

Polyacrylamide Hydrogel Injection in the Management of Human Immunodeficiency Virus-Related Facial Lipoatrophy: A 2-Year Clinical Experience

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SUMMARY

- 24-month follow-up study at Modena University Hospital HIV Metabolic Clinic, Italy.
- 50 HIV patients were followed for 12 months, out of which 31 patients for 24 months.
- Cheek thickness measured with ultrasonography showed significant improvement in cheek thickness.
- Mean visual analogue scale improved significantly.
- The Assessment of Body Change and Distress showed significant increase in satisfaction with personal body image and indicated a less negative impact on patients' relational life after the procedure.
- The Beck Depression Scale showed a significant improvement in the passage from moderate to mild depression.
- An overall improvement in the self-esteem of the patients was achieved.
- Aquamid[®] provided stable correction over time with no complications.
- Aquamid is a safe soft-tissue filler and is an appropriate treatment option in restoring facial contours in HIV-infected patients.

BACKGROUND and INTRODUCTION

- Facial lipoatrophy is defined as the reduction in buccal and orbital fat pads with a more global loss of fat within the subcutaneous tissue.
- It is the most common and distressing sign of human immunodeficiency virus-related lipoatrophy.
- At present, aesthetic procedures are the best solution to alleviating the effects of this stigmatizing syndrome.
- Injectable polyacrylamide hydrogel (Aquamid®) is non-absorbable, homogeneous and particle-free consisting of 97,5% water and 2,5% cross-linked polyacrylamide.
- Favorable results with maximum aesthetic outcome with the use of polyacrylamide hydrogel for reconstruction of facial lipoatrophy on the face are being reported.
- The authors:
 - evaluated efficacy and demonstrated improvement in QoL (Quality of Life) in HIV patients.
 - determined long-term tolerance, durability and safety of Aquamid in HIV patients.

Study objective

The purpose of the study is to evaluate the efficacy of polyacrylamide hydrogel (Aquamid) injections over a 12 month period and to demonstrate an improvement in the quality of life of human immunodeficiency virus-infected patients. Furthermore to determine the long-term tolerance, durability and safety of the polyacrylamide injections.

Patients and Methods

50 consecutive HIV type 1 patients attending the Modena University Hospital HIV Metabolic Clinic in Italy were invited to participate in the study. The diagnosis of facial lipoatrophy was clinically defined as a moderate to severe thinning of the Bichat fat pad of the subcutaneous layer of the cheeks and zygomatic area and a deepening of the naso labial folds. Patients were asked to present pre-facial lipoatrophy photographs which were compared to the their current facial appearance. Facial lipoatrophy was confirmed by ultrasonography.

Among the inclusion criteria were CD4 cell count greater than 100 cells/ μ l and patients with previous permanent fillers at the same site were excluded. All 50 patients completed the 12 months follow-up period. Thirty-one of them reached the 24 months follow-up.

Clinical results and Discussion

Clinically no significant side effects were detected at the 12 months follow-up. Four percent of the patients experienced a transitory swelling or redness lasting from 12-24 hours after the procedure. No infection, color alteration or granuloma formation was registered. The average number of procedures was 6.1 for each patient.

The following variables were assessed.

- Cheek thickness measured with standard ultrasonography showed a significant improvement in contour.
- Visual analogue scale also showed a significant improvement already at the 6 months follow-up.
- The Assessment of Body Change and Distress (ABCD) question 7 showed a significant increase in satisfaction with personal body image.
- Also question 7 of the ABCD indicated that the lipodystrophy had a less negative impact on the patients'

relational life after the procedure with the Polyacrylamide hydrogel injections.

- The Bech depression Inventory Scale showed significant improvement which is consistent with a passage from moderate to mild depression.

Free fat transfer is another option and represents a well-established technique but is not ideal for HIV patients with lipoatrophy. Other fillers such as polyactic acid have been in use but are limited in time because of resorption.



Fig. 1. Before and after images of a 39-year old man with severe lipoatrophy of the face. 11 treatments of 2 ml of Aquamid per session corrected the lipoatrophy defect.

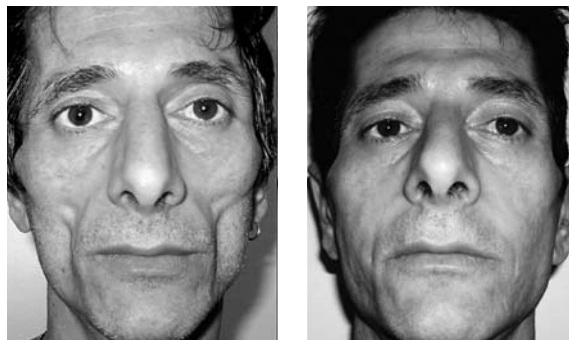


Fig. 2. Before and after images of a 51-year old man with severe lipoatrophy of the face. 11 treatments of 2 ml of Aquamid per session corrected the lipoatrophy defect.



Fig. 3. Before and after images of a 36-year old man with severe lipoatrophy of the face. Ten treatments with 1 ml of Aquamid per hemiface achieved correction of the lipoatrophy defect.



Fig. 4. Before and after images of a 42-year old man with moderate lipoatrophy of the face. Seven procedures of max 2 ml Aquamid per session were required to achieve the result.

Conclusion

HIV-related facial lipoatrophy is a stigmatizing condition inducing serious quality of life limitations. At present aesthetic procedures represent by far the best possible solution to minimize the psychological effects of this complex metabolic syndrome.

Polyacrylamide hydrogel (Aquamid) has been shown to provide stable correction over time when used in appropriate volumes. No local complications, aggravated tissue reaction, or interference with facial movement or function was noted in a significantly immunocompromised population over an extended duration.

Photographic and psychological assessment test evidence of the cosmetic results are consistent with a lasting improvement in the self-esteem of the patients.

Polyacrylamide hydrogel (Aquamid) has been shown to be an appropriate treatment option in restoring facial contours in the immunocompromised, human immunodeficiency virus-infected patient subset and is recommended as a safe soft-tissue filler material in aesthetic practice.



CONTURA

Contura is a medical technology company based in Denmark that develops and commercializes soft tissue fillers.

Contura's products – Aquamid® for facial contouring and Bulkamid® for the treatment of female urinary incontinence – are manufactured using the company's patented polyacrylamide hydrogel technology.

Aquamid is sold through a network of local distributors in 40 countries. Ethicon Inc., a Johnson & Johnson company, holds the exclusive worldwide distribution rights for Bulkamid, which is available in Europe.

Clinical trials evaluating Aquamid and Bulkamid are ongoing in the United States. Data from these trials will be used to support FDA applications for these products. Aquamid and Bulkamid are not approved for sale in the US.

Contura's products are developed, manufactured and tested in Denmark in compliance with the European regulatory requirements for medical devices.

AQUAMID

Aquamid® is a soft volume filler, which integrates with the body's own tissue and gives a natural look and feel. Produced using Contura's patented hydrogel technology, Aquamid is composed of app. 97.5% non-pyrogenic water and 2.5% cross-linked polyacrylamide and enjoys an unmatched track record of continuous high levels of patient satisfaction.

Aquamid was approved in Europe in 2001 and is available in 40 countries worldwide. Over 350,000 Aquamid infiltrations have been performed to date.

Science has always been the driving force behind Aquamid products. The efficacy and safety of Aquamid have been documented in more than a dozen clinical trials involving more than 5,000 patients. These studies have been published in peer-reviewed journals.

It is currently under clinical investigation in the U.S. for the aesthetic treatment of nasolabial folds. For more information please visit www.aquamid.com.