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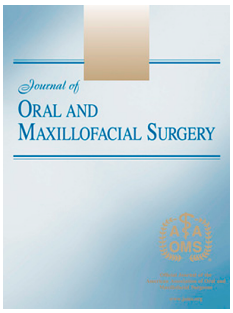

"Standard and customized alloplastic facial implants refining orthognathic surgery: outcome evaluation."

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"Standard and customized alloplastic facial implants refining orthognathic surgery: outcome evaluation."

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ABSTRACT

Purpose

Conventional orthognathic osteotomies provide appropriate functional outcomes but might be unable to correct mid-face deficiency, achieve a satisfactory outcome in asymmetrical cases, or allow sufficient chin advancement. The investigators have evaluated the outcome of both standard and customized facial high-density porous polyethylene (HDPE) implants, used to refine the cosmetic outcome of orthognathic surgery.

Methods

The investigators implemented a retrospective study. The sample was composed of all patients operated on for facial alloplastic augmentation between June 2011 and October 2018 in the department. Complication rate was recorded after a mean follow-up period of 41 months postoperatively as well as patient satisfaction assessed through a qualitative evaluation based on an 11-item questionnaire.

Results

The sample was composed of 24 implants placed in 14 patients: 13 mandibular angle implants, among which 4 were customized, 8 malar and 3 chin implants. No physical complications such as hematoma, infection, migration or hypoesthesia were observed. Two implants had to be removed due to an early unsatisfactory aesthetic outcome. Eleven patients out of 14 answered our questionnaire. Eighty-two percent strongly agreed that the overall outcome was satisfactory.

Conclusion

The results of this study confirm the low physical complication rate described in literature and the aesthetic complication rate remains lower than the ones observed in previous reports. There was a high satisfaction rate among patients. The lowest mean satisfaction score was noted regarding appropriate implant symmetry (3.5), whereas the highest mean satisfaction score (3.8) was achieved when using customized implants. If standard HDPE implants appear as relevant adjuncts to orthognathic surgery, customized implants seem to achieve higher satisfaction, although their prohibitive cost shall be considered.

INTRODUCTION

Restoring a proper dental occlusion was initially the primary goal of orthognathic surgery. In modern practice, achieving optimal aesthetics has become a major concern.

Conventional osteotomies, such as the Le Fort I and bilateral sagittal split are suited to provide an appropriate functional outcome. However, they might be unable to achieve a satisfactory outcome in asymmetrical cases. Besides, the upper midface deficiency often encountered in Class III patients is not always corrected by Le Fort I maxillary advancement. Although modified maxillary osteotomy lines, such as the Le Fort II or Le Fort III, can be used, they imply higher morbidity and are therefore usually reserved for severe deformities in syndromic patients. As a result, they do not seem appropriate for common Class III patients.

Correcting severe retrogenia using a sliding genioplasty is also challenging, as adequate contact between bone segments, mandatory for bone healing, restricts the amount of chin advancement.[1]

In all the above described cases, skeletal augmentation is required. If autogenous bone onlay grafting appeared as a solution, it is available in limited quantity and requires time-consuming and complex graft modelling. This is particularly critical when symmetry is sought in bilateral structures, such as zygomas and mandibular angles. Moreover, there is unpredictable postoperative resorption up to 50% and increased morbidity in the donor site. Prolonged surgical and hospitalization time increases procedure costs.[2-4]

Alloplastic augmentation appears as the solution to optimize skeletal facial contour. Numerous alloplastic materials have been used,[5,6] but are known to induce various complications such as infections, displacements, foreign body reaction and underlying bone resorption.[7]

High-density porous polyethylene (HDPE) (Medpor®) has been widely used for more than 40 years, particularly for aesthetic indications.[8,9] HDPE seems to offer many advantages compared to other biomaterials.[6,10]

Our aim was to evaluate the tolerance and satisfaction of both standard and customized facial HDPE implants, used especially to refine the cosmetic result of orthognathic surgery.

