EFFICACY AND SAFETY OF HA-BASED FILLERS

CASE STUDY

Facial contouring with hyaluronic acid products is one of the most in-demand procedure in aesthetic medicine. The most significant benefit of the procedure is an immediate result for the patient; and its safety is largely due to an existing direct counterpart, hyaluronidase, which is able to partially or completely dissolve the HA filler in an extremely short time, if necessary; and the products themselves are biodegradable.

Relevance

As with any invasive interventions, contour correction (CC) is associated with undesirable effects and complications. Those are fibrotic tissue changes in the site of injection of hyaluronic acid (HA) products.

The main cause for pathological fibrosis is the development of the inflammatory process. The factors inducing the inflammation in the injection site are as follows:

- HA fillers with pH and osmolarity values, different from those of the dermis;
- excessive amount of the product, provoking tissue swelling and ischemia in the injection site;
- extra trauma to tissues with some tools (needles, less often, cannulas), vascular injury, petechiae and hematoma;
- frequent injections of the products in one site or filler density inappropriate to the depth or quality of the dermis (hypodermis).

These causes share the same consequence, an aseptic (and sometimes septic) inflammatory process of various durations, resulting in the formation of a connective tissue capsule around the filler. This leads to the symptoms: tenderness, swelling (continous or intermittent), density to touch, visibility of the disturbed tissue relief, and to the signs: local persistent edema, including that associated with acute respiratory viral infections, palpatory bands or boluses of various densities, skin discoloration, such as Tyndall effect, cyanosis, hemosiderosis.

Table 1. Characteristics of Alexa HA-based fillers

Characteristics	Alexa Smooth	Alexa Medium	Alexa Volume
HA concentration	15 mg/mL	17.5 mg/mL	20 mg/mL
Proteins	-	-	-
Residual BDDE	<1 ppm	<1 ppm	<1 ppm
Volume in a syringe	1 mL	1 mL	1 mL
Needles	1 — 30G	2 — 27G	2 — 27G

The formed capsule, on the one hand, counteracts its own enzymes in biodegradation of the HA filler, and, on the other hand, is an active contributor to inflammatory and reactive processes in the area of implantation of HA products.

Study aim: To assess the clinical efficacy and safety of Alexa HA fillers as the products that do not cause pathological fibrosis.

Materials and methods. A study involving 16 patients was conducted in June 2018 to January 2019.

Age: 25-65 years.

Gender: female.

Corrections areas: nasolacrimal grooves and nasolabial folds, lips, cheekbones, chin.

Products: Alexa Smooth, Alexa Medium, Alexa Volume.

The product characteristics are given in **Table 1**.

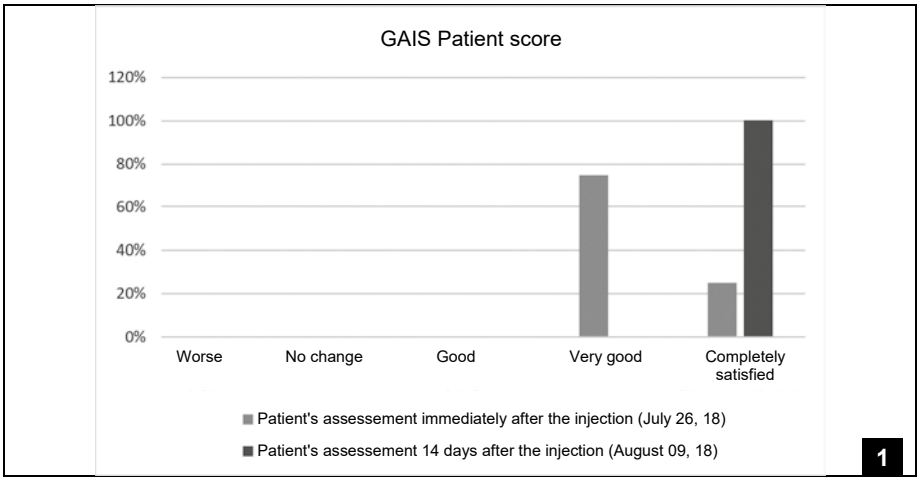
The study findings were assessed using Global Aesthetic Improvement Scale (GAIS Patient) (immediately after injection, 14 days and 6 months after the product was injected). Moreover, photofixation over time using VisiaFace scanner and photoshooting (prior to injection, after 14 days and after 6 months) were used. US on the Esaote apparatus (22 MHz) was used to assess the state of tissues in the site of filler implantation 6 months after implantation.

Results

Analysis of patient satisfaction using GAIS Patient score showed that immediately after injection, 75% of patients observed a very good result, and 25% of patients were completely satisfied. And on the 14th day after the injection, 100% of patients were completely satisfied with the procedure **(Fig. 1)**.

