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Evaluation of the Safety and Efficacy of Bio-Alcamid for Facial Soft Tissue Augmentation

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ABSTRACT

The use of injectable soft tissue fillers for facial contouring has risen dramatically over recent years, due to the increased demand for minimally invasive techniques. As a result, several new materials are currently available and constantly merging for clinical use. The purpose of this study was to evaluate the safety and aesthetic results of a new injectable material called Bio-Alcamid in correction of soft tissue deficits of the face. A retrospective review was conducted on 60 patients who underwent facial contouring by injection of Bio-Alcamid between April 2005 and October 2006. All cases were performed under local anaesthesia. The upper cheeks (malar areas) were treated in 35 cases, lower cheeks in 28 cases, nasolabial folds in 13 cases, chin in 6 cases, upper and lower lips (for contouring) in 4 cases and localized depressions in 5 cases. Twenty-nine patients (48.3%) required a minor touch up injection 6 weeks after the initial treatment, to correct unevenness or asymmetry. No major complications were reported apart from one case of infection. Evaluation after 3 months showed that 21 patients (35%) considered the volume gained after injection was insufficient. Among those patients, 14 (23.3%) agreed to have another treatment session in order to reach a satisfactory level of filling. Assessment of patient satisfaction 6 months later showed that 85% of the patients were satisfied with the results. The study concluded that Bio-Alcamid is an injectable implant of easy administration, safe for use in facial correction of soft tissue deficits and presenting a minimal rate of serious complications. Although 2-3 treatment sessions may be required to reach a satisfactory endpoint, the final outcome shows highly satisfactory aesthetic results in most of the patients.

INTRODUCTION

Injectable fillers have become an important component of minimally invasive facial rejuvenation modalities. Their ease of use, effectiveness, low morbidity, and fast results with minimal downtime are factors that have made them popular among patients **[1]**.

Several injectable fillers have been developed for facial soft-tissue augmentation and contouring. Preparations containing extracellular matrix components such as collagen or hyaluronan are injected intradermally for the treatment of wrinkles. These biological materials cause less soft-tissue reaction or proliferation to granulomas. In contrast, they are degraded by enzymes. Autologous fat is another material used for facial contouring. It has to be harvested by liposuction and processed before injection. A high rate of reabsorption is seen after lipofilling, even under optimized technical conditions. Artificial fillers are not degraded by enzymatic activity; thus, longer lasting effects can be expected. In contrast, several artificial filler substances have been recognized to cause foreign body reactions, soft-tissue proliferation, and formation of granulomas **[2]**.

The search for the ideal filling material has been ongoing for centuries. Various materials, including collagens, autologous fat, hyaluronic acids, poly-L-lactic acid, polyacrylamide, liquid injectable silicone and calcium hydroxylapatite, are among the products currently used for this indication **[3]**.

Bio-Alcamid (registered trademark in EU) is a novelty in the field of aesthetic and reconstructive surgery, because of its chemical and physical characteristics. It could be considered an intermediate between an injectable filler and a common prosthesis: It is often referred to as an injectable endoprosthesis **[4]**. Bio-Alcamid (commercialized by Polymekon s.r.l., via Savona 19IA, 20144 Milano, Italia), is a polymer with a reticulated structure, non resorbable, derived from acrylic acid. It is an alkylic resin characterized by amide-amide groups. The composition of Bio-Alcamid is 96% apyrogenic water and 4% alkylimide-amide group. These chemical features of Bio-Alcamid are responsible for stability, resistance to hydrolytic phenomena and high resistance to water. Unlike other materials, Bio-Alcamid can easily by removed even a long time after implantation **[5]**.

The aim of this study was to evaluate the injectable material Bio-Alcamid in soft tissue

augmentation of the face with respected to its ease of use, aesthetic outcomes, and safety.

PATIENTS AND METHODS

This work was a retrospective review of all the patients who underwent soft tissue augmentation for facial contouring with Bio-Alcamid at "Specialized Clinics Center" in Riyadh, Saudi Arabia, over 18 month period from April 2005 to October 2006.

Patient selection:

The line of treatment was applied for patients presenting for correction of contour deformities of the face such as lack of volume of cheeks, temples and chin, prominent nasolabial folds, localized depressions and those requiring lip contouring. Exclusion criteria were pregnancy, connective tissue disorders, facial skin disorders, known mental disorder, uncontrolled diabetes mellitus, acute inflammatory disorders and compromised immune system (patients on steroids or other immunosuppressive drug), facial correction within the past 6 months, and facial corrections in areas in which injection of a non absorbable material has been used previously.

