

# 48-MONTH EFFICACY AND SAFETY RESULTS OF POLYACRYLAMIDE HYDROGEL (AQUAMID®) FOR FACIAL SOFT-TISSUE AUGMENTATION

## A PROSPECTIVE MULTI-CENTRE STUDY FOR EVALUATION OF LONG-TERM SAFETY AND EFFICACY

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### BACKGROUND

The polyacrylamide hydrogel (Aquamid®) is a non-absorbable, homogeneous (no micro-particles) soft-tissue filler. It has been used in more than 200,000 injections since 2001 with complications reported in less than 1 in 1,000 treatments. The efficacy and safety were assessed in this long-term prospective clinical trial.

### METHODS

251 patients participated in this prospective, multi-centre study in 18 centres in 6 European countries. During the study, it was decided to extend the follow-up to 60 months.

Aquamid® was used for facial augmentation, primarily treatment of nasolabial folds, lips and glabella folds. The aesthetic outcome was judged by both the investigator and the patient.

In the extension study patients were offered re-injection of Aquamid® at the 24-month, the 36-month and 48-month follow-up. The total amount of injected gel ranged from 0.5 ml to 16 ml.

### RESULTS

At the 48-month follow-up 82 patients were available for evaluation. The aesthetic results were judged to be good or very good in more than 90% of the cases by the investigators. Also more than 90% of the patients were either satisfied or very satisfied with the aesthetic results after 48 months.

Of the 82 patients who completed the 48-month follow-up, 50 patients had not been re-injected at any of the follow-up visits since the beginning of the study. A total of 98% of these 50 patients were still satisfied

with their aesthetic results at the 48-month follow-up. Results were judged to be good or very good by the investigators in 98% of the patients not re-injected.

Adverse events possibly, probably or almost certainly related to the treatment were reported in 41 cases in the 48-month period. Most were mild or moderate, transient local reactions to the injection such as swelling, haematoma, redness, pain or itching. One possibly related adverse event was reported between the 24-month and 48-month follow-up. It was an infection that was resolved with appropriate antibiotic treatment.

### CONCLUSIONS

Aquamid® yielded satisfying aesthetic results in more than 90% of the patients after 48 months. There was no difference in efficacy between the 12, 24 and 48-month follow-up.

Adverse events related to the treatment were mostly mild or moderate local reactions to the injection.

### EXECUTIVE SUMMARY

- A prospective 48-month multi-centre study evaluating the efficacy and safety of Aquamid® in facial soft-tissue augmentation
- Follow-up visits at 12, 24 and 48 months
- 251 patients were enrolled in the study, 82 patients completed the 48 months follow-up
- More than 90% of results were judged as good/very good and satisfactory/very satisfactory by both investigators and patients
- 98% of patients who did not receive any re-injection for four years were satisfied with the aesthetic results; these findings were confirmed by the investigators' evaluation
- Adverse events related to the treatment were mostly mild or moderate local reactions to the injection
- Aquamid® is a safe and effective non-absorbable soft tissue filler