

## ABSTRACT

# The Utilization of Polyacrylamide Gel in the Recovery of Volume in Patients with Facial Lipodystrophy

## A Clinical and Histological Study

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Published in Revista Oficial da SBME, Brazil 2003.

## 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 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

To evaluate volumetric correction of the loss of face fat provoked by the intake of antiviral medication used in HIV positive patients and to analyse histologically the impact of implantation of the polyacrylamide gel, Aquamid®, into the subcutaneous tissue.

## Methods

18 HIV positive patients with facial lipodystrophy who did not present other associated illnesses were included in the study. The number of syringes (1 ml of Aquamid® per syringe) and injections varied according to the volumetric loss to be corrected (see table 1).

Identification	ML	No. injections
Patient 1	22	6
Patient 2	15	5
Patient 3	15	4
Patient 4	16	4
Patient 5	24	7
Patient 6	4	2
Patient 7	16	5

## Duration

One year histopathologic evaluations after 3 and 12 months after last injection. Photos were taken before and after the treatments.

**Table 1** Identification, number of ml applied and number of injections for the group of patients one year after treatment.

## Patient material

18 HIV positive patients, 4 women and 14 men.

## Indications

Facial lipodystrophy in HIV positive patients in treatment with retroviral medication.

## Procedure

Injections: Complete sterility was secured in the region to be treated. Furthermore, the patients were told not to apply any make-up or cream for a period of 4 days, not to allow others to touch the region treated, and to avoid exposure to the sun, long baths, saunas, and direct contact with domestic animals.

Anaesthetic gel was applied. The implant was injected in the subcutis, with retrograde technique, placing the gel in a fan-like pattern in small amounts and overlapping layers. The implanted material was massaged until a uniform distribution was observed. Depending on the volumetric loss to be corrected,

the injections were given at various intervals. So far, 7 patients have concluded their treatment. In total, from 4 to 22 ml of Aquamid® have been injected at 2 to 7 sessions per patient.

Histological analyses: The material implanted in the axillary region was removed through a small incision with a scalpel and included epidermis, dermis and subcutis.

## CLINICAL RESULTS

7 patients (2 women and 5 men) have completed one year's evaluation. The remaining of the group (2 women and 9 men) have started their treatment at different times. They are presently in their first year and histopathologic examinations have yet only been carried out in 9 of those 11 patients.

Aquamid® presents a great capacity for the correction of soft areas, allowing a considerable increase of facial volume and free movement of the mimic muscles thus giving a natural plastic appearance. There were no alterations of the functions of the skin in any of the patients, and no inflammation, fibrosis, or necrosis was observed.

Only one single adverse event occurred in a total of 64 applications using a total of 211 syringes. (An inflammatory nodule in one patient who had applied make-up 24 hours after treatment).

## Discussion

A large number of HIV positive patients under antiretroviral therapy have shown a gradual loss of facial fat tissue leading to a noticeable alteration of facial harmony, a condition which in some cases has caused serious psychological and social problems.

Aquamid® demonstrates to be a highly effective product for the correction of soft tissue, allowing a considerable increase of facial volume followed by free movement of the mimic muscles thus giving a natural plastic appearance. There were no alterations of the functions of the skin in any of the patients.

Previous works have proven the absence of hydrophilic cross-linked polyacrylamide gel and of its monomer or metabolites in the parenchyma of organs or in the lymphatic and blood system.

## Conclusion

Aquamid® revealed itself to be safe for facial application, allowing the correction of large areas which had suffered from considerable loss of facial volume. A natural look was obtained without intervening with the movement of functions of the face. The durability of the gel was also satisfactory.

After one year of evaluation the result remained stable, providing the patients with an important improvement of their self-esteem.

Histological analyses showed that the tissue reaction in some cases was practically absent, and in the vast majority of the remaining samples the reaction was moderate without displaying fibrosis or necrosis reactions. In all samples the gel remained stable. It had not fragmented and was not present in the interior of cells.

## EXECUTIVE SUMMARY

- 18 HIV positive patients, 4 women and 14 men
- Indication: Facial lipodystrophy caused by antiretroviral medication
- Histological analyses showed practically absent or only moderate tissue reaction
- The Aquamid® treatments allowed a considerable increase of facial volume
- The natural appearance of the implants provided the patients with an important improvement of their self-esteem.
- In all samples the gel remained stable
- Only one single mild complication occurred
- Aquamid® is safe for facial correction