Preoperative preparation:

Standard preoperative photographs of the face were taken. Patients were marked in the upright position. An occlusive dressing of topical anesthetic (Emla) cream was then applied on the area to be treated for 30 minutes. An intravenous antibiotic (1.5gm of Zinacef) was administered prior to injection.

Product information:

Bio-Alcamid is a biocompatible non resorbable synthetic polymer derived from acrylic acid. The composition of Bio-Alcamid is 96% apyrogenic water and 4% alkylimide-amide group. It is a stable substance, radio transparent, highly elastic and soluble in water. It can be extracted if necessary since it does not spread within the adjacent structures, given the fact that it gives rise to a very thin physiological capsule which isolates it from the surrounding tissues. The gel is colorless and transparent. It is supplied in packs containing two sterile 1-ml syringes for the lips (Bio-Alcamid LIPS) and one 3-ml syringe for the face (Bio-Alcamid FACE).

Technique of injection:

The "volume" technique was followed in according with the manufacturer's recommendations.

1- The surface to be treated was cleaned using gauze soaked in skin disinfectant (Betadine).
2- Local anesthesia was done by a regional block or a peripheral anesthesia of the area.
3- The point to be corrected was identified exactly taking into consideration the length of the needle and the potential point of penetration through the skin.
4- The syringe containing the Bio-Alcamid gel was screw on the injection needle (preferably 19-Gauge).
5- The needle was introduced through the skin, sliding it along the subcutaneous plane at the level of the hypodermis (only into the hypodermis).
6- Before starting the injection, the syringe should be gently flashed back to ensure that no intravascular penetration took place.
7- Once the correction point under the skin was reached, the substance was injected, piloting and controlling the direction of the gel with the free hand.
8- The injection was continued, without removing or shifting the needle, until the required corrective volume is reached.
9- The implant was shaped with the hands to give the prosthesis the required shape.
10- If correction was sufficient, the needle was removed by sliding it outwards.
11- The injection site was cleansed with hydrogen peroxide (H_2O_2) to remove any excess product.
12- The orifice was pressed for about two minutes to stop possible blood flow.
13- The orifice was medicated using an antibiotic ointment then sealed with steristrips.

If a greater volume was to be injected or another prosthesis was to be created adjacent to the first.

a- Starting from point "10" mentioned above, the needle was withdrawn without being completely removed from the orifice then it was slide under the skin, directing it towards the new correction point. If the volume of the first prosthesis was to be increased, this had to be performed as close as possible to the first implant so that no discontinuity is visible on the surface.

b- The syringe was screw on again and the injection proceeded, creating the volume necessary to form a new prosthesis.

c- If a prosthesis was to be created away from the initial point, the needle had to be inserted under the skin through a new orifice, and then proceeded as described above.

After extracting the needle from the inlet orifice, the treated area was massaged gently but firmly to shape the future prosthesis.

For cheek augmentation, the zygomatic bone was the reference point for the final profile. During the injection, the substance being distributed subcutaneously had to be piloted by the contralateral hand in order to prevent it taking an undesired subcutaneous route Submalar areas were injected in a similar way in cases with cheek hollowness.

The nasolabial folds were approached from 1cm lateral to the fold and the needle was directed perpendicular to the nasolabial line. Once the desired plane had been reached, a series of subsession movements were done to create a pocket along the nasolabial groove. Then, the Bio-Alcamid was injected until the desired volume is reached.

For the lips, Bio-Alcamid was only used to correct and project the labial profile. A 23G needle was a good choice. Entrance of needle was made 0.5cm medial to the oral commissure. Infiltration was done along the vermilion border. Each hemilip was injected with a maximum of 0.5ml of Bio-Alcamid.

The areas that should be avoided in the face for modification with Bio-Alcamid were the lip mucosa and the eyelids.

The total volume of injected Bio-Alcamid filler for each treated area was recorded.

Postoperative care:

Applying ice meant for topical external use to limit post implant edema. No particular dressings or compression bandages were necessary. Broad spectrum antibiotic (Augmentin 625mg/12hrs) for one week and a mild analgesic (Paracetamol) were prescribed. No massage was required. Anti-inflammatory drugs were contraindicated.

Follow-up:

Patients attended the clinic for follow-up after two days then after one week later to check for early complications such as haematoma, bruises and infection. At that stage, the implant could be contoured and redistributed if presenting any deformity in its shape. Patients were then seen at 6 weeks, 3 months and 6 months from the treatment. Any complication occurring was recorded. At 6 weeks time, areas presenting with minor contour deformities were corrected by touch up injections.

