

## ABSTRACT

# Experience with a New Non-Biodegradable Hydrogel (Aquamid®): A Pilot Study

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### Background

Polyacrylamide gel (PAAG) is widely used in biomedical research as well as in the industry. PAAG has water-binding capabilities and has been used for decades in preparation of soft contact lenses as well as in tissue implants, tissue models, detector of penicillin antibodies and as carriers of hormones and drugs in animal studies.

The toxicity of PAAG has been studied for >30 years and a review of the scientific literature indicates that PAAG is considered to be non-toxic, non-allergenic, non-teratogenic, non-embryotoxic, non-mutagenic and non-biodegradable.

### Purpose of the study

There are a great number of different biomaterials for the purpose of soft tissue augmentation with both bioresorbable and non-resorbable effect.

These materials should be biocompatible, non-pyrogenic, non-inflammatory, non-toxic, easy to use, non-migrating, long lasting and natural looking.

Aquamid® represents a new generation of soft tissue fillers thanks to the lack of particles and a very high concentration of water. Aquamid® contains 97.5% of water and 2.5% of cross-linked polymer.

### Methods

This is a pilot study based on the experience with Aquamid® following 59 patients treated mainly for aesthetic corrections in order to evaluate the safety and the long-term aesthetic results.

### Patient material

A total of 59 patients (58 women and 1 man) were treated. The follow-up period was 9 months (range: 2 to 16 months).

### Indications

Aquamid® was used for aesthetic correction in 56 cases and in one case it was used on medical indication for reconstruction of the chin after skeletal surgery. In total 77 syringes of Aquamid® were used with an average of 1.3 ml per individual (range: 1 to 5 syringes of 1 ml).

The treated areas are specified in table 1

Treated areas	Age Groups							
	20-25	26-30	31-35	36-40	41-45	46-50	51-55	56-60
Lip	16	3	3		4	4	6	6
Naso labial fold					1		1	1
Cheekbone	3	1	2	1				
Glabella					1		2	
Chin						2	1	
Scar						1		

Lip augmentation was the most frequent procedure (72%) dominating the age groups from 20-25 years and from 50-60 years. Cheekbone enlargement was carried out in 13% of the cases. The rest concerned augmentation of deep naso labial folds, glabella and chin with 5% representation of each of the indications.

### Procedure

The injection of Aquamid® was performed under sterile conditions with a 27 G needle. For lip augmentation nerve block of the maxillary and mental nerves was used. In connection with the injection a light manipulation was carried out to obtain a perfect distribution of the gel.

## CLINICAL RESULTS

### Patient satisfaction

100% of the patients were satisfied with the result at the 9 months follow-up. All patients were very satisfied with the aesthetic result as well as the consistency and the elasticity of the treated area. One patient experienced minor irregularities on her upper lip.

### Short-term side effects

Slight redness and temporary swelling were found directly after the injection with duration of <36 hours. Patients reported moderate pain localized within the treated area during the first day.

### Long-term side effects

No long-term side effects were reported during the follow-up period. Every subject was content with the aesthetic result and the long-lasting effect of Aquamid®.

### Discussion

Aquamid® is an effective and easily used soft tissue filler material for facial corrections.

Only qualified and experienced staff should administer Aquamid®. A correct indication and careful patient selection are of basic importance together with a precise consideration of the recommendations and cautions of the manufacturer. Treatment should be performed under sterile conditions to minimize the risk of bacterial contamination. Careful planning to limit the number of needle pricks serves the same purpose.

### Conclusion

Aquamid®, a new generation of soft tissue fillers with no microparticles and a very high concentration of water (97.5%), was evaluated in 59 patients for aesthetic facial corrections.

100% of the patients were satisfied with the aesthetic results at the 9 months follow-up.

No long-term side effects were observed and the patients were also satisfied with the consistency and the elasticity of the treated area.

## EXECUTIVE SUMMARY

- 9 months pilot trial
- 59 patients
- Indications: Lip augmentation, naso labial folds, cheekbones, glabella, chin and scar
- 100% of the patients were satisfied with the aesthetic result after 9 months
- All patients were satisfied with the consistency and the elasticity of the treated area
- Aquamid® is easy to use without any pre-testing
- Aquamid® seems to be a promising long-lasting soft tissue filler