Radiographic assessment of soft tissue changes with PEEK onlay versus conventional osteotomy protocol in advancement genioplasty: A randomized clinical trial

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Research Article

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Abstract

Background

The breakthroughs in virtual planning and computer guided surgeries improved the accuracy and predictability of guided surgical procedures and enhanced the use of patient specific implants. The aim of this study was to describe a radiographic method for assessment of soft tissue gain with patient specific PEEK chin implants versus computer guided advancement genioplasty in patients with retruded chins.

Materials and methods

Patients with retruded chins indicated for corrective genioplasty were recruited and randomly allocated into two equal groups; Group A received a patient specific onlay PEEK chin implant, while group B received fully computer guided advancement genioplasty. The preoperative and the one-year postoperative CT scans were superimposed and the 3D generated soft tissue contours were compared.

Results

Each group included ten patients. The mean amount of chin advancement in the osteotomy group was 8.12 mm ± 0.69 which was significantly higher than 5.22 mm ± 1.18 for the PEEK group. The mean one-year soft tissue gain in the osteotomy group was 7.63 mm ± 0.49 which was also significantly higher than 3.72 mm ± 1.7 for the PEEK group.

Conclusion

Radiographic soft tissue assessment is a reliable way of evaluation of soft tissue changes. Also, Computer guided advancement genioplasty could provide better net soft tissue gain than PEEK chin implants.

Clinical relevance:

This study emphasized the reliability of CT based soft tissue assessment and set the base for using facial laser scanning in future studies. It also proved that autogenous genioplasty is still the gold standard.

Introduction

Facial beauty relies on the form, position and symmetrical proportions of various structures. The chin is one of the most apparent facial structures that play a vital role in the overall facial appearance and judges the “human character”, contributing to the equilibrium between the nose, lips and perioral area. Only within the last quarter century surgical techniques were refined to alter the chin contour and many
genioplasty techniques were used to reach the desired goal, such as; advancement, retraction, or adjustment of height and symmetry.  

Much controversy surrounds chin surgery, mainly concerning the surgical technique, osteotomy versus alloplastic augmentation, in terms of ease of use, predictability, low morbidity, and excellence of results. Osteotomy-dependent genioplasty provides superior versatility and predictability than alloplastic genioplasty; it can be utilized to address various chin deformities and has the distinct advantage of being an autologous technique. On the other hand, placing an alloplastic chin implant is technically easier, faster and requires less dissection. Hence, it can reduce both intraoperative time and cost. Moreover, it can be performed under local anesthesia.  

The continuous advancements in three-dimensional (3D) surgical simulation, computer-aided designing and manufacturing (CAD / CAM) enabled us to deal with complex cases by virtually performing the desired intervention, then transmitting it to the operating room using virtually designed surgical stents. This resulted in less invasive operations, accurate positioning of patient-specific implants and bony segments, reduced postoperative complications and last but not least, a more precise overall assessment of the performed intervention. Attempts are also being made using surface laser scanning or stereophotogrammetric techniques to obtain a realistic three-dimensional prediction of the soft tissue envelope while augmenting the hard tissue 3D model generated from the CT scan.

Patient-specific PEEK implants are well documented in the literature for their excellent biocompatibility, adjustability, good mechanical strength properties, inertness, sterilization endurance at high temperatures and radiographic translucency. Moreover, being preoperatively tailored to the exact shape and size of the defect shortened the operative time and reduced – if there is any – need for intraoperative modifications. All that secured reliable postoperative stability together with an excellent cosmetic result. Hence, this study aimed to compare two virtually driven corrective surgical techniques for the chin that were not compared before, computer-guided genioplasty and patient-specific PEEK chin implants, regarding their impact on soft tissue gain using a new radiographic assessment method.

**Materials and Methods**

**Study design:**

This study was registered on clinicaltrials.gov with the ID: NCT04817930, approved by the research ethics committee of Cairo University's faculty of dentistry with the ref. number: 19825, and was compliant with the principles outlined in the declaration of Helsinki. It was conducted on twenty patients seeking correction of chin deficiency. All the subjects signed written informed consents.