Patients were photographed 3 and 6 months postoperatively. Assessment of patients' satisfaction with respect to the filling's esthetic results was done through subjective self-evaluation of preoperative photographs. This assessment took place 3 and 6 months postoperatively. The result was classified as very satisfactory, satisfactory and not satisfactory.

RESULTS

A total of 60 patients, 51 females and 9 males, underwent this procedure. The average patient age was 27.5 years, with a range of 19 to 46 years. As for the indication for filling, 38 cases presented with wasting or lack of volume of one or more regions of the face, 13 cases had deep nasolabial folds and 5 cases had localized depressions in the face due to previous trauma or infection, and 4 cases required for lip contouring.

The upper cheek (malar area) was the most commonly treated site (35 cases=58.3%). The average amount of gel injected to this site was 4.2ml for each malar eminence. Submalar area was the second most frequent site (28 cases=46.7%). The average amount of gel injected to this area was 2.6ml for each side. Bio-Alcamid was injected for correction of nasolabial fold in 13 patients (21.7%). The average amount of gel injected to this site was 1.3ml for each side. Four cases (6.7%) had lip contouring with an average amount of 0.8ml of gel per lip. In 39 percent, more than one site was injected (Table 1).

Total volume of Bio-Alcamid injected in the first treatment session varied between 2 to 20cc with an average of 9.5cc.

Transient local reactions that resolved spontaneously were detected in all patients. Redness was seen immediately after injection, in all patients who later reported its disappearance within few hours. All cases presented a mild post-operative oedema which resolved during the following days. Mild or no pain was reported in most of patients and was relieved by paracetamol tablets.

During the follow-up visits, it was observed that 29 patients (48.3%) required a slight touch-up injection, which was scheduled 6 weeks after initial treatment, to correct unevenness and asymmetry. The average volume injected for touch-up treatments was 2.3ml of Bio-Alcamid.

Evaluation of patient satisfaction after 3 months (Table 2) showed that 23 patients (38.3%) judged

their aesthetic results to be satisfactory and 16 patients (26.7%) judged their aesthetic results to be very satisfactory, 21 patients (35%) reported being non satisfied with the aesthetic results. These patients felt that the enhancing effect was insufficient. Fourteen of them (23.3%) agreed to undergo another treatment session to reach a satisfactory outcome.

Assessment of patient satisfaction after 6 months showed that 85% of the cases were satisfied or very satisfied about the results. Figs. (1-4) show results in some of the studied cases.

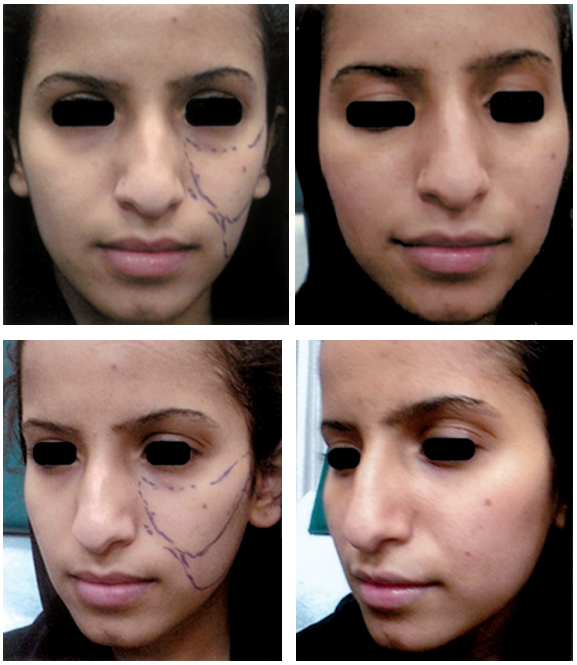

Fig. (1): A 23 year old female who underwent malar and submalar augmentation and lip contouring by Bio-Alcamid. A total of 11.2cc were injected. Left = Preoperative views. Right = Postoperative views after 6 months.

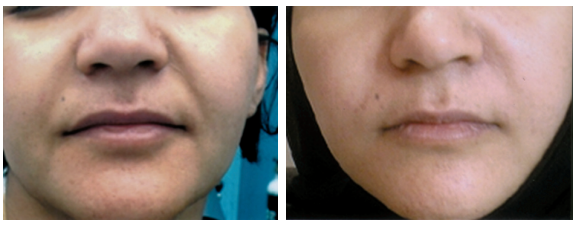

Fig. (2): A 31 year old female who underwent nasolabial filling by Bio-Alcamid. 0.8cc was injected on each side. Left = Preoperative views. Right = Postoperative views after 3 months.

