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 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.

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>
<thead>
<tr>
<th>Injection site</th>
<th>Women (N)</th>
<th>Percent (of 129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheekbones</td>
<td>6</td>
<td>4.7</td>
</tr>
<tr>
<td>Chin/Malar</td>
<td>3</td>
<td>2.3</td>
</tr>
<tr>
<td>Corners of the mouth</td>
<td>32</td>
<td>24.8</td>
</tr>
<tr>
<td>Forehead incl. glabella</td>
<td>8</td>
<td>6.2</td>
</tr>
<tr>
<td>Lip augmentation</td>
<td>30</td>
<td>23.3</td>
</tr>
<tr>
<td>Nasal area</td>
<td>3</td>
<td>2.3</td>
</tr>
<tr>
<td>Nasal-labial folds</td>
<td>100</td>
<td>77.5</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>7.0</td>
</tr>
</tbody>
</table>

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

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 aesthetic 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 aesthetic 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.