The complications of polyacrylamide hydrogel augmentation mammoplasty: A case report and review of the literature

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The use of Polyacrylamide Hydrogel (PAAG) as an injectable filler for breast augmentation has fallen out of popularity since its first use in the 1980's, but has produced an increasing patient population presenting with complications related to PAAG injections. PAAG use was popularized most notably in China, Russia and Iran. However, given immigration trends and medical tourism, PAAG related complications have become increasingly more common in North America. These complications can be difficult to treat, often necessitating complex surgery that includes gel removal, debridement procedures, and often breast reconstruction. Approaches to surgical treatment and subsequent breast reconstruction are not universally defined primarily because of the limited knowledge about this group of patients. This paper presents the option of autologous free flap reconstruction for a patient with extensive muscular involvement, and aims to summarize complications and risks associated with PAAG through case report and a review of the literature.

Key Words: Polyacrylamide hydrogel; Autologous breast reconstruction; Breast augmentation

Polyacrylamide Hydrogel (PAAG) injectable filler is 2.5% cross-linked polyacrylamide combined with non-pyrogenic water. No clinical trials were ever conducted for the safety and use of PAAG for tissue augmentation but it was used for over 2 decades in the treatment of breast tissue atrophy, reconstruction following malignant tumor mastectomy, and breast augmentation due to mammary dysplasia (1,2). This form of augmentation was popularized in the former Soviet Union and was most notably practiced in Russia, China and Iran (3). PAAG injections were further portrayed by the media and advertised as a relatively cheap procedure requiring no anesthesia or surgical skill that could be performed in an office setting (4). As many as 300,000 women have been treated for PAAG injections (5). PAAG injections have been used in both legal and illegal institutions, such as beauty parlors by non-medical professionals (2).

Aquamid is a representative of PAAG. The monomer of Aquamid in low enough concentrations has been regarded as atoxic to humans and other animals. However, the acrylamide monomer possesses neurotoxicity and teratogenicity. These monomers can often be residually present during the synthesis of PAAG which has potential to cause toxicity to nerve and muscle function (1,5). With these findings, in 2006 the Chinese State Food and Drug Administration announced that PAAG would be prohibited from production and clinical application in plastic surgery (6).

CASE REPORT

45 year-old female Asian patient presented initially with complaints of painful breast masses. She had immigrated to Canada from China in 2010, and had previous received PAAG for breast augmentation in 1996 at a local city hospital. She was an otherwise healthy female who had become recently pregnant with her first child. She was referred to our plastic surgery service by Obstetrics/Gynecology and Genetics as they were following her for her new pregnancy and were worried about the teratogenicity surrounding her PAAG injections and wondered about removal of the implants and termination of her current pregnancy. Given this history of PAAG injections, MRI of the breasts were obtained.

The MRI revealed multiple masses in both breasts. The right sided injectable was more subglandular and the left injectable was more intra and submuscular. At the initial assessment by our service, painful hard mass was observed in both right and left breasts. The patient stated this had been unchanged soon after her initial augmentation. There had been enlargement of breasts with pregnancy but no signs of infection, nipple drainage or inflammation (Figure 2).

A decision to continue with the pregnancy was made by the patient and the Genetics service given the lack of specific known teratogenic effects. The patient went on to deliver her child in May of 2012, she did not attempt to breastfeed post-partum. Shortly after the birth of her son, during a second consultation with Plastic Surgery, she was given the option of PAAG removal and subsequent prosthetic or autologous reconstruction. The patient had wished for the PAAG to be removed as much as possible in order to minimize future complications. Therefore, given the amount of pectoralis major muscle resection required, concerns about placement of breast implants was raised. Ultimately the patient elected to undergo bilateral mastectomy with immediate bilateral DIEP flaps (Figure 1).

Surgery was carried out at the end of December 2012. Intraoperative findings included large amounts of PAAG with a porridge-like consistency deeply infiltrated in multiple planes of gland and muscle. Partial capsule formation was identified around some pockets of filler (Figure 3).

There was diffuse infiltration throughout pectoralis major, especially on the left side, which necessitated significant amounts of muscle to be removed for maximal PAAG eradication. An uncomplicated immediate reconstruction with bilateral DIEP flaps was performed.

The patient had an uneventful recovery in hospital with complete flap survival bilaterally. On follow up, good healing was noted of all surgical sites with no wound dehiscence and the painful masses had a complete resolution. Patient was pleased with the result with future plans to excise the flap skin paddle which was used for monitoring and perform bilateral mastectomy discussed (Figures 4 and 5).

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DISCUSSION

Global public awareness of PAAG injections has been increasing as of late. Surgeons without any experience with these injections are now beginning to see patients with PAAG related complications (5). Knowledge of this implant is important as Canada has a high Asian population, as well as increasing immigration from the Ukraine, and the recent popularity of the medical tourism industry.

Complications

The largest case series of PAAG breast augmentation-related complications was described by Luo et al in their experience with 235 patients (6). The population ranged in age from 20-38 years of age, and the time from injection to complication presentation ranged from 6 months to 10 years (39 months). They found the most common complication to be induration and masses (single or multiple) after PAAG breast augmentation, accounting for 78.9% of patients. The second most common being pain (67.2%) (6). Other more infrequent complications include asymmetry (20%), psychological problems or worry (12.3%), mastalgia with movement (8.5%), distant gel migration (8.9%), nipple retraction and infection (2.5%). 72.8% of patients had multiple complications simultaneously, accounting for 171 patients total (4,6).

