

Challenging Gluteal Augmentation Due to Late Complication of Permanent Filler: Case Report and Literature Review

SAAD M.S. IBRAHIEM, M.D., MRCS, EBOPRAS; HASSAN M. KHOLOSY, M.D. and ALY H.S. ABULHASSAN, M.D.

The Department of Plastic Surgery, Reconstructive Surgery and Burn Management, Faculty of Medicine, Alexandria University

Abstract

Polyacrylamide hydrogel (PAAG) has been used for more than two decades as a permanent injectable for facial and soft tissue augmentation. With the advent of so-called “minimally invasive” techniques, permanent injectables became popular with both patients and physicians. However, several late complications have been reported worldwide.

Here, we present a 43-year-old female patient who experienced late complications 8 years after buttock augmentation with PAAG injections with a difficult reconstruction of the gluteal region.

We also reviewed the literature on clinical management issues and available reconstructive options for this problem. The search in the clinical key using the term polyacrylamide hydrogel yielded 169 results in various fields of medicine, limiting the search in plastic surgery yielded 67 results, 14 in facial rejuvenation, 9 in breast augmentation, 7 in buttock augmentation, 2 literatures on the use of u/s in the diagnosis of PAAG complications, and 35 literatures on the composition, histologic analysis, and general complications from the use of PAAG.

Searching for the term gluteal augmentation after excluding augmentation modalities other than PAAG ends at 7 literatures, however, the total number of these clinical reports on complications of PAAG use for buttock augmentation is striking, accounting for more than 50% of the studies.

All literatures conclude that the PAAG filler is easy to inject, but once complications occur, they are difficult to manage.

Key Words: Polyacrylamide – PAAG – Gluteal – Augmentation – Complications.

Ethical Approval: The present study was conducted in accordance with the Good Clinical Practice Guidelines and the Alexandria Medical School Scientific Committee Institutional Review Board (IRB) ethical approval number 0305776, the

National Research Committee, and the 1964 Declaration of Helsinki of 1975, as revised in 2008.

Informed Consent: The authors’ note that full-informed written consent has been obtained from the patient described in this case report, including the use of the images provided.

Statement of human and animal rights, were observed.

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Introduction

Minimally invasive gluteal augmentation has been touted as an alternative to autologous fat grafting to attract patients for volumetric gluteal augmentation with non-biodegradable fillers. With the wide acceptance of biodegradable fillers, many patients can easily imagine permanent fillers having the same safety profile but for a longer period of time. Permanent fillers are quickly gaining popularity for gluteal augmentation because it applied easily in the plastic surgeon’s office after local anesthesia, unlike autologous fat transfer, which is a surgical procedure with requirement for an operating room and sedation [1].

The FDA has approved liquid silicone for the treatment of retinal detachment, but many physicians administer it off-label for esthetic purposes, including gluteal augmentations. Because of the negative publicity associated with silicone injections, Polyacrylamide hydrogel (PAAG) was introduced as promising alternative. The nature of PAAG contributes much to its widespread use because it is physically and chemically stable, can be stored at room temperature, is inexpensive, and has a uniform formulation with the possibility of mass production, limited immunogenicity with long-term effects.

The PAAG was developed in Ukraine in 1997. It was approved in 2001 by the European Commit-

Correspondence to: Dr. Saad Mohamed Saad Ibrahim,
E-Mail: saad.saad@alexmed.edu.eg

tee for cosmetic use in facial contouring and soft tissue augmentation, and was introduced to the global market under different trade names. Aqualift (National Medical Technologies Center Co., Ltd., Ukraine), Bio-Alcamid (Polymekon, Italy), Argiform (Bioform, Russia), Aquamid (Ferrosan, Denmark), Aquafilling (Biomedica, spol, s.r.o., Czech Republic), and Amazingel (NanFeng Medical Science and Technology Development Co., Ltd., Shijiazhuang, People's Republic of China).

Around 2005, PAAG began to be used in the Middle East for facial and corporal augmentation. The PAAG efficacy was supported by several investigators who overwhelmingly rated its esthetic results, and considered it a near-ideal filler material; its widespread use in Europe, Asia, and the Middle East led to an increase in filler market share [2-3]. Unfortunately, they ignored its long-term effects on the human body.

Around 2010, its use for cosmetic purposes was banned by several countries around the world due to the nature and frequency of complications, which could occur many years after the first injection [4-5].