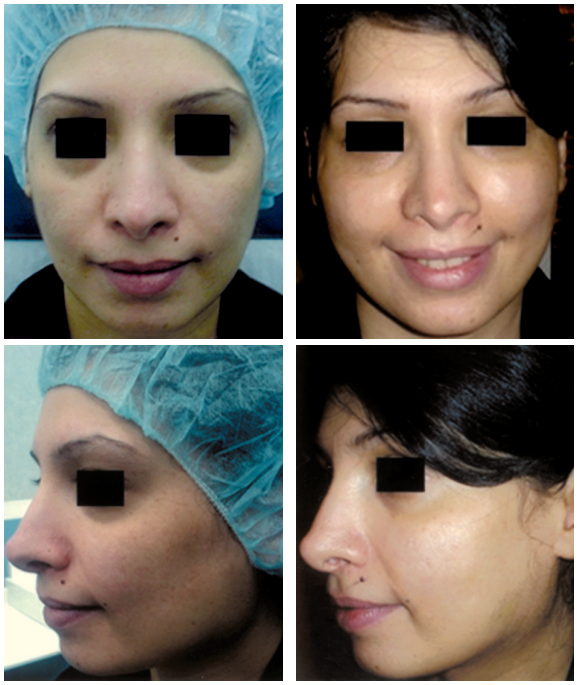

Fig. (3): A 33 year old female who underwent malar and submalar augmentation by Bio-Alcamid. A total of 15cc were injected. Left = Preoperative view. Right = Postoperative views after 6 months.

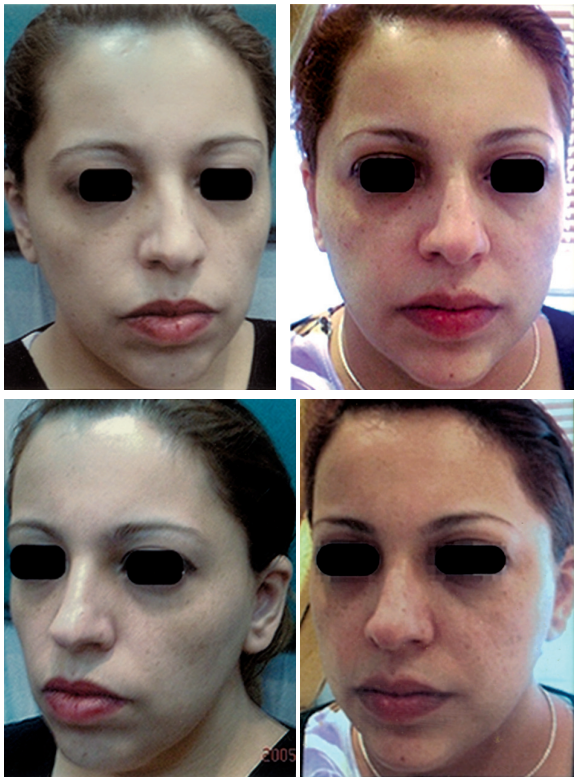

Fig. (4): A 41 year old female who underwent upper and lower cheek augmentation and nasolabial filling by Bio-Alcamid. A total of 18.4cc were injected. Left = Preoperative views. Right = Postoperative views after 6 months.

Complications (Table 3):

Major complications like systemic allergic reactions, foreign body granulomas or implant migration were not encountered in this series except infection in one case. The infected case was a case of cheek augmentation complicated by a small localized abscess which was treated by drainage through a small incision, from which the implant was also squeezed out. Minor complications were reported in the form of: Bruises, unevenness and minor asymmetry.

Table (1): Treated areas in the studied 60 cases.

Area	No. of cases	Average amount of filler
Upper cheek	35 cases (58.3%)	4.2ml
Lower cheek	28 cases (46.7%)	2.6ml
Nasolabial folds	13 cases (21.7%)	1.3ml
Chin	6 cases (10%)	1.2ml
Lips	4 cases (6.7%)	0.8ml
Temples	3 cases (5%)	0.5ml
Localized depressions	5 cases (8.3%)	0.8ml

Table (2): Patient' satisfaction (by self-evaluation) after Bio-Alcamid injection.

