

## RADIOGRAPHIC ASSESSMENT OF SOFT TISSUE CHANGES IN ADVANCEMENT GENIOPLASTY: COMPUTER GUIDED OSTEOTOMY VERSUS PEEK ONLAY APPROACH: A RANDOMIZED CLINICAL TRIAL

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### ABSTRACT

**Background:** Advances in computer-aided surgeries and virtual planning have increased the precision of surgically guided techniques and have improved the utilization of specific-patient implants. The purpose of this research was to present a radiographic technique for evaluating the gain of soft tissue with computer guided advancement genioplasty versus specific-patient PEEK chin implants in patients having recessed chins.

**Materials and methods:** Patients with recessed chins who required corrective genioplasty were selected and divided arbitrarily and evenly into 2 groups. **Group A** underwent computer-guided advancement genioplasty. While, **Group B** was given a specific-patient PEEK onlay chin implant. Preoperative and 1-year postoperative CT images were superimposed, and the 3D produced soft tissue shapes were compared. Patients were provided with information on the study's purpose, as well as the potential risks and advantages associated with the surgery and treatment plan. Verbal consent was obtained from all patients to confirm their approval to participate in the present study.

**Results:** Ten patients were included in each group. The chin advancement mean in **Group A** was 7.569 mm ± 0.82 having significantly higher mean than 6.20 mm ± 1.26 for **Group B**. The 1 year gain of soft tissue mean in **Group A** was 7.195 mm ± 0.67 having significantly higher mean than 4.745 mm ± 1.65 for **Group B**.

**Conclusion:** Radiographic soft tissue assessment is a dependable method for evaluating changes in soft tissues. In addition, Computer guided advancement genioplasty may result in greater improvement of soft tissue than PEEK chin implants.

**KEYWORDS:** PEEK, Genioplasty, retruded chin, Patient specific implant (PSI), Computer guided

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**Clinical relevance:** The focus of our investigation was to highlight the dependability of CT-based evaluation of soft tissues and provide a foundation for the utilization of face laser scanning in forthcoming research. It also shown that autogenous genioplasty continues to be the established and well accepted gold method.

## INTRODUCTION

The aesthetic appeal of the face is established by the arrangement, form, and harmonious ratios of various facial characteristics. Among these, the chin, prominently visible, significantly influences facial aesthetics and is associated with perceived personality traits, harmonizing with the nose, lips, and surrounding areas. Recent decades have seen improvement in surgical techniques, including procedures like advancement, retraction, and adjustments for height and symmetry to modify chin contour and achieve the intended outcome.<sup>1-3</sup>

Chin surgery is a topic of considerable debate, particularly regarding the choice between osteotomy and alloplastic augmentation techniques, with considerations including ease of use, predictability, minimal complications rates, and quality of outcomes. Compared to alloplastic surgeries, osteotomy-based genioplasty is more predictable and adaptable since it can address a variety of chin abnormalities and has the added benefit of being an autologous procedure. Conversely placement of an alloplastic chin implant is more convenient, quicker, and involves less tissue dissection, thereby it might possibly decrease both the duration and expenses of the surgery. Furthermore, the procedure may be performed with local anesthetic.<sup>4,5</sup>

Ongoing progress in three-dimensional (3D) surgical modeling and computer-assisted design as well as fabricating (CAD/CAM) have allowed researchers to address intricate cases<sup>6</sup> by digitally executing required intervention and then transferring it to the operating theatre via surgically prepared guidance.

As a consequence, less invasive surgeries, precise placement of specific-patient implants and bone segments, decreased postoperative problems

& overall evaluation accuracy of the performed intervention is enhanced. Additionally, efforts are being made to enhance the 3D model of the hard tissues generated by the CT scan by utilizing surface laser scanning technique to provide a realistic 3-dimensional divination of the soft tissue envelope.<sup>7,8</sup>

Many literatures<sup>9,10</sup> provide evidences of the superior adjustability, biocompatibility, mechanical strength qualities, sterilization durability at elevated temperatures, and radiological transparency of specific-patient PEEK implants. Additionally, being precisely shaped and sized to the defect before surgery decreased the amount of time needed for the procedure and, if necessary, the requirement for intraoperative adjustments.<sup>11</sup> Together with an excellent esthetic outcome, all of it ensured dependable postoperative stability<sup>12-15</sup>. Therefore, utilizing a novel radiographic evaluation technique, this study intended to evaluate the effects of two different virtually driven surgical methods for the chin: computer-guided genioplasty and specific-patient PEEK chin implants, with respect to soft tissue gain.