Between 2017 and 2022, the authors have seen a steady influx of new patients who have suffered complications from putative permanent fillers (PAAG) for gluteal augmentation in the form of severe scarring and irreversible deformities that require complex reconstructions. Aside from the poor psychological impact of a failed purely esthetic procedure such as gluteal augmentation, the economic burden of complications (repeated infections, debridement, frequent dressing changes, and hospitalizations) associated with permanent filler must also be considered.

Objective:

The authors present an interesting case of a 43-year-old female patient who presented to our plastic surgery department with severe, deep gluteal scarring after undergoing multiple surgeries to remove an infected PAAG 8 years after injection as well as unsuccessful gluteal augmentation using silicone implants. In addition, review of the literature of issues related to clinical management and available reconstructive options of the problem are discussed.

Case Report

In 2012, a 33-year-old woman was treated for esthetic gluteal augmentation after successfully losing 34kg in 5 months. An unspecified amount of Aqualift (National Medical Technologies Center Co., Ltd., Ukraine) was injected at a local clinic for gluteal augmentation in 2 sessions 3 weeks apart. The patient was initially satisfied with the esthetic result of the procedure.

In 2016, the patient presented with redness and swelling on both halves of her buttocks. The patient admitted that the area was hard and extremely painful to the touch. All attempts at antibiotic therapy failed to relieve the symptoms.

Ultrasonography revealed cystic multilobular masses of varying sizes in the subcutaneous fatty layer of the buttocks that invaded the gluteal muscles and infiltrated the dermis of the skin.

The patient underwent several surgical procedures to drain the gluteal abscesses. 6 months later, the patient underwent bilateral exploration of the buttocks to remove the filler, which left severe scarring in the form of multiple saucerized depressions of the buttocks.

In 2017, the patient traveled abroad for gluteal augmentation with silicone implants. During the return flight, she developed shortness of breath, tachycardia, and local tenderness below the xiphoid region. The admission diagnosis was pulmonary embolism in addition to thrombosis in the left leg. She was admitted to the intensive care unit, where she was treated with standard parenteral therapy for pulmonary embolism. After a week, she was discharged with oral anticoagulant therapy for 6 months.

In 2020, she presented to us because she was completely dissatisfied with the deep scarring on her buttocks, and she was not satisfied with the results of her silicone buttock augmentation performed abroad. Clinical examination revealed several deep scars in her buttock, small irregular bulges in the previous buttock augmentation (Figs. 1-3).

A preoperative MRI scan was performed to determine the exact location of the old silicone implants and to rule out the presence of permanent filler material in the buttock, and routine laboratory testing, including a detailed bleeding and coagulation profile of the patient was also performed. The patient agreed to the following surgical plan: a staged gluteal augmentation with two tissue expanders in the buttock to create an adequate soft tissue pocket, followed by placement of 2 silicone implants in the second stage.

Preoperative markings of the optimal position of the tissue expanders were made on the patient in the standing position. The patient was admitted for low-molecular-weight heparin injections preoperatively one day before surgery and up to 72 hours postoperatively.

Surgical technique:

First stage: Placement of tissue expanders:

The procedure was performed on the patient in the prone position under general anesthesia.

Warming and physical protective measures against the risk of DVT included alternating pneumatic compression of the lower extremities intraoperatively and compression stockings postoperatively.

A 10cm transverse incision was marked at the level of the bikini line immediately behind the anterior superior iliac spine. The surgical incisions were infiltrated with 10cc of xylocaine. (Lidocaine 10mg/ml + 5mg/ml epinephrine; Astra-Zeneca, Sweden). Soft tissue pockets were created on each side, with the aid of Ferreira light retractor (Integra LifeSciences, Princeton, New Jersey), the severe scars were removed with sharp dissection using Metzenbaum long scissors and blunt dissection using Tebbetts breast scissors augmentation dissector (Black & Black Surgical, Atlanta). Breast sizers were used to verify that there was no tethering points and that the soft tissue pockets were optimally dissected.

A good hemostasis was noted, and a 14-French drain was placed in the surgical field.

A 400-cc circular expander (Polytech health aesthetic, GmbH, Duisburg, Germany) was used in the right pocket and a 300-cc circular expander (Polytech health aesthetic, GmbH, Duisburg, Germany) in the left pocket. The ports were tunneled in a subcutaneous plane to be placed subcutaneously in the lower back skin. The incisions were closed in two layers with 2-0, 3-0 Vicryl and 4-0 Monocryl for the dermis. The patient was encouraged to have an early ambulation and was discharged home on the third postoperative day.