METHODS

All patients operated on for facial alloplastic augmentation in our Department between June 2011 and October 2018 were included in the study. They all presented with a Class II or Class III dentofacial deformity and requested facial skeletal refinement. Most of the included patients had a context of orthognathic surgery procedure. Among them, a first group had a history of previous orthognathic surgery and these patients asked for postoperative alloplastic morphologic refinement simultaneously with osteosynthesis plate removal, thereby allowing them to be considered as their own control. The second group consisted of patients who underwent alloplastic augmentation simultaneously with orthognathic surgery (Table 1).

After clinical examination and photography (frontal view facial photographs with the face at rest and when smiling, lateral and submental vertex views) by the first author, standard frontal and profile cephalometric radiographs, 3D cone-beam computed tomography (CBCT) or computed tomography (CT) scan (when considering customized implants) were achieved. The esthetic evaluation was then conducted on the photographs by the surgical staff of the department involving six senior surgeons and ten residents in order to confirm the indication for implant placement. The treatment planning and actual surgeries were performed by the first author (JCL).

The customized implants were initiated using the Stryker® patient specific solution web application (CMF Customized Implants Stryker Orthopaedics®, 325 Corporate Drive, Mahwah, NJ 07430, USA). A CT scan was performed with a slice thickness of 1 mm. Anonymized DICOM data were electronically uploaded to the Stryker Platform from which engineers achieved 3D reconstruction, using Mimics Medical v.20 and 3Matic v.12 (Materialise® NV, Leuven, Belgium) and design with Freeform Plus v.2016, (Geomagic/3D Systems® Rock Hill, South Carolina, USA). The customized implants were designed particularly using the mirroring technique during a web session involving the first author and a Stryker engineer. A design proposal was uploaded for surgeon review and approval before

manufacturing. The sterile customized implant was then delivered to the maxillofacial surgery department.

The patients were involved in the planning process. The catalogue of alloplastic implants was presented to them to help choose the size of the implant according to their expectations, as well as a powerpoint slideshow summarizing the surgical procedure. When customized implants were designed, the graphic rendering of the virtual surgical planning was also presented.

This study was approved by the Strasbourg University Hospital IRB under n° FC/dossier 2017-68 and all participants signed an informed consent agreement.

Surgical procedure

All the procedures were performed by the first author. HDPE implants were placed simultaneously either with orthognathic surgery or with plate removal, which is often scheduled at 1 year postoperatively in our Department.

Standard implants were chosen when bilateral implantation was indicated, whereas customized implants were preferred at a later stage, when addressing the correction of an obvious asymmetry through a single implant (Figs. 1A-J).

Initial subperiosteal infiltration of the operative site was performed using a 1% lidocaine solution with epinephrine (0.05 mg/mL). Intravenous perioperative antibiotic prophylaxis (amoxicillin/clavulanate 2g) was administrated.

All implants were placed through an intra oral incision, except in one case of unilateral mandibular angle implant, where a trans-cutaneous approach used a scar left in the skin by a previous orthognathic procedure (Fig.1C, E). Sterile silicone sizer sets were used intraoperatively to help choosing the appropriate size. Before placement, the chosen implants were immersed into hot saline solution to ease fitting. Minor individual implant contouring was performed when needed, using a large scalpel blade (n°23) or a round bur. The edges were feathered to obtain a smooth contour and to prevent any “step” deformity.

Care was taken not to damage or compress any nerve adjacent to the implant. Once positioned in its subperiosteal pouch, every implant was fixed to the underlying bone using two 2.0 self-tapping titanium screws placed intraorally to prevent migration (Modus, Medartis® Holding AG, 4057 Basel, Switzerland). Only for mandibular angle implants, were the screws inserted through a transbuccal approach using a drill guide/cannula.

Before suturing, the implantation site was rinsed with 100 mL of saline solution. A transcutaneous silicone drain was placed for the mandibular angle and chin implants.

submucosal and mucosal sutures were performed with polyglactin (4.0 and 3.0).

Systematic compressive bandage and a cooling facial mask (Allegre®, Saint-Etienne, France) were applied. Intravenous methylprednisolone (2 mg/kg/day) was administrated intraoperatively, then orally at day 1 postoperatively. Postoperative amoxicillin/clavulanate (3 g/day) was administered for 7 days.

Postoperative follow-up and assessment of implant tolerance

Drainage was removed, radiographs were performed, and patients were discharged at day 1 postoperatively.