## PATIENTS AND METHODS

This study was directed to 20 patients seeking chin deficiency corrections. The inclusion criteria comprised adult patients, aged 18 for males and above 16 for females, necessitating surgical repair of a chin retrognathia solely through genioplasty. While exclusion criteria included patients with previous chin surgery, patients eligible for alternative mandibular correction operations, or having systemic disorders incompatible with general anesthesia. Chosen patients underwent random allocation into 2 equally sized groups using block randomness with stratification (Block size: 4) employing a method in Microsoft Excel.

Patients included in the study were educated verbally about the nature of the study as well as risks & benefits of the procedure & the treatment plan. Verbal consents from all patients were taken for their approval to participate at the current study.

Every patient underwent extraoral and intraoral examinations to evaluate occlusal relationships. Preoperative CT scans without head tilting, spanning from the vertex to the hyoid bone, with 0.2 mm intervals and thickness, along with lateral cephalometric views, confirmed suitability for chin corrective surgery and ruled out other pathologies. DICOM files were loaded into Mimics 21.0 software for 3D modeling, including masks for the skull, mandible, and facial soft tissues, all of which were utilized in creating 3D models. (Fig 1)

**Group A :** A curvilinear osteotomy line, positioned 3–5 mm beneath the mental foramina on both sides of the mandible, was sketched to delineate a virtual incision (Fig 2). The primary template, referred to as the cutting template, was devised to direct the saw during the intended osteotomy (Fig 3). Boxes have been integrated into the template, placed 2 higher and 2 beneath the incision, aligning with the facial contour of the chin. Every box featured a 1.05 mm aperture to fit monocortical 2.0 mm screws. Projected motion of the chin was digitally replicated, with precise quantification of the designed surgical adjustment based on cephalometric analysis, complying with identical concepts as **Group A**, aiming to position the pogonion (P) 2–4 mm posterior to the Nasion (N)

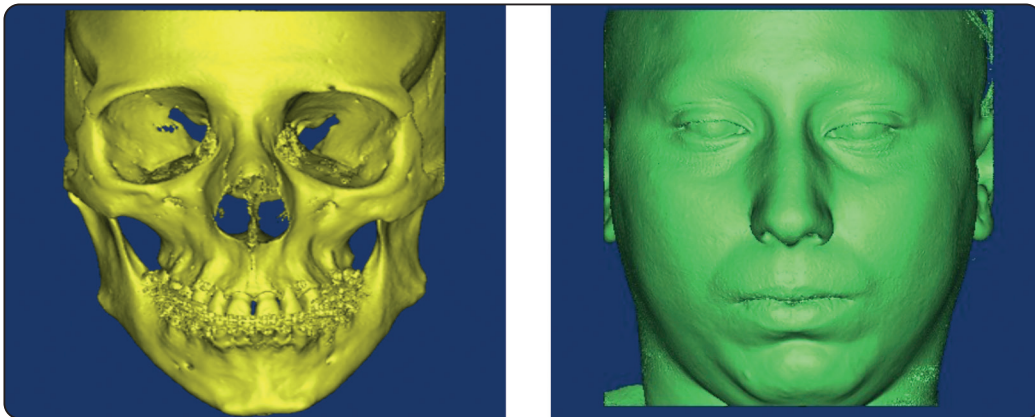


Fig. (1) Showing Three-Dimensional of the facial bony skeleton and soft tissue respectively

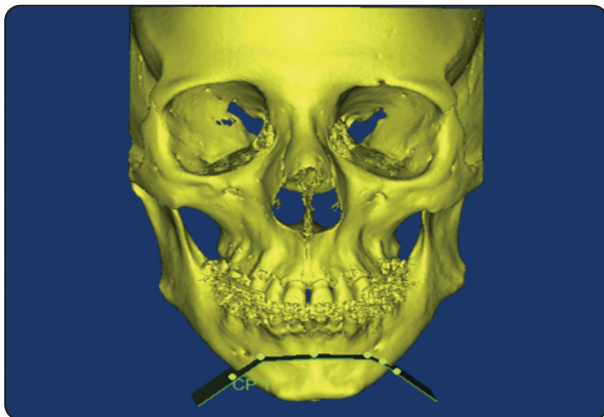


Fig. (2) showing the cutting plane which designed to complete virtual osteotomy of the chin for Group A