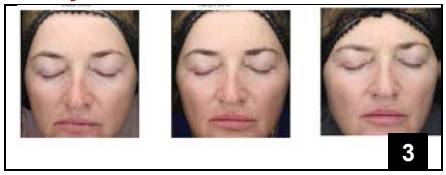
VisiaFace photofixation of the results of contour correction over time verified the maintenance of the results for a 6-month period **(Fig. 2-4)**.

6 months after the injection, US showed that 100% of patients had subcutaneous fragments Alexa gel, with distinct location in the dermis and hypodermis **(Fig. 5)**. No signs of blood flow were observed in the areas of determination of the HA gel, i.e., product fragments do not have capsules around **(Fig. 6)**. Tissue US also confirmed the absence of signs of inflammatory processes around the implants and manifestations of pathological fibrosis in all patients **(Fig. 7)**.

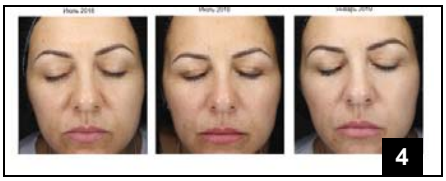


Patient satisfaction with procedures after 14 days

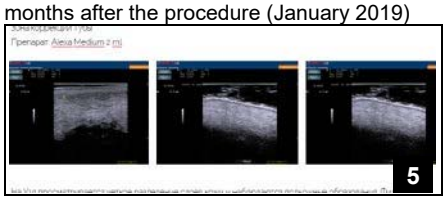
Patient P., 27 years old. Correction area: Lips Product: Alexa Medium 2 mL VisiaFace photofixation: Before procedure (June 2018); 14 days after the procedure: (August 2018); 6 months after the procedure (January 2019)



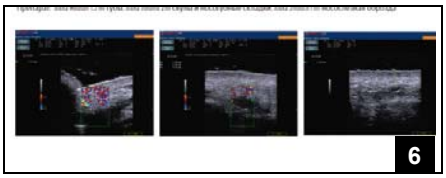
Patient S., 54 years old. Correction area: Nasolabial folds, chin, cheekbones, lips. Product: Alexa Volume 3 mL: nasolabial folds, Alexa Medium 1 mL: lips. VisiaFace photofixation: Before procedure (June 2018); 14 days after the procedure: (August 2018); 6 months after the procedure (January 2019)



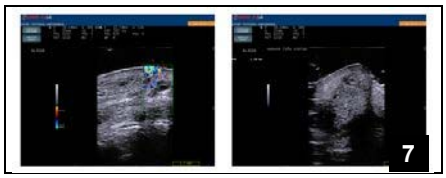
Patient O., 42 years old. Correction area: Lips, cheekbones, nasolabial folds, nasolacrimal groove. Products: Alexa Medium 1.5 mL: lips; Alexa Volume 2 mL: cheekbones and nasolabial folds; Alexa Smooth 1 mL: nasolacrimal groove. VisiaFace photofixation: Before procedure (June 2018); 14 days after the procedure: (Jule 2018); 6 months after the procedure (January 2019)



Patient P., 27 years old. Correction area: Lips Product: Alexa Medium 2 mL At the ultrasound scan, a clear separation of the skin layers is visible, and subcutaneous formations are observed. The filler is visualized at a depth of 1.7-3.92 mm as hypoechoic formations with no signs of blood flow



Patient O., 42 years old. Correction area: Lips, cheekbones, nasolabial folds, nasolacrimal groove. Products: Alexa Medium 1.5 mL: lips; Alexa Volume 2 mL: cheekbones and nasolabial folds; Alexa Smooth 1 mL: nasolacrimal groove. At a depth of the nasolabial folds, 2.93 mm and deeper (3.28 mm, 5.65 mm, 6.09 mm), there are hypoechoic areas without clear contours and borders 2.05 * 6.95 mm, with clear irregular shape without capsules and signs of blood flow



Patient S., 54 years old. Correction area: nasolabial folds, chin, cheekbones, lips. Alexa Volume 3 mL: nasolabial folds, Alexa Medium 1 mL: lips. In the area of lips, small rounded anechogenic formations are determined at a depth of 2 mm, 1.66 * 0.91 mm or less. Above the lip contour at a depth of 1.68 mm, hypo- and anechogenic cavernous branching formations without signs of blood flow are observed

Conclusions

Analysis of patient satisfaction using GAIS Patient score showed complete satisfaction in 75% of patients immediately after the contour correction with the above products, and in 100% of patients after 14 days of the procedure.

VisiaFace photofixation of the results of contour correction before the procedure, after 14 days and 6 months showed the maintenance of the effect for a 6-month period in all patients.

Ultrasound of the skin and soft tissues of all areas of HA filler implantation 6 months after the procedure showed, on the one hand, the product in the patient's tissues at the points of primary injection, and, on the other hand, no signs of fibrotic tissue changes.

All these features verify the efficacy of contour correction with the products used for at least 6 months and their safety in relation to fibrotic tissue transformation in the implantation sites.

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