Satisfaction	After 3 months	After 6 months
Very satisfied	16 patients (26.7%)	22 patients (36.7%)
Satisfied	23 patients (38.3%)	29 patients (48.3%)
Dissatisfied	21 patients (35%)	9 patients (15%)

Table (3): Complications of Bio-Alcamid injection in the studied cases.

	No.	%
Infection	1	1.7
Unevenness	19	31.7
Unequal contours	10	16.7
Cutaneous bruises	6	10

DISCUSSION

The use of injectable filling agents for soft-tissue facial defects has a long history of successful use based on xenogeneic collagen materials. The past 5 years have seen the emergence of numerous new fillers of differing compositions. The role of injectable soft-tissue augmentation continues to expand **[6]**.

The evolution, properties, and availability of soft-tissue fillers were extensively reviewed recently **[6-14]**. Soft-tissue fillers can be classified into four general categories: 1- Xenogeneic materials (Bovine collagen) like Zyderm and Zyplast; 2- Autologous materials like injectable fat, autologous dermal filler and autologen; 3- Allogeneic materials like Dermalogen, Alloderm, cosmoderm, and cymetra; and 4- Synthetic materials like hyaluronic acid fillers (Restylane, Perlane, Hylaform), polyacrylamide (Aquamid), poly-L-lactic acid (Sculptra), calcium hydroxyapatite (Radiesse), polymethylmetacrylate (ArteFill and ArteColl and liquid silicone) **[6]**.

Several bovine collagen products are currently available. Although they are easy to use and have a history of safety and reliability, disadvantages include allergic reactions (1 to 3 percent) requiring pretreatment skin tests and relatively short-lived corrections **[15]**. Bovine collagen is associated with poor long-term outcomes, and there is no metabolic pathway for removing it from the body **[16]**.

Autologous materials are commonly and successfully used to replace or augment body tissues. However, procedures using autologous fillers like dermal grafts and injectable fat require the extraction and processing of the patient's tissues. High resorption rates have been reported **[14]**.

Allograft tissue is less desirable because of concerns regarding viral transmission and potential immunologic reactions, and heterologous material carries a greater risk of immunogenicity and associated tissue reactions. Because inflammation results in elevated levels of active proteases, the degradation of biological replacement materials may be further accelerated **[14]**.

Synthetic materials have been developed for soft-tissue augmentation, including polytetrafluoroethylene (Teflon) and silicone. However, each of these exhibit limitations that may compromise their use. Both have been associated with an increased risk of granuloma formation and migration to distant areas of the body. Silicone has been associated with autoimmune reactions and malignancy **[17,18,19]**.

Restylane implantation produces similar clinical effects and longevity of correction as does bovine collagen (Zyplast), with the advantage of minimal risk of allergic reaction. However, the 8 percent rate of intermittent swelling and the possible severe granulomatous tissue reaction may render its use unacceptable **[14]**. Both collagen and hyaluronic

acid fillers are metabolized by normal catabolic processes, correction persistence typically fails to exceed 6-9 months [16].

Poly-L-lactic acid is a tissue volume-enhancing material. It increases volume within the tissue slowly over time, and multiple injections are required to obtain the desired corrective effect. Subcutaneous papules in 30-50 percent of subjects have been reported [16]. The effects typically last 1 to 2 years. The potential for long-term tissue reactions, such as granulomas, is much higher than for most other injectable fillers [6].

Aretcoll (polymethylmethacrylate) is a permanent filler suspended in bovine collagen. Skin testing is required to eliminate the risk of allergy. Like all particle based injectable fillers, the risk of clumping and localized foreign body reactions exists. It also has a risk of palpability [6].

Hydrophilic polyacrylamide gel (Aquamid) may evoke a human tissue inflammatory response similar to other foreign materials. Lumpy subcutaneous nodules and difficult removal may limit its application [20].

Radiesse (Calcium hydroxylapatite) is considered an injectable implant. The majority of the injected material is the carrier gel (70 percent) which is rapidly absorbed and so much of the perceived augmentative effect may be gone quite quickly. There is a potential for "clumping" with formation of a foreign body reaction. Furthermore, Radiesse is radiopaque and may interfere with facial radiographs [6].

The ideal agent for facial soft-tissue augmentation should be safe and effective; easy to obtain and administer; have a minimal risk for infection, extrusion, or migration; produce a minimal inflammatory reaction; and last for an acceptable degree of time. It should also be cost-effective, show consistency, and ultimately yield highly acceptable, positive aesthetic results [21]. However, there is no single injectable filler that has all of the desired characteristics [6].