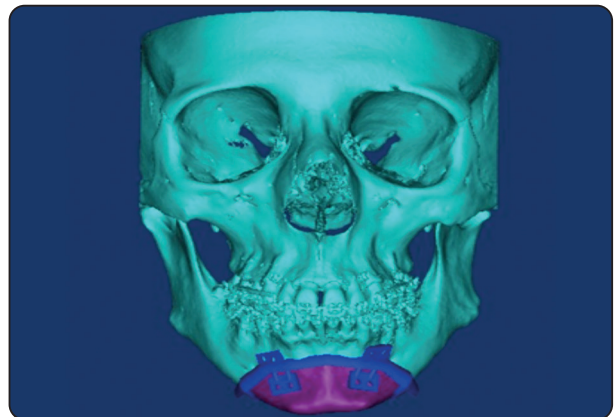


Fig. (3) Showing first cutting template which direct the saw during the intended osteotomy

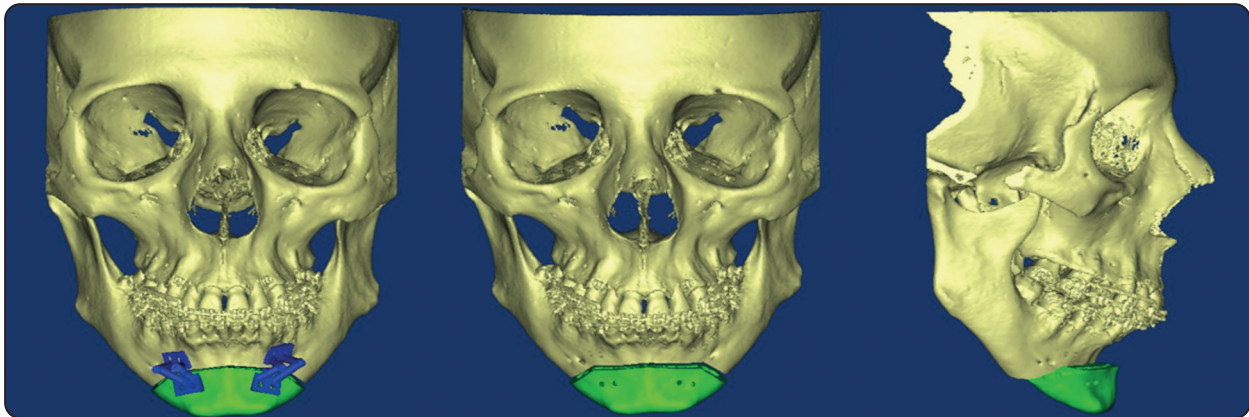


Fig. (4) Showing secondary repositioning templates were formulated to reflect the updated location of the chin.

perpendicularly in females and 0–2 mm posterior in males. Subsequently, secondary repositioning templates were formulated to reflect the updated location of the chin. (Fig 4)

All templates conformed closely to the contour of the bony surface. Consequently, three templates supported by bones were devised for every patient and then converted into STL format to a plastic laser based additive fabricating machine (FORMIGA P 110, EOS system, ermany), the templates were sculpted from a plastic substance known as Polyamide 12, produced by (EOS GmbH-Electro Optical Systems).

**Group B:** An innovative digital augmentation for correcting chin retrusion was devised to overlap the



Fig. (5) Showing the virtually designed patient specific PEEK implant for Group B

lower border of the jawbone. Utilizing cephalometric evaluation, the chin implant was meticulously designed to the pogonion (P) forward. (Fig 5) To ensure optimal adaptation, the mandibular surface was subtracted from the design, and a minimum of 3 screw vents for fixation were integrated. Subsequently, the design was exported in STL format (Standard Tessellation Language) and fabricated from radiopaque (PEEK) blocks, specifically BioHPP (BioHPP®, Bredent, Chesterfield, UK), using a state-of-the-art five-axis milling machine (IMES-ICORE Coritec. 250i CAD/CAM, Elterfeld, Germany). Following manufacturing, the specific-patient implant underwent a 12-hour immersion in a 2% glutaraldehyde solution (Cidex, Johnson & Johnson Co. NJ, USA) for sterilization.

