17 mL of fluid was aspirated from the area and offered immediate relief from her symptoms. She returned weekly for additional aspirations, which decreased over the course of that month. In early May, the patient presented for a scheduled visit and was found to have no further fluid accumulation. She was scheduled for routine follow-up in 3 months.

Discussion

PAAG, although being available in other parts of the world for more than 30 years, has never received FDA approval. A list of currently approved fillers, both absorbable and nonabsorbable, can be found on the FDA website at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm. Presently, none of the aforementioned fillers are approved to increase breast size (breast augmentation).[11]

Between 2002 and 2010, there were more than 140 000 patient visits during which dermal filler was injected, and this number has continued to increase each year.[12] With the increasing use of fillers, the number of patients experiencing adverse events has proportionately increased as well. The FDA has published a comprehensive list of known complications of filler use which includes rare but devastating complications including severe allergic reactions; formation of permanent hard nodules in the face or hand; open sores; necrosis; vision abnormalities, including blindness; stroke; injury to vasculature; and damage to the skin or the lips. They also acknowledge that similar or greater risks may exist as "the risks associated with unapproved uses are not known."[10] A review of the literature has revealed numerous accounts of both severe acute side effects and chronic disabling sequelae from nonapproved filler injections which may require extensive, disfiguring surgery; reoperations; and long-term follow-up and may, in some cases, never be fully resolvable. There are currently several published case reports and case studies that explore the topic of PAAG-related complications as well as discuss recommended approaches to treat these complications. Our initial evaluation of the patient utilized ultrasound imaging of the breasts, the most widely accepted and affordable approach to localization and mapping of the PAAG. This was correlated with the physical exam, and a detailed diagram was created and placed into the patient chart. The ultrasound report, subsequently created diagram, and palpation of the areas of concern guided the surgeon in aspiration of the gel pockets. Additional imaging using magnetic resonance imaging (MRI) has been useful in some cases which allows even

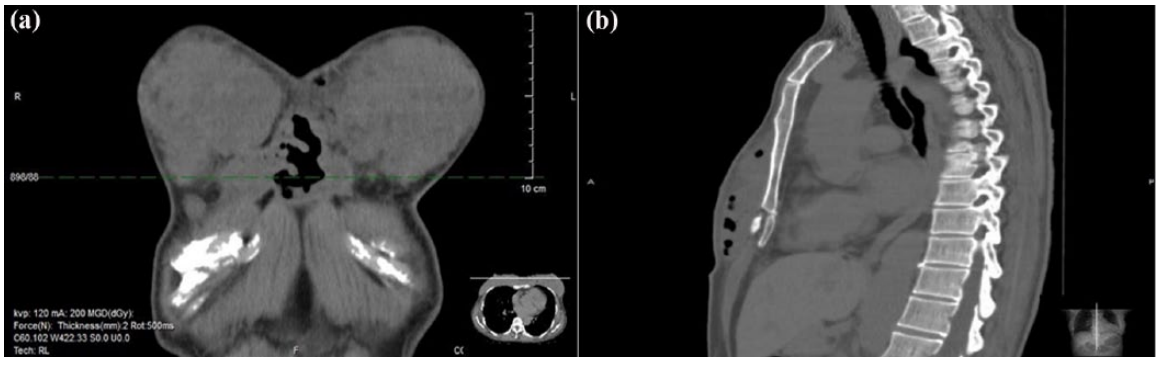

Figure 4. Transverse computed tomography images showing fluid collections, air bubbles, and foreign material. (a) is first photograph on the left (b) on the right.

Note. Images are not enhanced as the patient reported a contrast dye allergy.

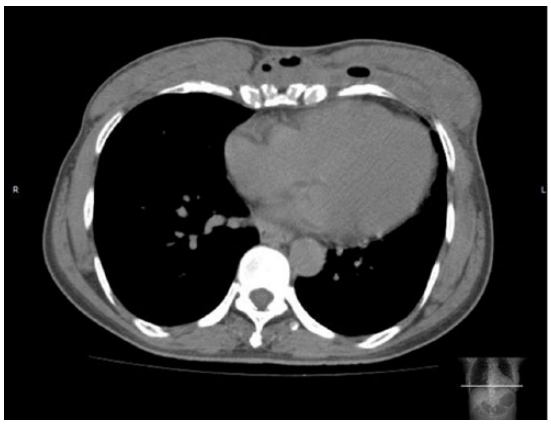

Figure 5. Coronal computed tomography image showing large air pocket superficial to the sternum and the overall heterogeneous appearance of the breasts.

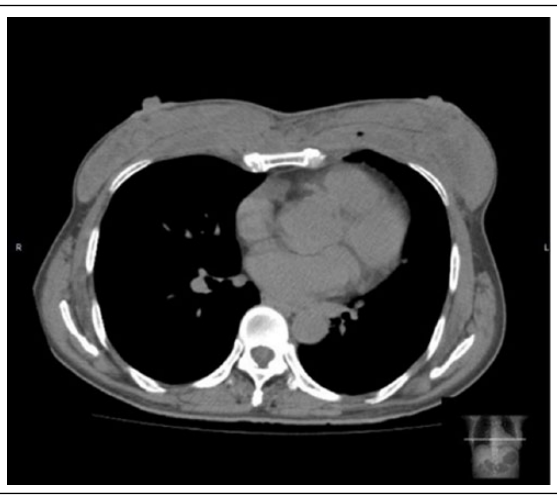

Figure 6. Sagittal computed tomography image showing subcutaneous air pockets superficial to the sternum.