Patlazhan et al shared their 10-years’ experience in treating patients for PAAG breast augmentation complications in Ukraine and Sweden as fitting into two broad categories; those with (21%) and without (79%) signs of acute inflammation at presentation (mastalgia, hyperaemia, fever, swelling, fistula or discharge). All of them complained of breast asymmetry and/or deformity, with 54% showing significant gel migration (4).

The most concerning complication by far is the increased risk of breast cancer. Cheng et al describe two cases of breast cancer following PAAG augmentation. There is evidence to suggest that injectable biomaterial such as PAAG does put patients at a greater risk for breast cancer for several reasons. PAAG will inhibit the growth of human fibroblasts and may
cause the apoptosis of human fibroblasts, which leaves the potential for carcinogenicity (7). PAAG also can alter physical parameters such as the size and the granularity of human fibroblasts and induce an increase of mRNA expression of c-myc, a regulatory gene that codes for transcription factor and growth control (7). Also given the most common clinical manifestations are in fact induration or lump and inflammatory reaction caused by PAAG, this might mask the presentation of breast cancer, delaying correct early diagnosis of malignant changes. Other reasons for a delay in recognition can be accounted for by confounding effect on interpretation of radiologic studies, as mammography cannot accurately assess the postoperative state of a PAAG injected breast (7).

Wang et al have described special considerations for complications related to pregnancy, claiming that PAAG injections cause acute inflammation and galactocele formation during breastfeeding (2). A large number of PAAGs have the potential to cause mastodynia. The mechanism being secondary to fibrosis and blockage of ducts due to osmotic self-expansion of PAAG. This gel like substance mixes with breast milk and cannot be excreted. The deposits of PAAG can become a culture medium for infection and inflammation in breast tissue. Additionally, the pressure that is a result of injection may oppress lactiferous ducts, resulting in narrowing. Breast milk outflow becomes obstructed leading to fermentation in a short time and rapid breeding of bacteria contributing to infection (2).

**Treatment**

Eliciting the appropriate history and early recognition is key to diagnosis and treatment of PAAG related complications. MRI is recommended as the most reliable screening method for detection of masses following augmentation; the same is true for a PAAG injected breast. Sentinel lymph node biopsy is also suggested for a PAAG-augmented when a palpable mass is indistinguishable from a gel collection (4, 5, 7).

A treatment protocol developed by Patlazan et al uses the presence of acute inflammation and infection as major factors as to whether or not a patient will receive single stage or two-stage treatment. Those with signs of infection received two-stage treatment, removal and delayed reconstruction, whereas those with no signs of infection had PAAG masses excised and immediately reconstructed (4). Similarly, Wang and Li suggest treating local and systemic infections first, allowing for the breast to retain its normal shape before performing surgery. This process ranged from about 2-8 weeks (5). The literature describes either inframammary or periareolar incision for evacuation of the injectable PAAG (8).

Successful treatment of the PAAG augmentation complication requires removal of as much of the material as possible. Conservative management, such as aspiration is ineffective. Discussion with the patient should explain complete removal is impossible, and that residual PAAG will be left behind. The location, size and extent of infection and the interrelation between infected tissues and surrounding tissues will influence surgical planning and technique. Commonly, incisions at inframammary fold and drainage at low sites are applied (8). In addition, the injected PAAG that is scattered, loci usually have a capsule and fibrous septum is common between lesions. The key to surgical procedures is to completely separate the infected tissues and cysts and thoroughly remove the materials and necrotic tissues, granulation tissues and fistula. Given the hydrophilicity of PAAG, the wound should be repeatedly irrigated with antibiotics in normal saline until the fluid in the drainage is clear and PAAG granules and pus are not observed (5).

**Reconstruction**

There is no literature documenting immediate autologous tissue reconstruction. Reports have only been made on prosthetic reconstruction. Luo et al. performed periareolar evacuation of hydrogel in 235 patients, 136 desired volume reconstruction, which was performed via implantation post-surgical resection of PAAG. Dual-plane silicone implants placed immediately in 108 patients or after 6 months in 28 patients. Out of the 136 that underwent reconstruction three developed a Baker 2-3 capsular contracture, and one inflammatory reaction was documented. Nearly all patients reported a complete resolution of pain, lumps, and infection (6).

Deep inferior epigastric perforator autologous free flap was chosen in our patient because of the extensive amount of PAAG deposits involving the left pectoralis major muscle necessitating removal of majority of the muscle, thus an implant could not be placed. Furthermore, the patient also did not desire the look of implants. That being said, in other patients choosing an implant based reconstruction and the recent popularity of acellular dermal matrix, a total subglandular positioning of an implant could be carried out.

**CONCLUSION**

While polycrylamide hydrogel breast augmentation has been confined to Europe and Asia, North American surgeons may increasingly encounter foreign patients with PAAG-related problems given globalization and the recent popularity of medical tourism in today’s society. Complications from PAAG injections present from months to years following injection and include lumps, pain, asymmetry, and inflammation. Other concerns include breast cancer detection, long-term toxicity of the material, and breastfeeding issues. While PAAG is difficult to eradicate, surgical drainage and debridement is successful in relieving most symptoms. Post-debridement reconstruction is primarily reported with prostheses. We present a case using autologous free-flap reconstruction to be a potentially successful form of reconstruction.

**DISCLOSURES:** This material has not been published previously and will not be submitted for publication elsewhere. No conflicts of interest exist.

**REFERENCES**