### Surgical Procedures

Under general anesthesia (GA), all patient in both groups had surgery. Using a mandibular vestibular approach, surgical access was extended from the second premolar on one side to its counterpart on the opposite side. The mucosa was first incised, then dissection via the mentalis muscle, throughout the dissection procedure, the mental nerve and its branches were meticulously preserved. **For Group A**, the cutting template was affixed to the chin initially and secured in place with 2.0 mm screws through the predetermined holes. (Fig. 6-A) Subsequently,

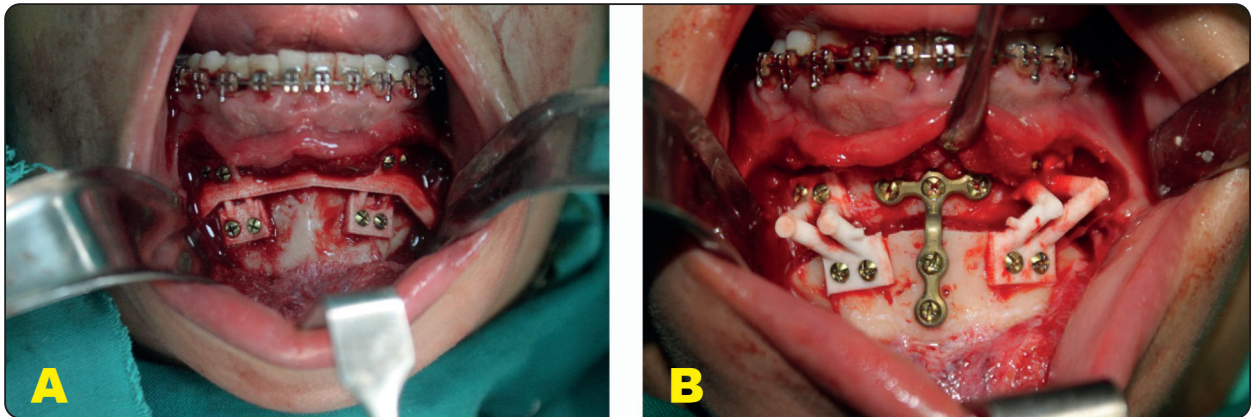


Fig. (6) (A) showing intraoperative cutting templet. (B) Showing the advanced chin held by repositioning template before and after being fixed in Group A

reciprocating saw was employed along the guiding plane of the template to bicortically incise the chin. After removing the cutting template, the positioning templates were affixed to the previously drilled holes on the upper aspect of the osteotomy. With the chin now mobilized, it was manipulated until its pre-drilled holes aligned with those in the two lower boxes of the templates, and secured with 2.0 mm screws. Finally, the chin was stabilized to the mandible using 2.0 mm titanium mini plates (Walter Lorenz, U.S.A.) (**Fig. 6-B**). Meanwhile, in **Group B**, the specific-patient chin implant was placed in situ following subperiosteal incision and bone exposure. After verifying that its extension and adaption went according to plan, the 2.0 mm fixing screws were inserted by drilling through the pre-



Fig. (7) showing intraoperative fixation of the patient specific chin peek implant for Group B

made screw vents (**Fig. 7**) Closure of the incision involved layered suturing using 3-0 polyglycolic acid (AssuCryl, Assut, Switzerland).

#### Clinical assessment

All patients received regular follow-up assessments during the first postoperative week, in order to identify and treat any possible infection-related signs or symptoms (such as redness, warmth, discharge, or wound opening) according to the Calvien Dindo classification.<sup>(16)</sup> Then weekly follow-ups were then scheduled until the end of the first month in order to track the healing process, the decrease in edema, and the return of normal neurosensory function. Following that, recall visits were arranged for a period of one year, every three months for a duration of one year. The assessment of neurosensory recovery was conducted by subjective testing techniques, such as the directional stroke test, light touch test, and two-point discrimination test. Likewise, nociceptive stimuli were administered using a dental probe<sup>(17)</sup>, and patients described any tingling or numbness as well as the location and resolution of such symptoms. Every evaluation was carried out by the same operator; the upper lip was assessed first to establish a baseline before the lower lip was examined. The data was recorded and assessed using the Medical Research Council (MRC) scale.<sup>(18)</sup>