more precise localization of the gel pockets. The main advantage that MRI offers is the ability to clearly distinguish between the gel, glands, fat, and muscle, offering an even more precise mapping modality to use in targeting areas for gel removal.[12] Following the initial in-office aspiration, the sample was sent for pathology analysis, but culture was not performed. In hindsight, given the acute reaction that followed, this would have been an invaluable step in the workup as a preexisting subclinical infection could have been identified and ruled in as a possible cause of the patient's reaction. In one study, focused on patients who developed infection following PAAG injection, the range for development of infection after initial injection ranged from 3 to 108 months.[8] Given this wide range of time to onset, the possibility of subclinical infection and subsequent seeding of the surrounding tissues during removal of the gel cannot be ruled out. Another possibility that would explain the patient's acute reaction following aspiration would a foreign body reaction. As the gel is generally encapsulated following injection, and there has been ample evidence of patients experiencing foreign body reactions which occur following the initial injection, it is logical to assume that rupture of these encapsulated pockets and exposure of naive tissues to the gel could initiate a similar reaction. At least 1 case study has shown that administration of steroids "may reduce the foreign body reaction and eventually make it disappear" and could have been considered as a treatment modality.[13] Given the inherent difficulty in attempting to aspirate the gel from numerous pockets, and the likelihood of incomplete evacuation, it is widely accepted that the preferred approach is an open technique. This allows the capsules to be removed in their entirety, while also allowing for irrigation of the tissues to minimize the possibility of postoperative infection and/or inflammation reaction.[4,14] Several valuable lessons were learned during the treatment of this patient that would significantly influence the workup and treatment of a similar patient in the future. Additional imaging, cultures, postoperative antibiotics, and/or steroids could be considered as well as abandoning needle aspiration and opting for a more invasive, but likely much more effective open surgical technique.

The FDA continues to patrol the global and domestic markets, and, as recently as 2015, issued warnings to physicians and practices found to be marketing injectable PAAG within the United States. Even with this safeguard in place, as more people travel abroad for cosmetic surgery and more illegal medical products reach the United States, clinicians need to stay informed of the potential risks, complications, and treatment modalities so that they are prepared to treat patients suffering side effects and sequelae of PAAG injection.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. Fox BS. Autologous fat injection and breast augmentation. *Med J Just*. 1988;149:284-286.
2. Patlazhan G, Unukovych D, Pshenisnov K. Breast reconstruction and treatment algorithm for patients with complications after polyacrylamide gel injections: a 10-year experience. *Aesthetic Plast Surg*. 2013;37:312-320.
3. Cheng NX, Wang YL, Wang JH, Zhang XM, Zhong H. Complications of breast augmentation with injected hydrophilic polyacrylamide gel. *Aesthetic Plast Surg*. 2002;26:375-382.
4. Chen L, Sha L, Huang SP, Wang ZX. Treatment for displacement of PAAG mixture after injection augmentation mammoplasty. *Int J Clin Exp Med*. 2015;8(3):3360-3370.

5. Leung KM, Yeoh GP, Chan KW. Breast pathology in complications associated with polyacrylamide hydrogel (PAAG) mammoplasty. *Hong Kong Med J*. 2007;13: 137-140.
6. Zhao Y, Qiao Q, Kou X, Zhuang Q, Liu C, Liu ZF. [Clinical and histological evaluation of the injectable hydrophilic polyacrylamide gel]. *Zhonghua Zheng Xing Wai Ke Za Zhi*. 2004;53(3):267-272.
7. Namazi N, Ershadi S, Nikoukar LR, Ghassemipour M. Delayed inflammatory reaction 12 years after PAAG injection. *Iran J Dermatol*. 2015;18(3):128-132.
8. Wang Z, Li S, Wang L, et al. Polyacrylamide hydrogel injection for breast augmentation: another injectable failure. *Med Sci Monit*. 2012;18(6):CR399-CR408.
9. Ghasemi H, Damsgaard T, Stolle L, Christensen B. Complications 15 years after breast augmentation with polyacrylamide. *JPRAS Open*. 2015;4:30-34.
10. Peters W, Fornasier V. Complications from injectable materials used for breast augmentation. *Can J Plast Surg*. 2009;17(3):89-96.
11. US Food & Drug Administration (2017). *Soft Tissue Fillers (Dermal Fillers*). Silver Spring, MD; US FDA.
12. Sandoval LF, Huang KE, Davis SA, Feldman SR, Taylor SL. Trends in the use of neurotoxins and dermal fillers by US physicians. *J Clin Aesthet Dermatol*. 2014;7(9):14-19.
13. Amin SP, Marmur ES, Goldberg DJ. Complications from injectable polyacrylamide gel, a new nonbiodegradable soft tissue filler. *Dermatol Surg*. 2004;30:1507-1509.
14. Do ER, Shim JS. Long-term complications from breast augmentation by injected polyacrylamide hydrogel. *Arch Plast Surg*. 2012;39:267-269.

Author Biographies

Victoria Karlinsky is a board-certified cosmetic and general surgeon, and the owner of New Look New Life Surgical Arts in New York, NY. She is Chair of the American Academy of Cosmetic Surgery's General Cosmetic Surgery Fellowship Committee.

Judson Boisvert is a board-eligible cosmetic surgeon and OB/GYN. He is an attending physician at Triad OB/GYN in Wareham, MA. He is a member of the American Academy of Cosmetic Surgery's Continuing Education Committee. His clinical interest include cosmetic surgery, comprehensive women's healthcare, transgender medicine, and sexual health.