Virtually all biological materials are ultimately reabsorbed, and previously used synthetic materials have been associated with side effects, such as migration, granuloma formation, and late allergic reactions [22].

Bio-Alcamid is a new "filler" being used for facial rejuvenation and soft-tissue augmentation [23]. It can be considered a novelty in the field of aesthetic and reconstructive surgery, for its chemical and physical characteristics and also for its application procedure [24].

Bio-Alcamid is a non reabsorbable polymeric material composed of 96% of apyrogenic water and 4% of an alkylimide-amide group. These chemical aspects of Bio-Alcamid are responsible for a greater chemical stability of the polymer, a better resistance to basic and acid hydrolytic phenomena, and high resistance to water. Unlike other materials, Bio-Alcamid can be easily removed even after long time. Its structure is quite similar to the adipose tissue [24].

As described by manufacturer, Bio-Alcamid is a filler created to obtain a biological continuation, to provoke a reaction to the mechanical action of swelling and filling following the injection, in such a manner as to get transformed into a sort of "endogenous" prosthesis, i.e. with a small fibrous capsule.

Only few studies have been carried out recently to evaluate Bio-Alcamid [23-26]. These studies have reported that Bio-Alcamid, thanks to its chemical, physical and biological characteristics is completely a biocompatible substance, absolutely non toxic and non allergenic, easily injectable and quickly removable. These characteristics are responsible for the long-term aesthetic results and efficiency of the implants. These studies concluded that Bio-Alcamid can be used as an injectable endoprosthesis for soft tissue augmentation and for the correction of different tissue deficiencies, whether in the face or the body.

These few recent studies have initiated the current study to be carried out with the aim of evaluating the safety and efficacy of Bio-Alcamid in facial soft tissue augmentation. A retrospective review involved 51 females and 9 males who underwent Bio-Alcamid injection for correction of facial defects within a period of 18 months duration.

The average patient age was 27.5 years which is significantly lower than the average age reported in other studies about facial filler agents, being usually almost double this figure [2,22]. The explanation is that most of the patients in other studies present with deficiencies of the fat in their face as a result of the aging process [27], while most of the cases of the current study were young females desiring cheeks enhancement due to lack of volume, or to wasting following body weight loss.

Bio-Alcamid injection was performed under local anesthesia in the form of regional block or

peripheral anesthesia, same as mentioned in many articles about facial augmentation by injectable fillers **[2,6,15,22]**. The procedure of Bio-Alcamid injection applied the "volume' technique recommended by the manufacturer (Polymekon Laboratory, Italy) to facilitate the formation of the capsule, which is fundamental for a correct prosthesis.

The manufacturer also advises not to use the "backward slipping injection" or the "droplet technique" that are used for classic fillers. This is because Bio-Alcamid is an injectable prosthesis, and not merely a filler.

In the studied cases, administration of Bio-Alcamid gel was found easy and simple and did not require effort while infiltrating the substance into the treatment area. Also, the manipulation of the injected material and shaping it within the desired area was an easy task. Orenstein, and Bar-Meir **[23]** studied Bio-Alcamid and reported a major problem which is a leak of the filling material immediately after injection. Actually this event was not encountered at all in the current work and could be easily overcome if the practitioner stops injecting the product few millimeters before withdrawing the needle from the entry orifice.

Recently, a specific device "catheter-type needle" has been supplied by the manufacturer for use to facilitate the injection (easier injection with less pressure on the plunger).

The most frequently treated area in this series was the malar area (58%). Submalar area was the second most frequently treated (46.5%). The FACE form of Bio-Alcamid gel was used for these sites as well as in other areas of the face. The LIP form was used in cases of lip contouring (4 cases), to correct and project the labial profile. Bio-Alcamid injection is contraindicated into the lip mucosa and eyelids for fear of complications especially hardening and infection.

Total volume of Bio-Alcamid injected in the first treatment session varied between 2 to 20cc with an average of 9.5cc.

Since a prosthesis was being implanted, aseptic measures were followed strictly during injection. For the same reason, pre and post injection antibiotics were given.

Bio-Alcamid's physiological inflammatory reaction was minor and disappeared within few days. Patients felt mild pain which was overcome by paracetamol tablets. Anti-inflammatory drugs were contraindicated in the postoperative period as stated by the manufacturer because preventing the inflammatory process would compromise the formation of the capsule and therefore of the endoprosthesis.