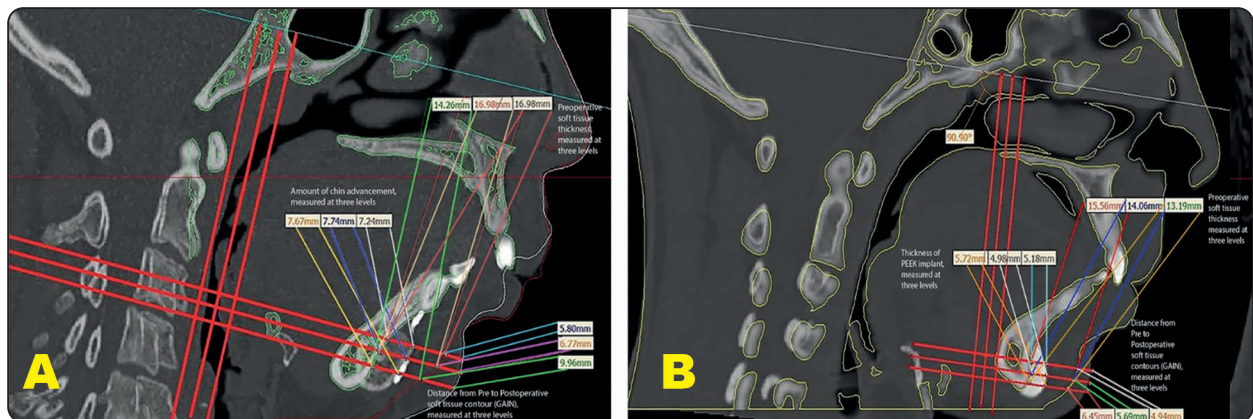


Fig. (8) (A) Showing the superimposition of the pre and postoperative CT sagittal view for Group A. (B) Showing the superimposition of the pre and postoperative CT sagittal view for Group B

### Radiographic assessment:

One year postoperatively, a CT scan was conducted for all patients by the exact radiologist using the exact machine. The resulting DICOM files were once again loaded into the Mimics software to generate 3D models of the skull and soft tissues. Utilizing the “image registration” module, the project file of the postoperative CT scan was imported into the preoperative project file, containing the initial plan. This process entails selecting distinctive features on the 2D slices in each scan to enable the software to overlay both sets of CT data.

The assessment mostly depended on the sagittal view, where perpendicular lines were made to the Frankfurt plane. Subsequently, three planes that were perpendicular to these lines and parallel to the Frankfurt plane were defined. Measurements were collected for the thickness of the PEEK onlay (indicating chin advancement), preoperative soft tissue thickness, and soft tissue gain along each of these three planes. In the genioplasty group, the measurement of chin advancement was taken from the surface of the mandible to the surface of the advanced chin. This resulted in three measurements for each outcome from each of the five selected cuts. Measurements were recorded pre-operative and again one-year post-operative. (Fig.8 A&B)

### Statistical Analysis

Collected data were statistically analyzed using SPSS ver. 22 software (statistical package for social science on windows 2013) with probability value ( $p \leq 0.05$ ). Changes in preoperative and postoperative data regarding soft tissue gain and chin advancement in the same group were evaluated using the Student T test (paired) to assess the significance of the difference. The groups were then compared to each other similarly using ANNOVA test (Analysis of variance).

## RESULTS

### Demographic results

The current study involved 20 patients, divided equally in the two groups. **Group A** consisted of 5 males and 5 females with age average of 25.3, while **Group B** consisted of 6 females and 4 males with age average of 23.9. There was no statistically significant variance between the mean gender distribution nor age values between both groups ( $P > 0.05$ ). (Table 1)

All patients had full healing at the surgical site and resolution of the postoperative course, except for one instance in **Group B**, which exhibited wound dehiscence during the initial follow-up visit, three days after the operation. Based on the Calvien Dindo categorization of surgical

TABLE (1) Comparison between demographic data results in the two groups

Gender	(Group A) computer guided genioplasty	(Group B) PEEK Implant
female	5	6
male	5	4
age	25.3 years	23.9 years

TABLE (2) Comparison between different results of measurements in the two groups

Measurement	Group A	Group B	P-value
Base line soft tissue thickness (mm)	17.10(1.44)	14.88 (2.12)	0.014
Soft tissue gain (mm)	7.19(0.67)	4.74(1.65)	0.00
Chin advancement (mm)	7.56((0.82)	6.20(1.26)	0.01

\*: Significant at  $P \leq 0.05$

complications, it was categorized as Grade 1. The patient was given clear instructions on how to maintain good oral hygiene. An elastic bandage was used to restrict the mobility of the mentalis muscle. The wound fully healed after 10 days. By the conclusion of the first month, all cases had normal neurosensory recovery, as indicated by a score of S4 on the MRC scale.