Tissue expansion was started in the third postoperative week with 50ml of normal saline per week and gradually increased to 80ml, which was adjusted according to the patient's degree of discomfort. Overexpansion of about 50-100% was planned, both expanders allowed expansion to 700-800cm³.

The second stage: Insertion of silicone-gel-filled gluteus implants:

The expansion phase lasted up to 3 months before the second stage. The surgical incision was opened, first the port of the expander was removed, the expander was drained of saline and removed, no capsulotomy was performed and the expander was replaced with a 450ml Oval MESMO silicone gel-filled gluteal implant (Polytech health aesthetic, GmbH, Duisburg, Germany). The skin incision was sutured with 3-0 Vicryl (Ethicon, Inc., Somerville,

N.J.) for the subcutaneous layer and 4-0 Monocryl (Ethicon, Inc., Somerville, N.J.) for the skin. The same procedure was repeated for the other side.

Postoperatively, the patient received prophylactic antibiotics with a second-generation cephalosporin for 1 week, and she was advised to wear a buttock enhanced pressure garment for 1 month.

Review of the literature:

A systematic literature search was performed in the following search engines: ScienceDirect, PubMed, Medline, and Embase, using the following search terms: [(Polyacrylamide hydrogel) OR (PAAG) OR (buttock augmentation) OR (gluteal augmentation) AND (buttock enhancement)]. References from clinical trials, commentaries, reviews, and consensus reports were considered for the analysis.

Results

The patient was very satisfied with her postoperative result, Figs. (1-6) show the pre-operative and late post-operative results.

The search yielded 712 reports in various fields. After eliminating duplicates and irrelevant reports, the search in the clinical key using the term polyacrylamide hydrogel yielded 169 results in various fields of medicine. Limiting the search in plastic surgery yielded 67 results, 14 in facial rejuvenation, 9 in breast augmentation, 7 in buttock augmentation, 2 references on the use of ultrasound in the diagnosis of PAAG complications, and 35 references on the composition, histologic analysis, and general complications from the use of PAAG.

Searching for the term gluteal augmentation leads to 55 search results, after excluding augmentation modalities other than PAAG the result ends at 7 references.

Compared to the large number of references on the use of PAAG in facial rejuvenation and esthetic enhancement, breast and urinary incontinence treatment, there are few clinical reports on the use of PAAG in buttock augmentation. However, the total number of these clinical reports on complications of PAAG use for buttock augmentation is striking, accounting for more than 50% of the studies.

All references conclude that the filler is easy to inject, but once complications occur, they are difficult to manage.



Fig. (1 : 3): Clinical images of a 43- year-old female patient with severe and deep gluteal scarring after undergoing multiple surgeries to remove an infected PAAG 8 years after injection as well as irregular small bulge due to unsuccessful gluteal augmentation using silicone implants.

Fig. (1) Posterior view.

Fig. (2): Oblique lateral view of the right side of the buttock.

Fig. (3): Oblique lateral view of the left side of the buttock.

Fig. (4 : 6): Clinical images of the same patient at 12-month follow-up visit after staged gluteal augmentation.

Fig. (4): Posterior view.

Fig. (5): Oblique lateral view of the right side of the buttock

Fig. (6): Oblique lateral view of the left side of the buttock.

Discussion

Many European plastic surgeons reported the beneficial effects of PAAG for soft tissue augmentation. They have promoted these fillers but failed to evaluate the fate of these soft tissue fillers or predict their performance over a period of several years [6,7]. However, other studies criticized the use of PAAG as permanent filler because of the reported long-term complications that occur with its use and ended with disastrous consequences for many patients after gluteal augmentation. Many plastic surgery departments have become referral centers because of a large number of PAAG-related complications [8-10].

PAAG is a homogeneous material that contains no microparticles and has an immediate filling ef-

fect, unlike tissue fillers that rely on a foreign body reaction to achieve the desired effect.

Chalcarz and Żurawski [11] reported that the tissue immunologic response to PAAG may be related to the amount of filler injected and the time elapsed since injection, as evidenced by extensive inflammatory infiltration and granulomas, fibrous connective tissue that is partially hyalinized, and the presence of numerous small blood vessels in the histologic tissues. They also advised that the filler be removed with extreme precision along with the altered surrounding tissue by surgical intervention.

