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CASE REPORT

Complications from Repeated Injection or Puncture of Old Polyacrylamide Gel Implant Sites: Case Reports

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Abstract Polyacrylamide gel has been used for soft tissue augmentation outside the United States since 1997. Despite some adverse events, the long duration of the augmentation and the tangible filling effect has increased its use in Asia and the Middle East. In this era of mesotherapy and fillers, patients are more likely than ever to have additional injections. The response of old polyacrylamide gel implant sites to puncture or repeated injection has not been reported previously. A total of 12 cases were treated for acute inflammation after puncture of polyacrylamide gel implants with injection needles or minor surgical intervention. The duration of augmentation after the initial injection was from 6 months to 4 years. Acute inflammation followed a certain pattern. Patients presented with pain, swelling, redness, and significant induration after puncture of the dormant implant. Resolution was achieved gradually with drainage, empirical antibiotics, and antiinflammatory agents in 1 to 2 weeks. Cultures of removed gel were negative. The cause of inflammation was difficult to define, but a definite link to puncture of the implant could be found in all patients. Puncture of the implant violates the tissue–implant barrier and induces inflammation or introduces bacteria that are not detectable in culture but may contribute to inflammation in the presence of the filler material. Further research is needed to assess the inflammation observed with repeated puncture of old polyacrylamide gel implants and its implications. In the meantime, patients should be warned about the possibility of inflammation in the case of puncture or surgery to the implant site, even years after the polyacrylamide gel injection.

Keywords Complication · Polyacrylamide gel · Puncture

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Numerous fillers are used currently for soft tissue augmentation in the face and body. Fillers based on hyaluronic acid produce short-term results, whereas fillers based on polyacrylamide produce more lasting improvement [1]. A large supply of body filler secured at low cost is another advantage of polyacrylamide gels, which may play down safety concerns. Recent years have seen few reports about isolated cases of complications from injectable polyacrylamide hydrogel [2, 3]. All occurred in the short term and did not follow a certain pattern pointing to a clue for prevention. In this era of mesotherapy and fillers, patients require more injections than ever. The response of the old polyacrylamide gel implant site to puncture or repeated injection has not been reported.

We report inflammatory reactions long after injection of polyacrylamide gels in the face and body that followed a certain pattern. Acute inflammation started after puncture of the implant site with an injection needle or minor surgical intervention.

Patients and Methods

A total of 12 patients presented with acute inflammation after injection or minor surgery to the face or body. They ranged in age from 27 to 61 years. All had received an

injection of polyacrylamide gel at the site 6 months to 4 years previously. Two of three patients who had received additional injections 1 to 2 months after the initial injection showed signs of implant migration. All the patients presented with signs and symptoms of acute inflammatory reactions including pain, fever, swelling, edema, redness, and tenderness with significant induration.

Drainage was established through the intraoral approach (for inflammation of nasolabial fold implants) or a minimal stab incision on the skin surface. Yellowish granular gel was expressed in most cases and submitted for culture.

Case Reports

Case 1

A 61-year-old woman presented with red, tender, indurated swelling in the lower part of the right nasolabial fold after fat injection of the lips. The swelling was associated with severe throbbing pain. Her history showed injection of polyacrylamide gel in the nasolabial folds 4 years previously. Immediate pain relief followed drainage of yellowish granular gel (2 ml) through a minimal stab incision. Culture of the gel showed no bacteria. However, antibiotic and antiinflammatory agents were administered.

After 5 days, aspiration of a small fluctuating swelling produced 0.5 ml of yellowish gel. The swelling and induration subsided, and resolution was complete in subsequent follow-up visits (Fig. 1).

