Prospective multi-center study, Brazil

AQUAMID®
FOR LONG-LASTING DECISIONS

ABSTRACT

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

Prospective multi-centre study, Brazil

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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®.
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 129)
Cheekbones	6	4.7
Chin/Malar	3	2.3
Corners of the mouth	32	24.8
Forehead incl. glabella	8	6.2
Lip augmentation	30	23.3
Nasal area	3	2.3
Nasal-labial folds	100	77.5
Other	9	7.0

Table 1 Number and percent of women (of 129) according to facial area(s) corrected at Visit Day 0.

Methods

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

Patient material

129 female patients between the age of 22 and 78. Mean age 50.2.

Indications

Aesthetic surgical correction of contour deformities of the face. 42 women (33%) received injections in more than one facial area (see table 1 and 2).

Number of facial areas injected

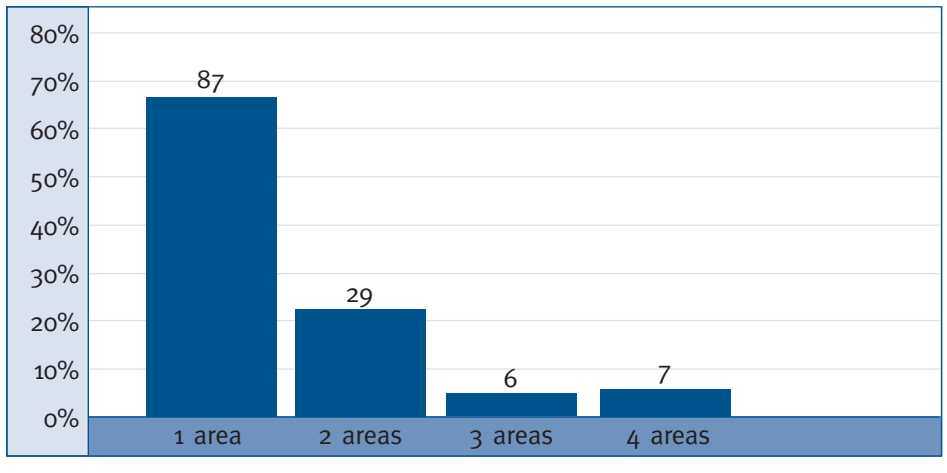

Table 2 Percent of women according to number of facial areas injected with Aquamid® at Visit Day 0. Numbers above bars indicate number of women.

Procedure

All procedures were conducted under aseptic 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 ml. Patients and surgeons evaluated the aesthetic result at day 28 and after 3 and 6 months. Surgeons used a scale from I to IV ranging from appearance absolute natural (I) to severe contracture (IV). Patients evaluated results on 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 99% of the patients (95% on day 28, 94% after 3 months, 99% after 6 months). All patients are at least satisfied with their treatment (scores A or B).

Comparing both patient and investigator evaluations after 6 months to that after 3 months, a small progress in the outcome from unchanged to a marginal improvement is seen. Thus, it can be concluded that the aesthetic correction is achieved after 28 days, maybe earlier, and that this effect is sustained after 6 months.

Adverse events

23 patients have experienced 29 adverse events, e.g. haematoma, oedema, and pain. Such events were expected and obviously related to the procedure and not to Aquamid® itself. Leaving those events out, only one adverse event is left which means a proportion of side effects <1%.

Discussion

Aesthetic surgical correction of contour deformities of the face is a very sensitive operation in the way that the results have great impact on both physical and psychological well being.

From this study it is only possible to evaluate the effect over a 6 months period. An identical study in France finished in April 2003. In this study 68 patients have been followed for 12 months under exactly the same conditions. From this study a progress in the aesthetic outcome, evaluated by both surgeons and patients, from unchanged to a marginal improvement is seen. Nothing indicates that results in this study will differ from the results of the French study.

Conclusion

The results after 6 months show that surgeon evaluations achieve the highest score (I) in 99% of the patients and all the women were at least satisfied with their treatment (scores A and B). It can be concluded that the aesthetical correction is achieved after 28 days, maybe earlier, and that this effect is sustained after 6 months.

No serious adverse events have been reported. When excluding events related to the procedure rather than the product, 1 event is left. This reveals a proportion of side effects <1%.

EXECUTIVE SUMMARY

- Open, non-comparative, consecutive, prospective, multi-centre study
- 129 patients (female)
- Indications: Aesthetic correction of contour deformities of the face
- Surgeon evaluations achieve the highest score (I) in >99% of patients
- All patients were at least satisfied (scores A and B)
- The effect of the aesthetical correction is achieved after 28 days, maybe earlier, and this effect is sustained after 6 months
- No serious adverse events
- Proportion of side effects <1% when excluding events related to the procedure rather than the product

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