Injection of PAAG in large quantities should be considered as injectable liquid endoprosthesis, relying solely on volume buildup from the gel itself [12,13]. Also, Lahiri and Waters [14] referred to

PAAG as an endoprosthesis because a thin capsule forms, isolating the injected material from the rest of the body and possibly contributing to the safety of the material. Unfortunately, the capsule is very thin (0.02mm) and may tear in mobile areas or with minor trauma.

Campana et al. [15] noted that permanent injectable endoprostheses might leave the treated area vulnerable to infection for the duration of their presence in the tissue with the constant risk of infection or complications. However, unlike regular endoprostheses, it will not be possible to ever remove them completely.

Lemperle et al. [16] reported that injection of PAAG in large quantities is similar to silicone, whose half-life in the human body can reach 20 years, in contrast to injection of 1cc of PAAG, which can disappear from the body within 9 months. They reported that with a large volume PAAG injection, which is usually low viscosity, most of the filler infiltrates multiple tissue planes and it will be extremely difficult to remove completely without causing severe scarring. Kadouch et al. [17] reported that 66 (78%) out of 85 patients had delayed-onset complications after injections with PAAG. 72% of the complications appeared to occur spontaneously.

Urdiales-Glaves et al. [18] classify filler complications according to the time of their occurrence: immediate occurrence (within 24 hours), early occurrence (within 4 weeks) with typical manifestations such as erythema, edema, hematoma, itching, and pain, with nodules or abscess formation. Delayed onset (more than 4 weeks) in the form of intermittent swelling, asymmetry, multiple recurrent abscesses, multiple surgical procedures, and scarring.

Mostly, delayed PAAG complications have been attributed to biofilm. Sadashivaiah et al. [19] defined biofilm as an aggregate of self-encapsulated microorganisms in a polymeric matrix that are irreversibly attached to a living or inert surface. Oral antibiotics cannot penetrate biofilms, which may contain bacteria, protozoa, or fungi. These low-grade infections chronically affect the local area and may even cause systemic infection [20].

Once the biofilm has been activated by minor trauma, acute purulent infection with dissemination or even sepsis occurs, depending on the immunity of the host. The active infection can be controlled with antibiotic therapy, but recurrence is the rule.

3 major causative organisms of infections after cosmetic fillers have been identified: *Mycobacterium chelonae*, an infection that can occur in patients from the ice used in the clinic tap water during injection, *Staphylococcus epidermidis*, and *Propionibacterium acnes* were identified in 98% of patients

with adverse reactions to PAAG up to 5 years after injection [21].

Based on PAAG is a liquid hydrophilic injectable that can absorb body fluids and exudates, this creates an ideal environment for bacterial proliferation and rapid infection.

Therefore, it is essential for plastic surgeons to prevent, recognize, diagnose, and properly treat infections associated with PAAG injections. Suspected infections should be treated with appropriate antibiotic therapy based on culture and sensitivity. Some investigators recommended a punch biopsy to initiate specific antibiotic therapy [22].

Close clinical monitoring of the patient's condition is critical to detect progression of the underlying infection. Systemic symptoms such as fever, chills, or malaise may indicate the formation of a biofilm, which is responsible for resistance to antibiotic therapy by providing a protective environment for bacteria [23].

It is important to use specific antibiotics that can penetrate the biofilm matrix, such as macrolides, lincosamides, tetracyclines, rifamycins, oxazolidinones, fluoroquinolones, nitroimidazole, and sulfonamides [12].

If antibiotic therapy cannot control the infection due to biofilm formation, the bacterium must be removed along with the associated foreign body.

Recently, there has been a growing interest in permanent fillers for aesthetic augmentation of the face and body [24,25]. We believe that studies should report their experience with cases of rejection, migration, or product shift in the long term and what procedure they recommend for complete removal of the filler from the patient's body.

Considering the serious complications associated with the injection of a large volume of PAAG for buttock augmentation, the presenting study introduces a comprehensive review of the late complications of the permanent filler and raises the question of the long-term safety of PAAG in aesthetic buttock contouring.

Procedures for the treatment of PAAG complications in the gluteal area:

The first step in preventing complications associated with PAAG is to avoid its use for soft tissue augmentation. In case of complications, a treatment algorithm should be followed to systematically treat complications. Management includes both diagnostic evaluation and an appropriate treatment plan for any complication related to PAAG injection.

The presented complications associated with the injection of PAAG for gluteal augmentation

include induration, lumpiness, inflammation, infection, persistent pain, poor cosmetic results due to migration of the gel, and severe scarring after multiple attempts at surgical removal of the complicated filler.