The inclusion criteria were: adult patients above the age of 16 for females and 18 for males requiring surgical correction of retruded chin by genioplasty alone as determined from the clinical and
cephalometric tracing or those who chose the corrective chin surgery over any other orthognathic procedure. Previous chin surgery was an exclusion criterion.

Other exclusion criteria were; patients indicated for other mandibular corrective surgeries and those with systemic diseases that contraindicates general anesthesia. The selected patients were randomly allocated into two equal groups, using block randomization with stratification (Block size: 4) using a formula on Microsoft Excel software.

All patients were examined extra-orally from the facial and profile views and intraorally to assess the occlusal relationship. A Radiographic examination of preoperative computed tomographic scans (CT scans) (Siemens CT SOMARIS/10 VA10A, Siemens Shanghai Medical Equipment Ltd.) with no head tilt, zero gantry tilt, extending from the vertex to the hyoid bone with 0.2 mm slice thickness and interval, and a CT scan generated lateral cephalometric views was done to confirm that they were indicated for a chin corrective surgery and to exclude any other pathology as well.

The DICOM files (Digital Imaging and Communications in Medicine) were imported to mimics 21.0 software (Materialise, Leuven, Belgium). Masks were created for the skull and mandible as well as for the facial soft tissues and all were calculated into 3D models. (Fig. 1)

**Surgical planning and virtual simulation**

**Group A:**

A virtual corrective augmentation for the retruded chins was designed to be overlapping the inferior border of the mandible. According to the cephalometric analysis, the chin implant was designed to advance the pogonion (P) and locate it 2–4 mm behind the Nasion (N) perpendicular in females and 0–2 mm behind it in males. The mandibular surface was subtracted from the designed part to maximize its adaptation, then a minimum of 3 fixation screw vents were created. The part was exported in STL format (Standard Tessellation Language) and manufactured from radiopaque (PEEK) blocks; BioHPP (BioHPP®, Bredent, Chesterfield, UK) using a five-axis milling machine (IMES-ICORE Coritec. 250i CAD/CAM, Elterfeld, Germany). The patient specific implant (PSI) was immersed for twelve hours in a 2% glutaraldehyde (Cidex, Johnson & Johnson Co. NJ, USA) for sterilization.

**Group B:**

A curvilinear osteotomy line, 3–5 mm below the mental foramina bilaterally was drawn on the mandible to complete a virtual cut (Fig. 2). *The first template* was the cutting template, which was designed to guide the saw while executing the planned osteotomy. Boxes were added to the template, 2 above and 2 below the cut, fitting on the facial surface of the chin. Each box had a 1.05 mm hole to accommodate for monocortical 2.0 mm screws (Fig. 2).

The intended movement of the chin was virtually simulated with quantification of the planned surgical movement according to a cephalometric analysis following the same principles as group A; to locate the
pogonion (P) at 2–4 mm behind the Nasion (N) perpendicular in females and 0–2 mm behind it in males. Then the repositioning templates were designed with the chin in its new position. A template was fabricated for each side, each consisted of 2 boxes connected with two cylindrical arms with the chin in its new position and each box had a 1.05 mm hole (Fig. 2). All templates accommodated the intimate contour of the bony surface. Hence, a total of 3 bony-supported templates were designed for each patient and were exported in STL format to a plastic laser sintering additive manufacturing machine (FORMIGA P 110, EOS system, Germany) where they were manufactured from a plastic material (Polyamide 12, EOS GmbH-Electro Optical Systems).

**Surgical procedure**

All patients in both groups were operated on under general anesthesia (GA). Surgical access was performed through a mandibular vestibular approach extending from the second premolar of one side to that of the contralateral side, cutting through the mucosa first then the mentalis muscle taking care to preserve the mental nerve and its branches. For Group A, after subperiosteal dissection and bony exposure the patient-specific chin implant was installed in place. Its adaptation and extension were checked to be as planned, then fixation was done by drilling through the predesigned screw vents to accommodate the 2.0 mm fixation screws.