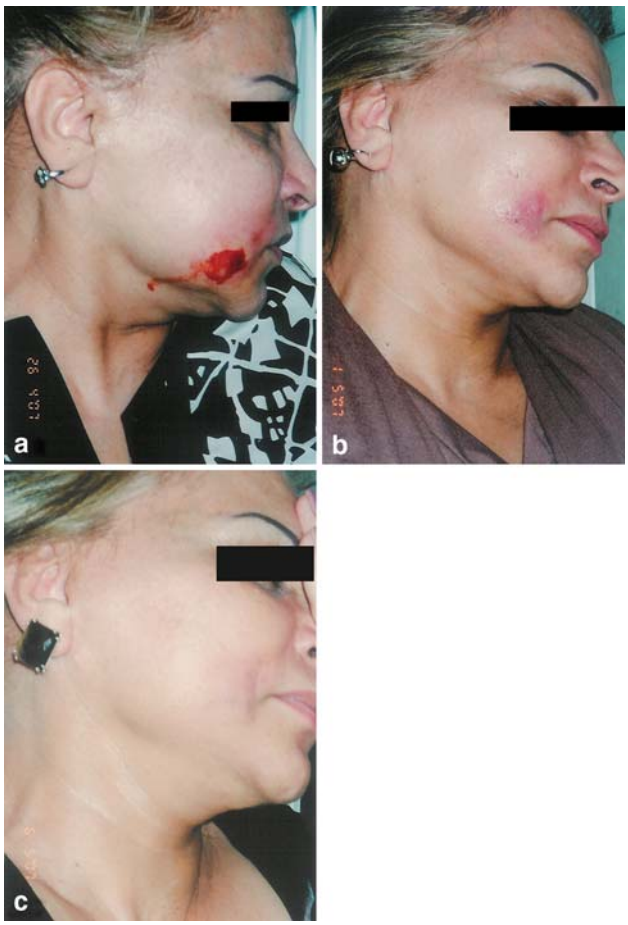

Fig. 1 Case 1. (**a**) Inflammatory swelling of the right nasolabial fold after puncture of a 4-year polyacrylamide gel implant during fat injection of the perioral region. Drainage of yellowish granular gel (2 ml) through a minimal stab incision. (**b**) Small collection aspirated a few days later. (**c**) Decreased inflammation after 10 days

Case 2

A 46-year-old woman presented with bilateral nasolabial swelling associated with severe pain, tenderness, redness, edema, and significant induration after injection of local anesthetic for upper lip definition with pink tattoo (Fig. 2). Her history included polyacrylamide gel injection of the nasolabial folds 2 years previously. Intraoral drainage of the lesion on both sides was performed. Yellowish granular gel was removed. No bacterial growth was seen in the culture. Again, antibiotics (for aerobes and anaerobes) and antiinflammatory agents were given, and the inflammation subsided slowly over 10 days.

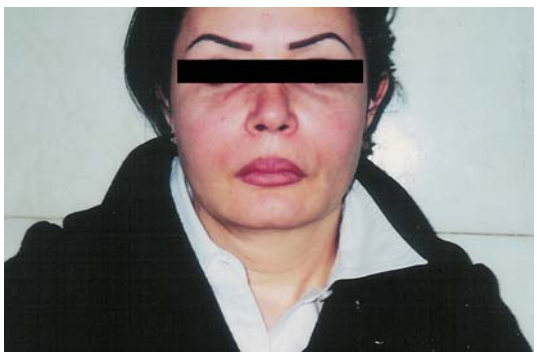

Fig. 2 Case 2. Swelling, redness, and edema of bilateral nasolabial folds 10 days after intraoral drainage subsequent to puncture of a 2-year polyacrylamide gel implant with anesthetic needle during a lip tattoo

Case 3

A 27-year-old male-to-female transsexual presented with pain, tenderness, diffuse dusk redness, and edema of both buttocks after a fourth injection of polyacrylamide gel 7 months after the initial injection (Fig. 3). The patient had bilateral silicone gel prostheses implanted through a gluteal crease approach, which were removed due to exposure of the left implant 1 year after the implantation. Four injections of polyacrylamide gel were performed at 3- to 6-week

intervals for buttock augmentation. Because there were no significant localized indurations, no attempt was made to drain the swollen buttocks at presentation.

A small fluctuating swelling was seen in the right gluteal crease after 4 days. Drainage of this swelling showed only serous fluid (reactionary). At home, large amounts of the gel drained through the wound. Resolution started gradually under conservative treatment with intravenous antibiotics, analgesics, and antiinflammatory agents. However, chronic redness remained, followed by a flare-up of acute inflammation in the left buttock 1 month later, for which 0.1 ml of steroid was administered in addition to the aforementioned measures.

Case 4

A 37-year-old woman presented with acute inflammation of the right nasolabial fold, including the right side of the face, after injection of local anesthetic for lip tattooing. The inflammation was associated with pain, redness, edema below the eye, and swelling of the right side of the face, with moderate induration of the right nasolabial fold (Fig. 4). The patient had undergone polyacrylamide gel injection of the nasolabial folds and cheeks 3 years previously. Antibiotics and antiinflammatory agents were administered, but the patient deferred drainage and did not show up for her follow-up visit because of a travel commitment.

Discussion

The long duration of polyacrylamide gel filler in soft tissue augmentation is a clear advantage. Reports of occasional adverse events developing early after polyacrylamide gel injection are not few [4]. As a normal physiologic response

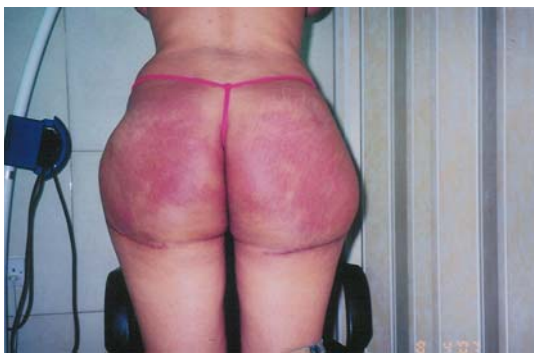

Fig. 3 Case 3. Diffuse dusk redness and edema of buttocks after the fourth injection with polyacrylamide gel 7 months subsequent to the initial injection. After drainage of right buttock, some redness remained, with flare-up of inflammation in the left buttock 1 month later

