

ABSTRACT

A Study on Patients Treated with Polyacrylamide Hydrogel Injection for Facial Corrections

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BACKGROUND

- PAAG, hydrogel, manufactured by Eastern European company.
- Aquamid® is a PAAG gel manufactured by a Danish company which is based on further state of the art development.

Purpose of the study

PAAG has been used as a tissue filler in facial corrective surgery and for breast augmentation in the former Soviet Union for more than 10 years. Approximately 30,000 patients have been treated with it.

The purpose of this retrospective study was to assess the tolerability and the cosmetic outcome of treatment with the PAAG injectable gel.

Methods

A retrospective study of 104 patients treated with PAAG injections for facial correction.

Patient material

The data contained information from 104 patients. 8 were left out of the overall analyses due to lack of essential data, resulting in a total of 96 patients. The examination of the patients took place from a few months to nine years after their facial correction, with the majority examined 2 to 6 years after PAAG injection. The mean time was 3.9 years.

Indications

The 96 patients had received from 1 to 3 facial corrections so that the presented material consisted of a total of 174 interventions. The majority had received up to 5 ml PAAG.

The distribution according to number of corrections in each patient and the facial site

	Forehead incl. glabella	Lip augmentation	Malar	Naso-labial cleft	Other	Total
1st facial correction	16	48	5	36	9	114
2nd facial correction	4	17	4	12	6	43
3rd facial correction	2	6	1	6	2	17
Total areas	22	71	10	54	17	174

A total of 49 patients (51%) had had breast augmentation as well.

Procedure

The cosmetic result was judged by both the investigator(s) and the patient and rated on an interval scale with four options ranging from very good to very unsuccessful.

The safety assessment included several specific signs and symptoms, which could possibly be related to the injections. All of these signs and symptoms were recorded as present or absent. In addition, the skin sensitivity at the injection site was assessed.

CLINICAL RESULTS

Tolerability

In total the complication rate due to facial corrections was small. All examinations demonstrated very good tolerability and low reactivity in the tissues around the sites of injection.

In 30 patients (31%) the gel was palpable as small, firm pearls, mainly in the lips. They were asymptomatic to the patients and could not be seen on naked eye inspection.

Displacement of the gel was demonstrated in 3 women, all in connection with the naso-labial fold, but the displacement was only a few mm.

Cosmetic outcome

The cosmetic outcome was judged identically by patient and physician. Treatment results were assessed as very good by 78% and good by 21% (physicians) / 22% (patients).

Discussion

The use of tissue fillers in facial corrective surgery has become a reality over the last 6 to 8 years. Several techniques have been described for augmenting soft tissues, some of these have been employed with more or less good results because of problems such as migration, reabsorption, scar tissue formation, and toxicity.

PAAG (now marketed as Aquamid®) has been used for facial corrective surgery and for breast augmentation in Ukraine for more than 10 years with reportedly good results. It is a highly bio-compatible, atoxic, stable, non-resorbable, sterile watery gel for injection.

Conclusion

The present retrospective study with its thorough investigation of a large sample of patients in one centre has demonstrated that the product injected has been very well tolerated and effective for facial augmentation. Both the physician and patient rated the outcome of the facial correction procedures as either very good or good. The examination of the patients took place up to 9 years after the facial correction, thus PAAG also seems to be a durable product for these interventions.

EXECUTIVE SUMMARY

- Retrospective study.
- 104 patients of which 96 patients were included in the overall analyses.
- Indications: Facial corrections
- All examinations demonstrated that the product injected was very well tolerated and effective for facial augmentation.
- Both physician and patient rated the outcome of the facial correction procedures to be either very good or good.
- The examination took place up to 9 years after the facial correction, thus PAAG is a durable and safe product.