Apart from a single case of infection which was treated by drainage, no major complications like allergy, foreign body granulomas, extrusion or implant migration were experienced in this series. During follow-up, 29 cases presented complaining of minor contour deformities either in the form of unevenness (19 cases) or asymmetry (10 cases). Touch-up injections were decided for them but were scheduled 6 weeks following the initial treatment, by the manufacturer.

Assessment of patient satisfaction was done by subjective self-evaluation of preoperative photographs, similar to that used by Jansen and Graivier **[16]**. After 3 months, 21 patients (35.3%) were not satisfied about the volume gained. Fourteen of them (23%) agreed to undertake another treatment session to reach a satisfactory level of correction.

Assessment of patient satisfaction after 6 months showed that 58% of the cases were satisfied or very satisfied with the results. Palpation of the infiltrated areas showed a smooth surface and soft consistency comparable to fat, and the implant felt exactly as the surrounding tissue. None of the unsatisfied cases asked for removal of the implant. Their complaint was only related to the insufficient volume and not the shape of the implant.

Reviewing literature has shown that volume fillers available for facial augmentation, other than Bio-Alcamid, include autologous fat, hyalorunic acid, calcium hydroxylapatite, poly-L-Lactic acid, polyacrylamide, polymethylmethacrylate and liquid injectable silicone. The current study and other similar studies on Bio-Alcamid **[23-26]** have found that Bio-Alcamid is superior to all these materials, thanks to its numerous advantages and very few disadvantages compared to others.

Contrary to Bio-Alcamid which is a ready-for-use material, autologous fat has to be harvested by liposuction and processed before injection. There is a high rate of reabsorption after lipofilling. Absorbable injectable fillers and implants such as poly-L-lactic acid, calcium hydroxylapatite, and hyaluronic acids are limited by cost and short duration of correction. Permanent volume fillers like polyacrylamide, polymethylmethacrylate and liquid injectable silicone are limited by the risk of clumping and localized foreign body reactions, lumpy subcutaneous nodules and difficult removal.

The only drawback that was associated with Bio-Alcamid in this study was the need for 2-3 sessions to reach a satisfactory cosmetic outcome in many cases. However, the same has been reported with most of the other volume facial fillers such as autologous fat **[14]**, poly-L-Lactic acid **[16]**, Hyaluronic acid **[15]**, silicone **[3]**, and polyacrylamide **[28]**.

Conclusion: Bio-Alcamid can be almost considered an ideal injectable substance for the treatment of facial aesthetic defects. The study has found that Bio-Alcamid features the following advantages:

1- Bio-Alcamid is a non invasive treatment meaning that there is no hospitalization required, no incision to be made (less risk of infection) and less cost for the patient.

2- Bio-Alcamid is a stable gel, ready-for-use, that can be saved in room temperature. It does not need reconstitution or preparation before use.

3- Bio-Alcamid is easily administered.

4- Bio-Alcamid can be shaped through massage directly after the treatment.

5- The implant has a very smooth surface, with no clumping or nodularity.

6- The implant is exactly similar to and can't be distinguished from the surrounding fat.

7- There is no post-operative recovery period and the patient can resume her/his daily activities right away.

8- The risk of post-operative complications is nearly absent and the product is reversible as it is easily removable without provoking scarring to the treated area.

REFERENCES

1- Glavas I.P.: Filling agents. Ophthalmol Clin. North Am., 18: 249-257, 2005.

2- von Buelow S. and Pallua N.: Efficacy and safety of polyacrylamide hydrogel for facial soft-tissue augmentation in a 2-year follow-up: A prospective multicenter study for evaluation of safety and aesthetic results in 101 patients. Plast. Reconstr. Surg., 118 (3S): 855-915, 2006.

3- Narins R.S. and Beer K.: Liquid injectable silicone: A review of its history, immunology, technical considerations, complications, and potential. Plast. Reconstr. Surg., 118 (3S): 77S-84S, 2006.

4- Bergeret-Galley C., Latouche X. and Illouz Y.G.: The valuve of a new filler material in corrective and cosmetic surgery: DermaLive and DermaDeep. Aesthetic Plast. Surg., 25 (4): 245-55, 2001.

5- Spira M.: Failure to remove soft-tissue injected with liquid silicone without the use of suction and honesty in scientific medical reports. Plast. Reconstr. Surg., 105 (5): 1909-2000.

6- Eppley B.L. and Dadvand B.: Injectable soft-tissue fillers: Clinical overview. Plast. Reconstr. Surg., 118 (4), 15: 98e-106e, 2006.

7- Narins R.S. and Bowman P.H.: Injectable skin fillers. Clin. Plast. Surg., 32: 151, 2005.