In Group B, the cutting template was applied to the chin first and fixed in place by 2.0 mm screws through the predesigned holes. These very holes were used again later to fix the positioning templates. Reciprocating saw was then used along the template’s guiding plane to bicortically cut the chin. The cutting template was removed and the positioning templates were fixed to the previously drilled holes on the superior part of the osteotomy. The now mobilized chin was held by a bone forceps and moved until its previously drilled holes coincided with the holes in the two lower boxes of the templates, to which it was fixed with 2.0 mm screws. The chin was fixed to the mandible using 2.0 mm titanium mini plate (Walter Lorenz, U.S.A.) (Fig. 3)

In both groups, the incision was closed in layers using a 3 – 0 polyglycolicacid (AssuCryl, Assut, Switzerland). The mentalis muscle was re-attached first then a running stitch was used to close the mucosal incision. Compression dressing was applied for 48 hours.

**Assessments and data collection method**

**Clinical assessment**

Patients were followed up every other day during the first postoperative week, to exclude any signs or symptoms of infection according to calvien dindo classification such as; redness, hotness, exudates or wound dehiscence. Then weekly till the end of the first month to further monitor the healing, resolution of edema and return to normal neurosensory function. After that, recall visits were scheduled every three months for one year.
Neurosensory recovery was assessed by seating the patients comfortably and asking them to close their eyes, a blunt caliper was used to perform the two-point discrimination test starting at 14 mm distance and decreasing gradually in increments of 2 mm while asking the patients if one or two points were felt. The light touch test was done using a cotton tipped applicator while asking if any stimulus was felt, while for the directional stroke test the patients were asked about the direction of the cotton tipped applicator moving from the right to the left or vice versa for a 1 cm distance. A dental probe was used to perform the nociceptive stimulus test, also the patients were asked about numbness and tingling sensations and their distribution and resolution.¹⁷

All tests were performed by the same operator and starting by the upper lip first to be used as reference while testing the lower lip. Data were documented and evaluated according to the Medical Research Council (MRC) scale.¹⁸

**Radiographic assessment**

Postoperative CT scan was requested one year later from all patients by the same radiologist with the same machine. The DICOM files were imported to the mimics software again and 3D skull and soft tissue models were calculated. The “image registration” module was used to import the project file of the postoperative CT scan into the preoperative project file which contains the preoperative plan; this was done by selecting landmarks on the 2D slices in each of them allowing the software to superimpose both CT data. The landmarks included the mental foraminae marked bilaterally on the axial views and the infraorbital foraminae marked on the sagittal views.

A midsagittal and Frankfurt planes were drawn to be used as references for the measurements. The midsagittal plane was drawn between the nasion (N), anterior nasal spine (ANS) and the center of the sella turcica (S) while the Frankfurt plane was drawn between the right and left orbitale (Or) and the right porion (Po). These planes were viewed on the 2D cuts then the outline of the preoperative soft tissue and bone contours was turned on so that they could be differentiated from the final contours. (Figs. 4 and 5)

For assessment, the sagittal view was used where lines were drawn perpendicular to the Frankfurt plane then three planes were drawn perpendicular to these lines and parallel to the Frankfurt plane. Along these three new planes (for each of them), the thickness of the peek onlay was measured from the bone surface to the peek outline representing the amount of chin advancement, the preoperative soft tissue thickness was measured from the bone surface to the preoperative soft tissue contour and the soft tissue gain was measured from the preoperative soft tissue contour to the final soft tissue outline and similarly for the genioplasty group except that here the amount of chin advancement was measured from the surface of the mandible to the surface of the advanced chin. The same was repeated in four more cuts. So, three measurements were taken for each outcome from each cut of the selected five cuts. Finally, an average of the 15 measurements was calculated for each outcome. All measurements were taken preoperatively and 1 year postoperatively. (Figs. 4 and 5)

