Seminars in Cutaneous Medicine and Surgery

Polyacrylamide Gel in Cosmetic Procedures: Experience with Aquamid

Trevidic Patrick, MD

Polyacrylamides have been used in tissue augmentation since 1980. AQUAMID injections amounting to 40,000 have been done for facial and body corrections in cosmetic and reconstructive medicine and surgery. Possible neurotoxic and carcinologic effects of acrylamide and their stability are reported. The most important complications are infection, granuloma, and migration. All actual studies and results are reported. Main indications are lips, nasolabial fold, and malar area.
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History

Since its discovery, polyacrylamide gel is widely used in drug treatment, water purification, ophthalmologic operations, and packaging. It was first used as tissue filler by Ukrainian surgeons in 1980 for breast augmentation.[1] More than 40,000 patients have been treated for facial- and body-contouring augmentation.

Since March 2001, AQUAMID has the European Community marked for injections. Other different polyacrylamides exist on the market (ARGIFORM, AMAZINGEL, BIO-FORMACRYL, BIOALCAMID, and OUTLINE).

Chemical Composition

AQUAMID (pH 7.5) is a polyacrylamide viscoelastic gel (PAAG) 2.5% with 97.5% water. It is a permanent biocompatible filler product produced by Ferrosan (Denmark). There is no microparticle inside or any animal content; the residual monomers are 1 to 2 ppm.

Toxicity

Acrylamide has neurotoxic and carcinologic effects. The U.S. Environmental Protection Agency calculated that the toxicity dose is 0.2 μg/kg/bw/day (14 μg/day). The concentration of monomer of acrylamide in AQUAMID is 2 μg/syringe.

The Danish Toxicological Centre calculated the toxicity of AQUAMID. If 10 mL AQUAMID (10 syringes) is injected into a 30 year-old man, 70 kg of the degradation product is 0.00002 μg/kg/bw/day. This dose is 10,000 times inferior to accepted limits.

Polyacrylamides have good stability and resistance to degradation and are considered nontoxic because of the size of the molecule. It is not allowed to cross the biologic membranes, but stability of the polymer depends on composition and environment. The more polyacrylamide is crosslinked and insoluble, the more stable it is.

Technique of Injection

AQUAMID must be considered a permanent implant and not filler for superficial wrinkles, so the injection procedure must be safe and reliable in surgical conditions. In fact, in our experience, the majority of problems occurred when the injections were done superficially and without any care. The injection must be done with 27-G needles and needs no testing before. The injection's layer must be the subcutaneous fat, the muscle, or the supra-periosteal plane.

No overcorrection is done. AQUAMID is not used in the case of pregnancy or lactation, inflammatory or infected process of the skin, herpes, or when another permanent filler has been used in the same area.

After injection, the laboratory's recommendations are that the patient must avoid sun and very cold weather for 8 days. We have no explanation by the firm, only that it is similar to all other fillers.

Results

Some publications and studies have been published in Europe. All these studies have been supported by Ferrosan. The first study, done by Christensen and coworkers,[2] was a retrospective toxicological study on long-term effects: 27

7 Rue de Sontay 75116 Paris, France.
Address reprint requests to Patrick Trevidic, MD, 7 Rue de Sontay 75116 Paris, France. E-mail: patrick.trevidic@wanadoo.fr

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Ukrainian women with PAAG breast injections with an average time of 5 years and 10 months were enrolled. One hundred eight biopsies (average 1-8 by women) have been done.

The conclusions were that the PAAG was stable, nondegradable, confined to the breast, and diffusion-migration resistant. When medium- or large-size quantities are injected, a cellular foreign body reaction histologically occurs, but only in six patients was this clinical reaction a small granuloma. Kebuladze[3] found no long-term immunologic reaction with these women.

Vissarionov studied, with 1.5 years mean average time, the use of gel combined with lip aspiration for legs. Fifty-two patients were enrolled. There is no toxic effect of gel on muscle (duplex scan, EMS), and the multiple choice questionnaire showed that 87% of patients had good results, 7.5 had satisfactory results, and 5.5 were unsatisfied.

Five patients had complications that were apparent between 1 and 6 months after injection, mainly inflammation. No operation was done for them, only medical treatment.

In a discussion, Nerobeev[4] was not so optimistic. In 630 patients injected with FORMACRYL in lower limbs, face, and breast, the main complications were pigmentation of skin surface due to periodic exacerbation of the protracted inflammatory process, developed 1 to 3 years later.