8- Murray C.A., Zloty D. and Warshawski L.: The evolution of soft tissue fillers in clinical practice. Dermatol. Clin., 23: 343, 2005.

9- Owens J.O.: Soft tissue implants and fillers. Otolaryngol. Clin. North Am., 38: 361, 2005.

10- Ascher B., Cerceau M. and Baspeyras M.: Soft tissue filling with hyaluronic acid. Ann. Chir. Plast. Esthet., 49: 465, 2004.

11- Biesman B.: Soft tissue augmentation using restylane. Facial Plast. Surg., 20: 171, 2004.

12- Kanchwala S.K., Holloway L. and Bucky L.P.: Reliable soft tissue augmentation: A clinical comparison of injectable soft-tissue fillers for facial-volume augmentation. Ann. Plast. Surg., 55 (1): 30-35, 2005.

13- Obagi S.: Correction of surface deformities: Botox, soft-tissue fillers, lasers and intense pulsed light, and radiofrequency. Atlas Oral Maxillofac. Surg. Clin. North Am., 12: 271, 2004.

14- Alster T.S. and West T.B.: Human-derived and new synthetic injectable materials for soft-tissue augmentation: Current status and role in cosmetic surgery. Plast. Reconstr. Surg., 105 (7): 2515-2525, 2000.

15- Matarasso S.L., Carruthers J.D. and Jewell M.L.: Consensus recommendations for soft-tissue augmentation with nonanimal stabilized hyaluronic acid (Restylane). Plast. Reconstr. Surg., 117 (3): 3S-34S, 2006.

16- Jansen D.A. and Graivier M.H.: Evaluation of a calcium hydroxylapatite-based implant (Radiesse) for facial soft-tissue augmentation. Plast. Reconstr. Surg., 118 (3S): 22S-30S, 2006.

17- Rapaport M.J., Vinnik C. and Zarem H.: Injectable silicone: Cause of facial nodules, cellulitis, ulceration, and migration. Aesthetic Plast. Surg., 20: 267, 1996.

18- Lupton J.R. and Alster T.S.: Cutaneous hypersensitivity reaction to injectable hyaluronic acid gel. Dermatol. Surg., 26: 135, 2000.

19- Lemperle G., Romano J.J. and Busso M.: Soft tissue augmentation with artecoll: 10-year history, indications, techniques, and complications. Dermatol. Surg., 29: 573, 2003.

20- Zhao Y., Qiao Q., Yue Y., Kou X. and Liu Z.: Clinical and histologic evaluation of a new injectable implant: Hydrophilic polyacrylamide gel. Ann. Plast. Surg., 53 (3): 267-72, 2004.

21- Fagien S.: Facial soft-tissue augmentation with injectable autologous and allogeneic human tissue collagen matrix (Autologen and Dermalogen). Plast. Reconstr. Surg., 105 (1): 362-373, 2000.

22- Cohen S.R., Berner C.F., Busso M., Gleason M.C., Hamilton D., Holmes R., et al.: ArteFill: A long-lasting injectable

wrinkle filler material-summary of the U.S. food and drug administration trials and a progress report on 4 to 5-year outcomes. Plast. Reconstr. Surg., 118 (3S): 64S-76S, 2006.

23- Orenstein A. and Bar-Meir E.: Bio-Alcamid: Avoiding the leak. Plast. Reconstr. Surg., 115 (6): 1729-17790, 2005.

24- Pacini S., Ruggiero M., Morucci G., Cammarota N., Protopapa C. and Gulisano M.: Bio-Alcamid: A novelty for reconstructive and cosmetic surgery. It. J. Anat. Embryol., 107: 3, 2002.

25- Pacini S., Ruggiero M., Cammarota N., Protopapa C. and Gulisano M.: Bio-Alcamid, a novel prosthetic polymer, does not interfere with morphological and functional characteristics of human skin fibroblasts. Plast. Reconstr. Surg., 111 (1): 489, 2003.

26- Protopapa C., Sito G., Caporale D. and Cammarota N.: Bio-Alcamid in drug-induced lipodystrophy. J. Cosmet. Laser Ther., 5: 226-230, 2003.

27- Satoh M., Mori S., Yoshizuka N., et al.: Facial distribution of subcutaneous fat in women. Int. J. Cosmet. Sci., 266, 2004.

28- Broder K.W. and Cohen S.R.: An overview of permanent and semipermanent fillers. Plast. Reconstr. Surg., 118 (3S): 7S-14S, 2006.