**Radiographic results:**

The preoperative base line soft tissue thickness was 17.101 mm ± 1.446 for **Group A** and 14.882 mm ± 2.125 for **Group B**. There was a statistically significant reduced mean in **Group B** compared to **Group A** ( $P \leq 0.05$ ). Regarding the increase in soft tissue after one year after surgery, **Group A** demonstrated an average gain of 7.195 mm ± 0.67, while **Group B** exhibited an average gain of 4.745 mm ± 1.65. The mean gain in **Group B** was substantially smaller than that in **Group A**, with a statistical significance of ( $P \leq 0.05$ ). The average amount of Chin advancement for **Group A** was 7.569 mm ± 0.82, whereas for **Group B** it was 6.20 mm ± 1.26. There was a statistically significant lower mean in **Group B** compared to **Group A** ( $P \leq 0.05$ ). (Table 2) and (Fig. 9)

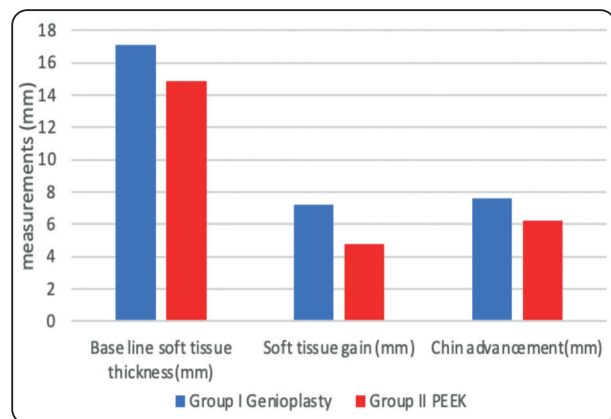


Fig. (9) Bar chart representing mean + (SD) values for different measurements in the two groups

**DISCUSSION**

Advances in computer-assisted surgery have now expanded to include the correction of maxillofacial deformities. Utilizing CAD-CAM software, surgical guides and specific-patient implants are designed to address these abnormalities<sup>(6)</sup>. Furthermore, the application of 3D printing technology in orthognathic surgery is expanding, particularly in genioplasty procedures, as evidenced by recent research assessing its effects on accuracy and usability. Therefore, this study aims to compare the efficacy of 2 computer-guided techniques used in

genioplasty: surgical guides bony supported versus specific-patient PEEK implants, evaluating their solidity and effectiveness in achieving advancement genioplasty and soft tissue augmentation.<sup>(19-24)</sup>

To maintain methodological consistency and eliminate the potential confounding effects, our study intentionally excluded patients undergoing simultaneous mandibular advancement with genioplasty. This was with agreement of previous research<sup>(25)</sup> which highlighting the impact of concurrent mandibular procedures on soft tissue in the anterior region, potentially influencing the degree of advancement.

Our treatment planning approach was comprehensive, integrating clinical assessments, radiographic analysis, and photographic documentation. For **Group A**, the software facilitated the simulation of intraoperative surgical movements across all dimensions, providing insights into the anticipated final chin position. While for **Group B**, Utilizing Mimics software, we conducted detailed evaluation and virtual planning, including skull model segmentation, guiding of different bone segments, and customization of PEEK implant thickness

Poly Ether-Ether Ketone (PEEK) is a semi-crystalline thermoplastic polymer with aromatic properties was used in **Group B** as specific-patient implant as it exhibits chemical inertness, a high melting temperature of 334 °C, and an elasticity modulus of 3–4 GPa, similar to that of natural cortical bone (7–30 GPa).<sup>(21)</sup> Various materials have been utilized in oral and maxillofacial deficiencies and abnormalities. For occurrence, Polydimethyl siloxane (Silastic rubber) was previously popular but led to severe inflammatory tissue reactions and associated complications across different applications.<sup>(22,23)</sup> Additionally, porous polyethylene implants were utilized in multiple areas, as the chin, zygoma, orbital floor and angle of the mandible, with reported infection rates of 23.7% for mandibular angle implants and 7.7% for zygomatic implants. Treatment for infection cases typically involved implant replacement.<sup>(24)</sup>

In this study, For **Group A**, 3 surgical guides were particularly developed and produced, which were supported by bone. One cutting-guide stent which precisely manipulate the location and angle of the saw during osteotomy execution, the other two positioning-stents acted as a positioning aid to accurately carry the virtual surgical plan to the patient during the procedure. This was consistent with the findings of other studies<sup>(7,26-31)</sup> who utilized virtual simulations to construct and create 3D-printed surgical guides for use during surgeries.