Grippaudo et al. [26] recommended the use of high-frequency diagnostic ultrasound as a useful tool for noninvasive imaging of healthy and pathologic skin and subcutaneous tissue. They reported that this could be a useful tool to differentiate between some temporary and permanent fillers. Suchyta et al. [27] illustrated the benefits of intraoperative ultrasound to identify the location of injected filler, thus enabling near complete excision of filler aggregates.

The following clinical situations may be encountered during management of late complications related to the use of PAAG in gluteal augmentation.

A case of previous gluteal augmentation but there is no signs of inflammation:

We believe that the best management is patient education to avoid minor trauma to this area, do not make any further injections into the buttocks, and avoid any type of intramuscular injection in this area.

No inflammation, but deformity of the buttocks due to hardening of the filler material:

Removal of the filler is recommended through bikini access (buttock lift incision). The use of intraoperative ultrasound is of great help to identify the location of injected filler. An incision is recommended where skin flaps are lifted, and a subcutaneous dissection is performed. Sometimes there is a capsule that encloses a large amount of the filling gel. In this case, the capsule is opened, and the gel is gently aspirated to allow it to drain, and the capsule is then carefully removed. Sometimes the filling gel clumps together and should be removed in pieces.

The surgical field should be thoroughly rinsed with copious amount of saline. Drainage of the remaining cavity is recommended. Pathological examination should be conducted for both bacterial counting and evaluation of the tissues for malignancy. Drug sensitivity testing should be performed, and antibiotics are prescribed based on the sensitivity results.

We do not recommend autologous fat transfer in the same sitting for fear of infection and loss of valuable autologous filler.

Chalcarz et al. [11] advised a follow-up MRI 6 months after the procedure, before performing secondary buttock augmentation by autologous fat grafting, silicone implant, or both (hybrid approach).

Mild inflammation without signs of abscess formation.

The condition should be treated with appropriate antibiotic therapy using specific antibiotics that can penetrate the biofilm matrix, such as macrolides, lincosamides, tetracyclines, rifamycins, oxazolidinones, fluoroquinolones, nitroimidazoles, and sulfonamides [12].

Close clinical monitoring of systemic symptoms such as fever, chills, or malaise is critical to detect the progression of the underlying infection. If antibiotic therapy cannot control the infection due to biofilm formation, the bacterium must be removed along with the associated foreign body.

Major inflammation or abscess formation:

Conservative management such as aspiration is ineffective, because the filler is usually injected in multi-layer fashion deep into the tissues in buttock augmentation.

Based on the severity of infection, several surgical interventions may be needed to control the infection. Incision, drainage, and direct removal of the filler are the best treatment options, as leaving the filler in place may lead to recurrence of the infection.

Disfigurement of the buttocks due to scarring after removal of the permanent filler.

Minimal scarring:

Echo et al. [28] reported correction of minimal buttock scarring by wire subincision of the subdermal attachments, followed by volume replacement by microfat grafting.

Severe scarring:

We recommend using tissue expanders as a temporary approach to obtain a stable pocket for placement of a silicone implant.

To the best of our knowledge, there are no reports of gluteal augmentation with paired silicone implants per side. Our patient is unique in that 2 gluteal silicone implants were used to augment each side after tissue expanders were used to overcome severe scarring of the tissue after repeated surgical procedures to remove the PAAG filler material.

Conclusion:

In theory, permanent injectable fillers have a good overall safety profile, but in practice they have serious adverse effects that often occur many years after injection with a high degree of unpredictability; therefore, it is important to gather all possible information about these serious complications and their possible treatment.

The lack of information to patients about the risks and side effects and the fact that the lack of

strict regulation of the growing market for the permanent filler has led to unqualified physicians and the use of unproven materials causing a growing number of difficult cases of gluteal reconstruction due to complications with the permanent filler.

The range of complications associated with permanent fillers adds to the growing body of evidence of their significant long-term adverse effects, which have led many countries to restrict their use to very limited indications or discontinue them altogether.

The use of high-frequency ultrasound in the preoperative evaluation of complications from permanent fillers helps to differentiate between a cystic or infiltrative complication.

We think that there is consensus that surgical excision is a mainstay of treatment for these complications. We recommend surgical removal of permanent filler from the buttocks through the buttock lift (bikini) incision to preserve the aesthetic appearance of the buttocks and not wait until disfigurement occurs due to complications with the filler when attempting to manage such an adverse reaction through a direct surgical incision.

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