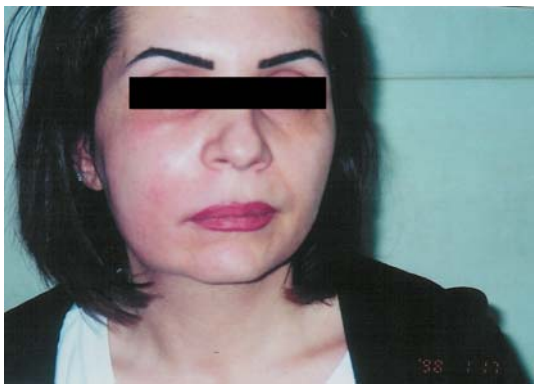

Fig. 4 Case 4. Swelling, redness, and edema of the right nasolabial fold and the right side of the face after puncture of a 3-year polyacrylamide gel implant during anesthesia of the lip for tattoo

to most nonabsorbable biomaterials, the body develops a fibrous capsule around the implant. The fibrous capsule helps to confine the distribution of the material and to maintain the correct shape and location of the implant [5]. The nature of this capsule is debated. Christensen et al. [6] described a thick fibrous capsule around the gel in breast tissue. Some animal experiments have shown a flabby capsule in subcutaneous and mammary tissue and even no capsule in or near muscular tissues [7].

In the current study, inflammation followed puncture of the implant with a needle or a minor surgical intervention more than 6 months after implantation. In all cases, a definite history of permanent filler injection could be traced. Although the cause of inflammation was difficult to define with certainty, a link to repeated injection or puncture of the implant was obvious. It seems that puncture of the implant violates the tissue–implant barrier and induces inflammation or introduces bacteria that are not detectable in culture but may contribute to inflammation in the presence of foreign material.

In one study, transient local tissue reactions and elevation of circulating immunoglobulins were observed in some cases [2], raising the possibility of immunogenic reaction. Histologic specimens from patients experiencing symptomatic delayed reactions after breast augmentation with polyacrylamide gel have shown macrophages and granulomas [6, 7]. Different tissue reactions from hyaluronic acid filler also indicate that responses in clinical practice are likely to be different [8]. On the other hand, it is claimed that the smooth surface of the polymer prevents phagocytosis by macrophages or mononuclear cells, the process initiating nonspecific immune reactions to foreign substances [2].

In one small study, the authors noted bacteria on histologic specimens of injected polyacrylamide gel even when wound cultures were negative [3]. They suggested that bacterial infections must be initially considered for

patients experiencing symptoms after injection of polyacrylamide gel.

Some studies show good results when polyacrylamide gel is used in small amounts [9]. When the gel has been used in small amounts, resorption has been reported in less than 9 months [10].

The inflammations in this report were related to delayed violation of polyacrylamide gel implants. Unilateral inflammation of the nasolabial fold in cases 1 and 4 may have resulted from puncture of the implant on that side only. One patient experienced acute inflammation only on the side of the face that received an intraoral incision for a smile dimple, although she had undergone polyacrylamide gel injection of bilateral cheek depressions 1 year previously. Because the mechanism of late inflammation or granuloma formation still is unknown, early histologic findings are not useful for predicting possible late reactions to filler substances [10]. From the current study, it seems that repeated injections are associated with more adverse events, and none of the studies evaluated the effect of repeated injections or late interference with old polyacrylamide gel implant sites.

This pattern of acute inflammation with puncture of the implant after such a long period has not been reported previously. Removal of the filler material in the face after inflammation usually is not complete and may result in contour defects. It is not known whether correction of these defects with injection will induce inflammation again because none was attempted at this stage. A case of erythematous cheek nodules reported 2 months after two injections with polyacrylamide gel did not respond to antibiotics yet showed a positive response to localized steroid injections [3].

In the reported cases, inflammation developed with puncture of the implant 6 months or longer after the initial injection. The patients responded to drainage, empirical antibiotics, and antiinflammatory agents. A localized steroid injection was used in only one case. Drainage is important in the presence of severe pain and significant induration even before fluctuation.

With patients now receiving more injections in 1 year than in an entire lifetime, the likely effect of repeated injections on a polyacrylamide gel implant site has to be considered. Patients tend to have injections (mesotherapy, filler, botox, lipolysis) every 3 to 6 months. Superficial injections such as mesotherapy and dermal fillers are less likely to hit the dormant implant.

Whether deep injections or facial surgery may lead to any similar type of inflammation remains a contentious issue. Patients should be provided with information (filler card) regarding the date, type, amount, and site of the filler injected and warned about the possibility of inflammation with repeated injection or puncture to the implant site, even after long periods. Injection of polyacrylamide gel in small amounts and avoidance of repeated injections may reduce complications. Further research is needed to assess the inflammation observed with repeated injection or puncture of old polyacrylamide gel implants and its implications.

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