Chlorhexidine mouthwash and a liquid diet were prescribed for 10 days postoperatively.

Follow-up clinical and radiological examinations were carried out on all patients at intervals of 1 week, 2 weeks, 1 month, 3 months, 1 year, and later once a year. Implant tolerance was assessed by the physical complication rate: infections, hematoma, seroma, implant displacements or exposure were recorded at all these follow-up intervals. Neurosensory disturbance was assessed using light touch test with Semmes-Weinstein monofilaments[11] before implant placement and during follow-up. Aesthetic complication was considered when obvious residual asymmetry was observed at 1 month postoperatively by both the surgeon and the patient (Table 2). This schedule was chosen in order not to deteriorate patient's experience with an obvious unsatisfactory cosmetic outcome and to proceed swiftly with revision surgery.

Qualitative Evaluation

Qualitative evaluation was based on a standard questionnaire sent electronically between November 2017 and September 2018 to all patients in order to assess their satisfaction regarding the aesthetic outcome. The questionnaire consisted of 11 items. A 4-entry Likert scale was used for answers, scoring 4/4 for “strongly agree”, 3/4 for “agree”, 2/4 for “disagree” and 1/4 for “strongly disagree” (Table 3).

In the case of early implant removal due to aesthetic complications, the patient only answered the questionnaire once revision surgery had been performed.

Descriptive statistics were computed. The follow-up period between surgery and the time of qualitative evaluation was recorded.

RESULTS

Sample and implant features

A total of 24 consecutive facial implants were placed by the first author through 16 procedures performed under general anesthesia.

The sample consisted of 14 patients, with a sex ratio (male/female) of 1.3 and a mean age (Standard Deviation (SD)) of 30.9 years (9.9) at the time of surgery (Table 1).

Twenty-one implants (13 patients, 92.8 %) were placed in patients with a context of an orthognathic surgical procedure. They were 71.4 % of patients in the first group (implants placed simultaneously with osteosynthesis plate removal, one year after orthognathic surgery) and 21.4 % of patients in the second group (implants placed simultaneously with orthognathic surgery) (Table 1).

The remaining 3 implants were placed for purely cosmetic purposes on a single Class II patient who did not consider orthognathic surgery.

There were 13 mandibular angle implants (among which 4 were customized) (Figs. 1A-J) 8 malar implants (Figs. 2A-I) and 3 chin implants (Figs. 3A-F) (Table 1).

Among the 13 mandibular angle implants, 8 references were “Design RZ” reference, 4 in medium size, 4 in large size. In the 5 asymmetry cases, 1 “Contoured mandibular angle” and 4 custom made implants were used. Seven implants were placed simultaneously with orthognathic plate removal, 3 were placed without any additional procedure, 2 together with chin wing genioplasty and 1 replaced a mandibular angle implant removed from the same position.

The 8 malar implants were all “Design RZ” reference, 6 in size “*petite*”, 2 in size “*super petite*”. Four implants were placed simultaneously with Le Fort I maxillary advancement together with advancement genioplasty, 4 implants were placed simultaneously with maxillary plate removal.

The 3 chin implants were “Contoured two-piece chin”. Two implants were placed simultaneously with chin plate removal, 1 was associated with no other procedure.

Tolerance

The mean follow-up period was 41 months (range 3-88, SD=22).

Complications are presented in Table 2.

Patient satisfaction

Eleven patients out of 14 replied to the questionnaire (79%). Overall patient satisfaction, regardless of the type of implant, reached a high mean score (3.8/4); so did satisfaction with the profile aesthetic outcome (3.8/4) (Table 3).

The highest mean satisfaction scores were obtained for chin implant centering (4/4). The lowest mean satisfaction scores were noted regarding the discomfort related to implant surgery (3.5/4) and implant symmetry (3.5/4) (Table 3).

DISCUSSION

Our aim was to evaluate the outcome of both standard and customized facial high-density porous polyethylene (HDPE) implants. The present study reported no physical complication during a mean follow-up period of 41 months, and an 8% aesthetic complication rate returning to 0% after revision surgery. A rate of 82% of patients strongly agreed that the overall outcome was satisfactory.