Five women showed "honey-combing." Twenty-five patients had infection with fistulas.

Xi and Shi[5] reported numerous complications with polyacrylamide gel. These complications were described for breast augmentation (so for important volume injection). Since 1997, 12 patients came for complications: three cases of hematoma, two cases of infection, and the others for indurations, lumps, mastodymia, unsatisfactory contour results, and abnormal skin sensations.

In 1995, Kassanikova[1] described the "gel psychosis" in Ukraine and Russia. After 1 or 2 years, complications appeared and inflammatory process, gel migration, infection, and lymphadenitis appeared after 6 to 8 years. The treatment was antibiotic and evacuation of some gel pocket. No data have been done. The notion of depolymerization of the gel was described with modification.

Some reserves must be done on this publication because the standard and quality of fabrication are not the same as the Danish publication nor the medical environment.

We agree with the conclusion of the authors that the use of PAAG for breast augmentation must be forbidden. Our French ethical committee refused this indication.

For the face, two studies have been done: One was a European (nonpublished yet), prospective, noncomparative multi-center study of safety and esthetic results in adults for correction of contour deformities of the face with 251 patients (231 women and 20 men).

The average amount of gel injected was 4.1 mL for women and 3 mL for men, 48% for nasolabial fold correction, 25% lips, 8% glabellas, and 19% others (jaws, chin). Average time of follow-up was 14 months.

Of 228 patients controlled, 100 were very satisfied, 12 satisfied, and only 16 were not (3 for absence of results, 5 for insufficiency of results, 5 for overcorrection, 2 for migration, and 1 for discoloration).

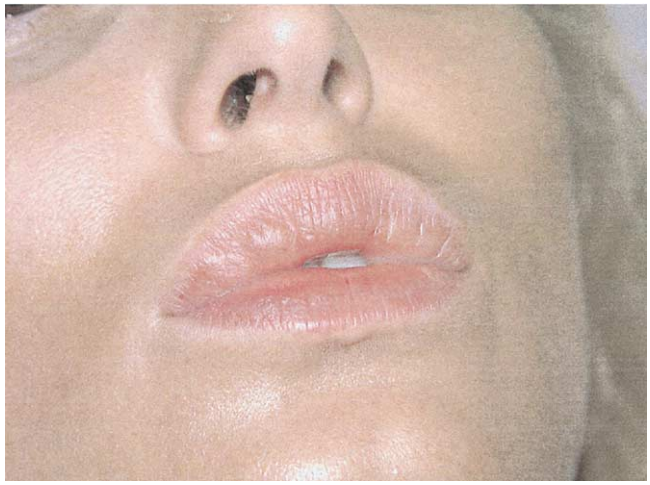

Figure 1 Lumpy aspect after lip augmentation. (Color version of figure is available online.)

Fifty-two (20.7%) patients presented adverse effects, and only 37 were related to the injection. Thirty-two were local reversible reactions, pain, and itch at the injection points. One patient had reversible oesinophily and hypergammaglobulinemy with no explanation and no clinical sign.

Four cases were nonresolute with one discoloration, two accumulations of gel, and one neutropeny with no explanation and no clinical sign.

One was French (not published yet) with the same protocol.

Seventy-five patients with an average follow-up of 13 months, and 60 patients were included, 75% for SNG and 58% for lips (Fig. 1). The average amount of volume was 1.85 mL.

The adverse effects were one hematoma, two superficial infections (treated only with antibiotic FUCIDINE 3 g/24 hour), and one itch.

De Bree and coworkers[6] described a severe granulomatous inflammatory paranasal response with no precision on the name of the product. Operation and antibiotics solved the problem.

Indications

For us, this product is only for informed and motivated patients, never for the first injection. We start with a nonpermanent filler to know if its really the indication and the amount of volume needed for the patient's satisfaction. From our point of view, it is a good filler to create a volume not for superficial wrinkles. So, the main indications are nasolabial folds, lips, malar, and chin. No severe complication occurs in our clinical study and we saw only one lip infection from another center (resolute with FUCIDINE 3 g/24 hour).

Conclusion

AQUAMID must be used in volume augmentation, not for superficial wrinkles. The injection must be in a deep layer,

with surgical conditions, and not overcorrected volume. As a permanent filler, its use and complications must be discussed with the patient.

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