For instance, **Berridge et al. and Keyhan et al.**<sup>(32,33)</sup> developed a 3D-printed guide specifically for chin osteotomy, while **Hsu et al. and Costa et al.**<sup>(34,35)</sup> designed guides to realign the chin to its preplanned location. While others used both types of guides.<sup>(8,26,27,36–39)</sup>

While for **Group B**, a specific computer-designed PEEK implant for each patient was fabricated to advance the chin horizontally. This was in conformation with **Katy Martin et al.**<sup>(40)</sup>, who utilized the patient's cone beam CT scan to create a specific-patient PEEK implant, enabling precise augmentation of both hard and soft tissues in three-dimensions. Additionally, **Owusu et al.**<sup>(41)</sup> noticed that it provided better precision and fault adaptation, improve stability with more expected results and higher facial contour refinement

In the current study, postoperative follow-ups for patients proceeded smoothly without any notable problems. It can be accredited to careful manipulation of Mentalis muscle, precise detection, abstain of excessive traction on the mental nerves intra-operatively, as well as the appropriate design of the implant. There were no documented cases of infection in either group, consistent with the findings of **Alasserri et al.**<sup>(28)</sup>, who utilized 10 specific-patient implants, 8 of which were composed of PEEK, for maxillofacial deformity reconstruction. Other studies have recited varying infection degrees ranging from 2.7% to 14.3% in patients with PEEK implants, **Brandicourt et al.**<sup>(9)</sup>



observed a case of infection (2.7%) following the analysis of the outcomes of 37 PEEK cranioplasties, necessitating the later removal of the alloplastic implant. In comparison of other case series **Järvinen et al.**<sup>(29)</sup> recorded infection degree of 8.3%, involving craniofacial PEEK specific-patient implants. **Alonso-Rodriguez et al.**<sup>(30)</sup> documented an infection rate of 14.3% in a series of 14 cases, while **Rosenthal et al.**<sup>(31)</sup> reported a 7.7% infection rate in a study of 65 cases.

In the present study, Wound dehiscence was observed in just one patient (**Group B**) without obvious signs of acute infection, categorized as grade I according to the Clavien-Dindo<sup>(16)</sup> classification of surgical complications. This outcome was attributed to the considerable size of the implant required to address this case with severe retrognathia. **Järvinen et al.**<sup>(29)</sup> similarly discussed such challenges, emphasizing that the insertion of very large sharp-edged patient-specific implant into the oral cavity with a thin mucosal membrane could result in wound dehiscence.

In this study, 20 patients diagnosed with retro-gnathic chins were divided into 2 groups to evaluate and compare 2 distinct treatment methods for addressing chin retrusion. The objective was assessment of the degree of soft tissue advancement achieved through the use of corrective osteotomy versus alloplastic augmenting material (PEEK). In spite of difficulties in finding patients requiring precisely matched amounts of chin advancement, corrective osteotomy yielded better results in both radiographic and clinical evaluations.

The percentage of chin advancement in (**Table 2**) reflects variations in pre-operative thickness. It was calculated as chin advancement divided by baseline thickness of soft tissues, multiplied by 100. Our findings indicated the advancement genioplasty group (**Group A**) had a statistically significant greater mean chin advancement percentage compared to the PEEK group (**Group B**). Additionally, **Group A** demonstrated greater

soft tissue gain, with advancement genioplasty resulting in a net soft tissue gain of  $7.195 \text{ mm} \pm 0.67$ , similar to findings from previous investigators like **S. Shaughnessy et al.**,<sup>(42)</sup> where pogonion soft tissue moved 6.9 mm. In contrast, the PEEK group showed a net soft tissue gain of  $4.745 \text{ mm} \pm 1.65$  considering the higher chin advancement in **Group A** (**Table 2**), the difference in postoperative soft tissue gain becomes evident.

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