HDPE facial implants were chosen when addressing facial skeletal alloplastic implantation cases. Indeed, many complications of silicone implants, such as exposure, infections and major bone erosion, had been treated in our department.[12]

In numerous studies HDPE facial implants unlike Silastic, Goretex or Mersilene, have been reported to provide very good tolerance and satisfactory aesthetics results.[5,13,14]

The most frequently reported complication was “patient dissatisfaction with appearance” ranging from 10.3 % to 26.3%. Infection rate varied from 0.9% to 12.5% mainly depending on implant location (orbit and nose locations were particularly vulnerable to infections). As opposed to other materials, HDPE implants allow fixation to the underlying bone. The rate of extrusion, implant removal, underlying bone resorption, hematoma and seroma was lower than 1%.[15,16]

Tolerance in the present study is consistent with these findings, since no case of infection, hematoma, extrusion, displacement or bone resorption was reported.

Residual asymmetry was observed in 2 patients (8% of all implants) at 1 month postoperatively (see Table 2). Both of them were treated with mandibular angle implants (see below).

Qualitative evaluation found a high satisfaction rate, since 100% of patients strongly agreed (82%) or agreed (18%) with the statement “I am satisfied with the overall result”.

The main negative feedback was related to step deformity and the discomfort experienced once the implant had been placed (Table 3). Such an outcome could be explained by the perfectible fitting of HDPE implants, which are often perceived as hard and rigid. We believe that the use of customized implants can help improve these results.

HDPE implants have a convenient versatility in facial augmentation. Their use in order to restore facial harmony following accidental trauma, radiotherapy or cancer surgery[10,15] has become consensual.[17,18] They are also used to correct congenital deformities and in aesthetic contouring surgery.[6,19-21]

However, the use of HDPE implants in order to refine the outcome of orthognathic surgery has been scarcely described in literature.[9,22]

In the present study, 93% of patients (13/14) presented with an orthognathic surgery context, meaning they either underwent plate removal (71.5%) or orthognathic surgery (21.5%) simultaneously with implant placement. In our Department, Plate removal is often recommended at 1 year postoperatively, as literature reports a complication or discomfort rate due to orthognathic fixation plates ranging from 10 to 30%.[23-26]

Our results have shown that placing HDPE implants in an orthognathic context does not entail any increased risk of complications.

Specific features can be emphasized depending on implant site (Tables 1, 4)

Mandibular angle: standard and customized implants

Increasing mandibular angle projection

Preoperative assessment of mandibular symmetry is crucial, using especially a low-angle frontal facial photograph, the patient's head being placed in extension. Indeed, a pre-existing asymmetry can be unveiled or worsened, when bilateral implants of the same size are used to increase mandibular angle projection. Such a pitfall was experienced in one of our cases.

Correcting asymmetry

An alternative to alloplastic implantation is "chin wing mentoplasty" consisting in a mandibular basal osteotomy which can simultaneously correct the position of the mandibular angles and the chin.[27-30] However, it is not appropriate for severe asymmetry as bone healing requires

contact between bone segments. Subsequent bone grafting makes this technique more invasive than alloplastic implantation.

Five patients were treated with unilateral mandibular angle implants in order to achieve symmetry (Table 1). In 2 patients, asymmetry of the mandibular angles occurred after a bimaxillary procedure respectively correcting a class II and a class III dentofacial deformity. Such an asymmetry probably resulted from the mechanical overload between bone segments following mandibular osteotomy and inadequate fixation.[31,32] One patient underwent revision surgery replacing one of the previously placed bilateral mandibular angle implants with a customized implant (see pitfall above). In the last two patients, asymmetry resulted from insufficient correction of mild (or severe) hemi facial microsomia (Goldenhar syndrome) (Figs. 1A-I).

The use of a unilateral standard mandibular angle implant in the first patient ("Contoured mandibular angle") did not provide a satisfactory outcome. Consequently, it had to be removed and no further procedure was performed, as the patient preferred to retain his initial appearance. Standard catalogue implants therefore seemed hardly appropriate for optimal correction of asymmetry. Subsequently, the four other mandibular asymmetry cases were successfully treated using customized implants. Mirroring was used through CT scan-based computer-assisted design and manufacturing, considering the larger side of the patient's face as reference.

