

ABSTRACT

Evaluation of the Aesthetic Results of Facial Corrective Plastic Surgery with Aquamid[®]

Prospective multi-centre study, France

Investigators: Patrick Trevidic M.D., Eric Auclair M.D., Alain Butnaru M.D., Patrick Bui M.D., Charles Gadreau M.D., France.

BACKGROUND

- Aquamid[®] is a PAAG gel manufactured by a Danish company which is based on further state of the art development.
- Aquamid[®], hydrogel, composed of 97.5% of apyrogenic water and 2.5% hydrophilic cross-linked polyacrylamide.
- Aquamid[®] is manufactured under strict quality control in the demanding approval environment of Denmark.
- Each batch is consistent, homogeneous and tailor-made for indications due the molecular structure resulting from the proprietary production process.
- Aquamid[®] is non-allergenic, non-toxic, non-resorbable, migration resistant and immunologically inactive.
- Extensive pre-clinical testing shows that Aquamid[®] is highly biocompatible.
- Due to the unique properties the implant is in dynamic equilibrium with the surrounding tissue.

Purpose of the study

The primary objective was to evaluate the short term (up to 3 months) and medium term (up to 12 months) aesthetic outcome of corrective facial surgery with the use of Aquamid[®] consisting of 2.5% polyacrylamide and 97.5% apyrogenic water produced by Ferrosan A/S, Denmark. The secondary objective was to investigate any side effects occurring following the use of Aquamid[®] and establish their relationship to the use or handling of the product.

Injection site	Women (N)	Percent (of 67)
Naso-labial folds	49	73.1
Lip augmentation	20	29.9
Corners of the mouth	19	28.4
Forehead incl. glabella	16	23.9
Chin/Malar	6	9.0
Cheekbones	2	3.0
Nasal area	2	3.0
Other	1	1.5

Table 1 Number and percent of women (of 67) according to facial area(s) corrected at Visit Day 0.

Methods

An open, non-comparative, consecutive, prospective, multi-centre study.

Patient material

68 female patients between the age of 25 and 70. Mean age 45.4.

Indications

The patients had injections in the facial area for correction of one or more facial soft tissue deficiencies or contour deformities. 31 women (46%) received injections in more than one facial area (see table 1 and 2).

Number of facial areas injected

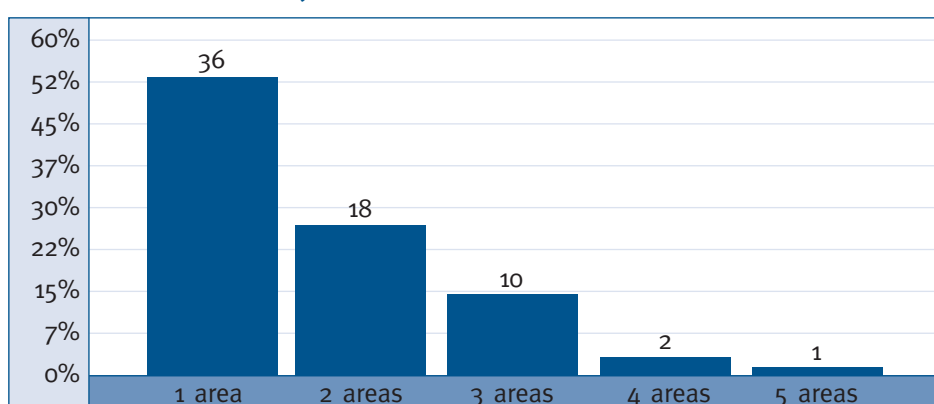


Table 2 Percent of women according to number of facial areas injected with Aquamid[®] at Visit Day 0. Numbers above bars indicate number of women.

Procedure

All procedures were conducted under sterile conditions. After the retrograde injection the area was gently manipulated to obtain an even distribution of the gel. Patients were instructed to avoid exposure to direct sunlight, solarium or heat on the treated skin area the first two weeks after the facial correction. Mean volume injected was 2.3 ml. Patients and surgeons evaluated the aesthetic result at day 28 and after 3, 6, and 12 months. Standardised photos were taken before and immediately after the injection on Day 0, and at the 3 and 6 months follow-up visits.

Surgeons used a scale from I to IV, ranging from appearance absolutely natural (I) to severe contracture (IV). Patients used a scale from A to D, ranging from very good (A) to very bad (D).

CLINICAL RESULTS

Aesthetic results

Surgeon evaluations achieve the highest score (I) in more than 90% of the patients (91% on day 28, 93% after 3 months, 98% after 6 months, 96% after 12 months). More than 90% of the women are at least satisfied with their treatment (scores A or B).

Comparing both patient and investigator evaluations after 6 months and 1 year to that after 3 months, a progress in the outcome from unchanged to a marginal improvement is seen. Thus, it can be concluded that the aesthetic correction is achieved after 3 months, maybe earlier, and that this effect is sustained after one year.

Adverse events

6 cases of adverse events were reported. Apart from two mild cases of small nodules the adverse events were as expected, and more related to the surgical treatment rather than to Aquamid[®] itself.

Discussion

PAAG has been used in plastic and aesthetic surgery in the previous Soviet Union for more than 10 years. Total number of patients treated with PAAG is approx. 30,000. There is comprehensive data regarding the safety of the gel including preclinical as well as clinical studies.

The objective of the present clinical study was to collect systematic, consecutive, and prospective information about the efficacy and safety of the use of Aquamid[®] as an injectable tissue filler in connection with facial corrective surgery at plastic surgery clinics in France.

Conclusion

After one year surgeon evaluations achieve the highest score (I) in more than 90% of the patients, and more than 90% of the women are at least satisfied with their treatment (scores A and B). It can be concluded that the aesthetic correction is finalised within 3 months, maybe earlier, and that this effect is sustained after one year.

No serious adverse events have been reported. 4 out of 6 reported adverse events were expected and judged to be related to the surgical treatment rather than to Aquamid[®] itself.

EXECUTIVE SUMMARY

- Open, non-comparative, consecutive, prospective, multi-centre study
- 68 patients (female)
- Indications: Facial corrections
- Investigator evaluations achieve the highest score (I) in >90% of patients
- >90% of patients are either very satisfied or satisfied with the results of the aesthetic corrections
- The aesthetic correction is achieved after 3 months, maybe earlier, and this effect is sustained after one year
- No serious adverse events
- 4 out of 6 reported adverse events were expected and judged to be related to the surgical treatment rather than to Aquamid[®] itself.