**Data Analysis**
Quantitative data were explored for normality by checking the distribution of data and using normality tests (Kolmogorov-Smirnov and Shapiro-Wilk tests). All data showed normal (parametric) distribution. Data were presented as mean and standard deviation (SD) values. Student’s t-test was used to compare between the two groups. Qualitative data were presented as frequencies and percentages. Chi-square test was used for comparisons regarding qualitative variables. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp

Results

Clinical results:

The current study was conducted on twenty patients, ten in each group. Group A included 6 males and 4 females with an average age of 26.2 ± 3.9, while Group B included 4 males and 6 females with an average age of 24.9 ± 2.9. There was no statistically significant difference between the mean age values or gender distributions in both groups. (Table 1)

<table>
<thead>
<tr>
<th></th>
<th>PEEK (n = 10)</th>
<th>Genioplasty (n = 10)</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender [n (%)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6</td>
<td>4</td>
<td>0.371</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Age [Mean (SD)]</td>
<td>26.2 (3.9)</td>
<td>24.9 (2.9)</td>
<td>0.406</td>
</tr>
</tbody>
</table>

All cases proceeded uneventful with complete healing of the surgical site and resolution of all normal postoperative course except for a case in the PEEK group (Group A) that showed wound dehiscence on the first recall visit two days after the operation. It was classified as Grade I according to Calvien Dindo classification of surgical complications \(^{16}\). Strict oral hygiene instructions were given and elastic bandage was employed to limit the mentalis muscle movements. All wounds healed completely 10 days later.

Regarding the neurosensory recovery, all cases showed normal function (S4, according to the MRC scale) by the end of the first month.

Radiographic results:
Regarding the amount of Chin advancement, the average chin advancement was 5.22 mm ± 1.18 for group A while it was 8.12 mm ± 0.69 for group B with a statistically significant lower mean amount of chin advancement in the PEEK group than Osteotomy group (P-value < 0.001, Effect size = 2.995).

Regarding the Base line soft tissue thickness (preoperative), for the PEEK it was 13.92 mm ± 2.77, while it was 17.86 mm ± 1.04 for Osteotomy group with a statistically significant lower mean base line soft tissue thickness in Group A than Group B (P-value = 0.001, Effect size = 1.883).

While regarding the amount of Soft tissue gain (after one year), the PEEK group showed an average of 3.72 mm ± 1.7 while it was 7.63 mm ± 0.49 for the Osteotomy group with a statistically significantly lower mean soft tissue gain in the PEEK group than the Osteotomy group (P-value < 0.001, Effect size = 3.12). (Table 2) (Fig. 6)

<table>
<thead>
<tr>
<th>Measurement</th>
<th>PEEK (n = 10)</th>
<th>Genioplasty (n = 10)</th>
<th>P-value</th>
<th>Effect size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base line soft tissue thickness (mm)</td>
<td>13.92 (2.77)</td>
<td>17.86 (1.04)</td>
<td>0.001</td>
<td>1.883</td>
</tr>
<tr>
<td>Soft tissue gain (mm)</td>
<td>3.72 (1.7)</td>
<td>7.63 (0.49)</td>
<td>&lt; 0.001</td>
<td>3.12</td>
</tr>
<tr>
<td>Chin advancement (mm)</td>
<td>5.22 (1.18)</td>
<td>8.12 (0.69)</td>
<td>&lt; 0.001</td>
<td>2.995</td>
</tr>
<tr>
<td>Chin advancement %</td>
<td>38.3 (8.8)</td>
<td>45.5 (2.4)</td>
<td>0.022</td>
<td>1.116</td>
</tr>
</tbody>
</table>

Significant at P ≤ 0.05

**Discussion**

The recent improvements in the field of computer-assisted surgery extended to incorporate surgical correction of maxillofacial deformities. Computer-aided designing and computer-aided manufacturing (CAD-CAM) softwares are being used to fabricate surgical guides and patient specific implants aiming to correct maxillofacial deformities. Also, 3D printing technology is being used more often in orthognathic surgery and a recent systematic review studied its impact on the simplicity and precision while performing genioplasty. All that is owed to the accuracy of CT scan based virtual planning and assessment which encouraged us to conduct this study intending to compare two computer guided techniques for genioplasty, either by bony supported surgical guides or patient specific PEEK implant and evaluate their reliability and efficiency in advancement genioplasty and soft tissue gain.