Among the 5 patients treated with unilateral mandibular angle implants, 3 out of 4 strongly agreed that the overall aesthetic result was satisfactory, 1 out of 4 agreed. Interestingly, no aesthetic complication was reported by the 4 patients treated with customized implants.

Throughout literature, aesthetic dissatisfaction with HDPE implants ranges from 10 to 20 %. This could result from the uneasy intraoperative fine-tuning of standard HDPE implants sometimes requiring instrumental contouring (in 40% of our case series). The use of customized implants could improve these results. Despite cost-related concerns, we definitely recommend the use of customized implants for the correction of asymmetry.

Malar implants

Some studies suggest that Le Fort I osteotomy alone achieves a marked subjective improvement in malar projection when advancement is performed[33] together with a more favorable relation among orbits, ocular globes and lower eyelids (reduction of excessive inferior sclera show) when vertical shortening is combined.[34] They emphasize that the decision for concomitant malar augmentation and Le Fort I advancement should be considered on a case-by case basis in conjunction with the patient's concerns and that it could be prudent to reassess any malar deficiency concern after Le Fort I advancement and after resolution of postsurgical edema.[33] In the present series, eight malar implants were placed in 4 patients, all affected with midface deficiency in the context of a class III malocclusion. Being consistent with literature,[33-34] the implants were placed simultaneously with orthognathic surgery in two patients who were considered to have severe midface hypoplasia, whereas malar alloplastic augmentation proceeded one year after Le Fort I osteotomy in the other two patients.

No postoperative complications were encountered. All patients were very satisfied (3/4) or satisfied (1/4) with the aesthetic outcome.

Implants were placed either simultaneously with Le Fort I osteotomy and genioplasty (2 patients) (Figs. 2A-I) or with orthognathic plate removal (2 patients) (Figs. 3A-F).

Although we did not identify any difference with the simultaneous procedure, we recommend implant placement one year after orthognathic surgery, together with plate removal. This allows more gradual facial changes compared to if implants had been placed simultaneously through orthognathic surgery. Moreover, since plate removal is a quick procedure, total operative time when combined with simultaneous implant placement remains short, and the risk of infection is therefore lower.

The mean age of malar implant patients was 32 (22-53), 3 of them being younger than 30. If malar implants achieve optimal facial contouring in young patients (Figs. 2B-H), they also

provide strong support to the lower eyelid in older patients, therefore inducing a rejuvenating effect.

Chin implants

One patient presented a purely cosmetic indication with no orthognathic surgery context, the other 2 were indicated for residual retrogenia and lip incompetence despite previous genioplasty. No postoperative complications occurred and a very satisfactory outcome was obtained in all three cases.

Genioplasty can be used either alone or combined with orthognathic surgery in order to refine the functional and aesthetic outcomes. However, appropriate bone healing requires contact between the osteotomized chin segment and the superior mandibular segment. This anatomical constraint usually restricts chin advancement to a maximum of 10 mm, even if more were required for morphological purposes.

As it has already been described in literature,[35] the present series shows that the placement of a chin implant to refine genioplasty, simultaneously with chin plate removal (after one year postoperatively in two cases) (Figs. 3A-F), is a promising solution.

An intraoral approach was used in our series, due to the orthognathic surgery context and in order to avoid scaring, except in one case where a previous cutaneous scar was used. The rigidity and size of the implants make their placement somewhat uneasy and sometimes require a large mucosal incision. Therefore, whenever possible, two-piece implants such as chin implants were preferred.

Among all implant references, the “RZ design”, available for mandibular angle and malar implants, is presented as the result of anatomical studies. In our series, this reference has proved to be the most straightforward to place. According to literature,[20] both extraoral and intraoral approaches are efficient, and the risk of postoperative complications is equivalent, including infections and migration.

We recommend implant placement simultaneously with plate removal whenever possible in order to allow progressive morphological changes and lower the risk of infection.

Despite sample size, our qualitative evaluation questionnaire is the first detailed one described in literature. It might be useful to standardize the assessment of patient satisfaction.

In the light of this series and confronted to literature, standard HDPE implants appear as a relevant solution for the refinement of facial contour as an adjunct to orthognathic surgery. This is especially true, when addressing upper midface deficiency in class III patients, insufficient advancement genioplasty and facial asymmetry.