Poly Ether-Ether Ketone is a polyaromatic semi crystalline thermoplastic polymer. It is chemically inert, its melting temperature is 334 °C and its modulus of elasticity is 3–4 GPa which is close to the natural cortical bone (7–30 GPa). Other materials were also implanted in various oral and maxillofacial
defects and deformities, for instance, Polydimethyl siloxane (Silastic rubber) was once widely used, however, due to the severe inflammatory tissue changes to the material, it was associated with a variety of complications through its various applications. For example; as interpositional articular device in temporomandibular joints it was associated with erosive changes of the condylar head \textsuperscript{22}, in orbital reconstruction it was associated with cystic encapsulation several years later, and as breast implant the cause of failure was their encapsulation by a firm thick capsule that is infiltrated by chronic inflammatory cells favoring fibrosis \textsuperscript{23}. Also, porous poly-ethylene implants were used in various regions as the zygoma, orbital floor, mandibular angle and chin, there were few reports of infection rates as 7.7\% for zygomatic implants and 23.7\% for mandibular angle implants. The infection cases were treated by replacing the implants \textsuperscript{24}.

In the current study, patients who agreed to have mandibular advancement simultaneous with genioplasty were excluded to eliminate the effect of this confounding variable. This was consent with several authors \textsuperscript{25}, who have revealed that mandibular procedures that accompany genioplasty affect the soft tissues of the anterior region and add to the amount of advancement. The treatment planning in this study was based on clinical examination, radiographic analysis and photographic records. Mimics software was utilized for analysis and virtual planning, segmentation of the skull model, manipulation of the bony segments, creation and adjustment of the thickness of the PEEK implant for group A or, simulation of the intra-operative surgical movements for Group B in all the three dimensions with prediction of the final chin position.

In the present study, two bony supported surgical guides were designed and fabricated for group B, a cutting guide to control the location and angulation of the saw while executing the osteotomy, and a positioning stent to transfer the virtual surgical plan to the patient intraoperatively. This was in accordance with many authors \textsuperscript{7,26–31} who virtually simulated the surgery and designed one or two guides that were 3D-printed to be used intra-operatively. Berridge et al and Keyhan et al fabricated a 3D printed-guide for the chin osteotomy \textsuperscript{32,33}. While Hsu et al and Costa et al fabricated a 3D printed-guide to reposition the chin in its pre-planned position \textsuperscript{34,35}. Some authors used both types of guides \textsuperscript{26,27,36–38}. Lim et al and Jenkins et al used a single guide to guide the cut and then reposition the chin simultaneously \textsuperscript{8,39}.

In Group A, a computer-designed patient specific PEEK implant was fabricated for horizontal chin advancement. This was in accordance with Katy Martin et al who constructed the patient specific PEEK implant using the patient’s cone beam CT scan to facilitate accurate hard and soft tissue augmentation in a three-dimensional way \textsuperscript{40}. Owusu et al also found that it offered higher accuracy and adaption to the defect, enhanced stability, more predictable outcomes and better facial contour refinement \textsuperscript{41}.

Postoperative follow-ups were uneventful for all patients in this study with no significant complications. This may be attributed to the proper handling of the Mentalis muscle, clear identification and avoidance of undue traction to the mental nerves during surgery and properly designing the implant.
Infection was not documented in either groups, this came in accordance with Alasseri et al who fabricated ten patient specific implants, eight of them were made of PEEK, to reconstruct maxillofacial deformities. Other researchers reported varying infection rates from 2.7 to 14.3% in patients with PEEK implants, Brandicourt et al. reported a single infection case (2.7%) after analyzing the outcomes of 37 PEEK cranioplasties, the alloplastic implant had to be removed later on. Järvinen et al reported an infection rate of 8.3%, which is comparable to other case series featuring craniofacial PEEK patient specific implants. Alonso-Rodriguez et al. reported a series of 14 cases with an infection rate of 14.3%, and Rosenthal et al. published a study of 65 cases and reported an infection rate of 7.7%.