The lowest mean satisfaction score was obtained regarding the symmetry of standard implants (3.5/4), whereas the highest one was reached when customized implants were used (3.8/4). Custom designed procedures are now performed in routine maxillofacial surgery.[36,37] Subsequently, customized implants are probably the future gold standard for alloplastic facial augmentation, although their current prohibitive cost can restrict their wider use.

Since HDPE implants cannot be visualized using conventional imaging techniques, interactive segmentation of the postoperative CT scan[38] was conducted in some cases of our series to render implant position (Figs. 2F, I). It might be interesting to develop an automated segmentation procedure[39] to investigate the long-term outcomes of HDPE implants on the surrounding facial tissues.

If implant customization can allow swift and accurate fitting, no convenient preoperative planning solution exists for standard implants. The development of a software program would be quite relevant in order to allow the surgeon to plan the size and position of facial implants. Different clinical scenarios could be simulated[39] and presented to the patient so as to deliver optimal information and optimize decision making.

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CONFLICT OF INTEREST STATEMENT

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TABLES

Table 1: Sample and implant features.

Table 2: Complications after a 41-months average follow-up.

Table 3: Satisfaction questionnaire regarding the aesthetic outcome.

Table 4: Indications depending on the type of skeletal refinement.

FIGURES

Figure 1: Customized implant in the treatment of severe asymmetry (hemifacial microsomia (Goldenhar syndrome) affecting the right side). This patient underwent multiple procedures during childhood, including mandibular distraction osteogenesis and bimaxillary osteotomy after growth. Together with agenesis of the left ear, obvious asymmetry of the mandibular angles was still present. Prior to reconstructing the ear and in order to determine its appropriate position, a customized right mandibular angle implant allowed satisfactory symmetry.

1A: submental vertex preoperative clinical photograph

1B : submental vertex view preoperative 3D CT scan

1C: three-quarter preoperative clinical photograph

1D: three-quarter view preoperative 3D CT scan

1E: intraoperative photograph of customized right mandibular angle implant placed through a cutaneous approach (because of an existing scar). Note the two screws fixating the implant.

1F: submental vertex postoperative clinical photograph (6 months postoperative)

1G: submental vertex view preoperative 3D CT scan displaying the virtual surgical planning of the customized left mandibular angle implant (yellow arrow)

1H: three-quarter postoperative clinical photograph (6 months postoperative)

1I: three-quarter view preoperative 3D CT scan displaying the virtual surgical planning of the customized left mandibular angle implant (yellow arrow)

1J: intraoperative photograph of a stock mandibular implant placed through an intraoral approach in another patient. Note one of the two screws (yellow arrow) fixating the implant

Figure 2: Malar implants simultaneously placed with Le Fort I advancement osteotomy and genioplasty in a skeletal class III patient with midface deficiency.

2A: frontal view preoperative 3D CT scan

2B: frontal view preoperative clinical photograph

2C: lateral view preoperative clinical photograph

2D: lateral view preoperative 3D CT scan

2E: intraoperative photograph of malar implants placed through intraoral approach. Note the two screws fixating each implant (yellow arrows).

2F: frontal view postoperative 3D CT scan displaying malar implants (cyan) that were interactively segmented.

2G: frontal view postoperative clinical photograph (2 years postoperative)

2H: lateral view postoperative clinical photograph (2 years postoperative)

2I: lateral view postoperative 3D CT scan displaying malar implants (cyan) that were interactively segmented.

Figure 3: Chin implant placed simultaneously with plate removal of bimaxillary surgery and genioplasty allowing improved facial contour and lip competence.

3A: lateral view preoperative clinical photograph

3B: lateral view postoperative clinical photograph (bimaxillary surgery and genioplasty, 1 year postoperative)

3C: lateral view postoperative clinical photograph (chin implant placed simultaneously with plate removal,1 year after chin implantation). Note restauration of lip competence.

3D: lateral view preoperative 3D CT scan

3E: lateral view postoperative 3D CT scan (bimaxillary surgery and genioplasty)

3F: lateral view postoperative 3D CT scan (chin implant placed simultaneously with plate removal). Note that area of chin implant has been contoured in cyan because it is X-ray transparent. Also note the screws fixating the implant (yellow arrows).