Wound dehiscence occurred in only one of the patients (Group A) without apparent symptoms of acute infection which was considered as grade I Calvien Dindo classification of surgical complications. This was attributed to the large implant volume in this case to overcome the excessive retrogenia. Järvinen et al. described similar problems, he found that when an excessively large and/or sharp edged patient-specific implant attempted to be put intraorally with a comparatively thin mucous membrane it may cause wound dehiscence.

In the present study twenty patients suffering from retrogenia were included into two groups to compare between two different treatment modalities to manage chin retrusion in order to assess the clinical amount of soft tissue advancement using alloplastic augmenting material (PEEK) versus corrective osteotomy, and despite the limitation in the difficulty to recruit patients requiring the exact same amount of chin advancement in all the cases, the corrective osteotomies showed better results regarding the radiographic and clinical assessment.

The chin advancement percentage in (Table 2) accounts for the difference in pre-operative thickness. The percentage was calculated as chin advancement/Base line soft tissue thickness x 100. The results showed that chin advancement % in the advancement genioplasty group had a statistically significantly higher mean value than the PEEK group (45.5 and 38.3 respectively). Group B showed also a higher soft tissue gain where the net soft tissue gain with advancement genioplasty reached 7.63 ± 0.49, which is comparable to other studies such as the study by S. Shaughnessy et al. in which the soft tissue pogonion moved by 6.9 mm. While for the PEEK group it was 3.72 ± 1.7. Taking into account the higher chin advancement percent (Table 2) in Group B, the difference in postoperative soft tissue gain could be understood.

**Conclusion**

- The radiographic assessment of soft tissue gain by superimposition is accurate, reliable and repeatable.
- Within the limitations of the study it seems that computer guided advancement genioplasty should be preferred over a genioplasty performed with PEEK implants regarding soft tissue gain of the chin.
Declarations

A. Author Contribution

G.A.: contributed to the conception of the work and interpretation of data for the work, drafted the paper, approved of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved. I.C.: contributed to the conception of the work and interpretation of data for the work, drafted the paper, approved of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved. M.S.: contributed to the interpretation of data for the work, revised the paper critically. M.M.: contributed to the interpretation of data for the work, revised the paper critically, approved of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved. M.A.: contributed to the conception and design of the work, interpretation of data for the work, revised the paper critically, approved of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.

B. Ethics Approval and Consent to Participate

- All patients signed a preoperative informed consent.
- This study was approved by the research ethics committee of Cairo University's faculty of dentistry with the ref. number: 19825

C. Funding

“No funding was obtained for this study”.

D. Conflict of Interests

The authors have no conflict of interest to declare

Disclosure Statement

The authors have nothing to disclose within the content of this article

Clinical trials.gov registered ID: NCT04817930

References


**Figures**
Figure 1

(A & B) Showing three-dimension reconstruction of the facial bony skeleton and soft tissues respectively, and (C) Showing the virtually designed patient specific PEEK chin implant

Figure 2

(A) showing the cutting plane constructed to complete the virtual chin osteotomy, (B) Showing the cutting template consisting of 4 boxes, 2 above and 2 below the cutting plane and (C) with the positioning templates relating the mandible to the chin in its new position.
**Figure 3**

(A) showing the chin PEEK implant in group A, and (B) showing the advanced chin held by the repositioning guide before being fixed in group B

**Figure 4**
Showing preoperative and one-year postoperative sagittal views for group A (A and B respectively) and group B (A' and B' respectively)

Figure 5

Showing the superimposition of the pre and postoperative CT sagittal views for the PEEK group (A) and for the genioplasty group (B). Demonstrating the three measurements taken for each of the assessed outcomes, in group (A) from the left to the right: peek thickness, preoperative soft tissue thickness and soft tissue gain. The same in group B except for the chin advancement values that are found on the left and were measured from the surface of the mandible to the outer surface of the advanced chin.

Figure 6

Bar chart representing mean and standard deviation values for different measurements in the three groups