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ORIGINAL ARTICLE
Reconstructive

Simulating the Morphological Changes of Facial Deformities after Using 3D-printed Polyether Ether Ketone Facial Implants

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Background: Patient-specific implants (PSIs) have been presented as an effective solution for diseases that require reconstruction. PSIs are designed to precisely fit anatomical defects or deformities in terms of shape and size. In addition to the possibility of predicting the results of surgery regarding soft tissue changes.
Methods: A research sample consisting of 10 patients with facial deformities underwent maxillofacial reconstructive surgery between 2020 and 2021 in the Tishreen University Hospital, Syria. All patients underwent computed tomography scans; then, the design of the required facial implant was carried out, and the three-dimensional soft tissues were reconstructed using the ExoCad 3.0 program based on the computed tomography. The final form of the facial implant was printed from polyether ether ketone, and then surgical work was performed. The patients were followed up after 6 months. Then, a comparison was made between the virtual design and the real result.
Results: The absolute difference between the expected soft tissue changes result and the actual result did not exceed three-tenths for all patients, and only two of 10 patients had measurements higher than 20%.
Conclusions: This technique can be relied upon with the placement of implants to predict the outcome of the surgical procedure in terms of morphological changes in the facial soft tissues covering PSI polyether ether ketone. Therefore, it is possible to make a virtual design based on the cosmetic requirements of the patient.
(Plast Reconstr Surg Glob Open 2024; 12:e6029; doi: 10.1097/GOX.0000000000006029; Published online 6 August 2024.)

INTRODUCTION

Reconstructive plastic surgery for deformities of the maxillofacial region is difficult to perform, even by an experienced surgeon, due to the complex anatomy of the head and the specificity of each deformity.[1] These defects arise after tumor surgery, trauma, congenital malformations, or stubborn infections, especially in our current time, which is witnessing a large spread of war injuries and tumors. The spread of the COVID-19 virus may have been accompanied by the emergence of black fungus cases, which are accompanied by huge defects of the maxillofacial region.[2]

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Received for publication February 24, 2024; accepted June 3, 2024.

DOI: 10.1097/GOX.0000000000006029

Autologous bone graft reconstruction techniques have been around for a long time, and autologous bone grafts have become the gold standard in reconstructing cranial defects, due to their advantages of low costs and bioreceptive properties. However, the processes of demolition, construction, and remolding result in limited volume of the graft that can be harvested, deformities that can affect the graft donor site, and difficulty of forming the graft appropriately, in addition to the morphological and size changes in the graft. These factors have prompted the search for new reconstruction techniques and materials. The need to restore the defect in the best possible way while reducing the time required to complete the surgical operation is important for surgeons to improve the results of surgical operations and patient satisfaction from a functional and aesthetic standpoint.[3] Subsequently, allografts, xenografts and synthetic and biological biomaterials have been used, but their limited quantity and difficulty in shaping have restricted their use in large-sized deformities.[4] With the development of radiography and magnetic resonance imaging (MRI) techniques, and

Disclosure statements are at the end of this article, following the correspondence information.

three-dimensional (3D) printing techniques for biomaterials, patient-specific implants (PSIs) have been introduced as an effective solution in these cases, as they are designed to precisely fit defects or deformities in terms of shape and size. The need to design PSIs has led to many innovations and technological advances in medicine.[5,6] Modern technologies such as additive manufacturing (AM), known as rapid prototyping, or 3D printing have been developed rapidly and have had a positive impact on the biomedical sector over the past decade, allowing surgeons and researchers to manufacture and use models.[7,8] Recently, the US Food and Drug Administration approved 3D-printed implants under 510K, which will allow the medical sector to use AM models in routine and complex surgical procedures.[3–9] With all these developments, AM has emerged as the main manufacturing technology recognized in medicine for designing anatomical models, surgical implants, surgical guides, prosthetics, and biofabrication.[10]

Several studies have been published proposing the use of AM in 3D printing of cells; blood vessels; bones; ears; bronchioles, including jawbones; and in the future, even corneas.[11] Three-dimensional-printed medical models are widely used in orthopedic, plastic, cardiac, and maxillofacial surgery, providing the opportunity to improve the level of treatment provided to patients.[12]

Many materials are used in 3D printing, such as metals, ceramics, and polymers. Metals include gold, titanium, stainless steel, titanium alloys, and cobalt chromium alloys. They are widely used in hospitals, either as permanent prostheses, such as artificial knees, hips, cranial prostheses, and dental implants, or as temporary implants (such as plates, screws, and rods) to stabilize bone fractures.[13] Many minerals are incompatible with MRI, so the possibility of examining the patient with MRI is limited, and the long-term presence of minerals in humans can lead to a hypersensitivity reaction and resorption of the bone.[14] Due to these reasons, ceramic materials have been used as alternative biomaterials. Ceramic materials such as metal oxides, calcium phosphate, and glass ceramics are commonly used, but they are not resistant to breakage, and therefore, not suitable for medical applications subject to pressure or stress.[13] Therefore, we turned to polymers, from which polyether ether ketone (PEEK) emerged as a good option for the manufacture of PSIs. PEEK is characterized by bioreceptivity, high-temperature tolerance, chemical resistance, stress resistance, lightness of weight, high resistance to deformation, hardness and durability, and a modulus of elasticity close to that of bone.[14]

Takeaways

Question: Is it possible to predict the cosmetic result before performing surgery to place a facial implant printed from polyether ether ketone?

Findings: A limited number of studies have studied the morphological changes in the face associated with the placement of facial implants, so we studied these changes on a number of patients who were treated using three-dimensional facial implants.

Meaning: This technique can be relied upon with the placement of implants to predict the outcome of the surgical procedure in terms of morphological changes in the facial soft tissues, Therefore, it is possible to make a virtual design based on the cosmetic requirements.

MATERIALS AND METHODS

This study complied with the Declaration of Helsinki and the International Conference on Harmonization and Good Clinical Practice and was approved by the Scientific Research Board Resolution, Tishreen University, Syria (SRBR-T.24/2/2020). This trial was registered on the ClinicalTrials.gov site, with identification NCT05348434. This study is a prospective clinical study, as it included patients visiting the department of oral and maxillofacial surgery, Tishreen University Hospital, Lattakia, Syria, during the period between 2021 and 2022, who had deformities in the facial area. The inclusion criteria comprised patients with war injuries in the maxillofacial region, patients with tumors in the maxillofacial region who had undergone a previous surgical procedure that resulted in a material deficiency in the hard tissues, patients with mucormycosis (the restoration and reconstruction phase), cases of severe chin recession, patients with congenital deformities (secondary repair of cleft palate), and patients with hemifacial syndrome. Exclusion criteria were patients with mucormycosis in the active stage, patients with tumors in the recovery stage, and patients with infection in the area receiving the facial implant and lack of sufficient soft tissue to cover the facial implants. Patients were received and their cases were diagnosed in the department of oral and maxillofacial surgery, Tishreen University Hospital, where all laboratory tests, surgical procedures, radiological imaging, and follow-up of patients were performed.

The computed tomography (CT) scan device used in this research is Toshiba model cxxg_010A JABAN. The printer used in this research is PEEK 3D Printer Katna, PEEK medical wires with 1.75-mm-thick fibers, especially for medical use (Evonik Industries AG, Germany). This wire is a semicrystalline polymer with a density of 1.30 g/cm^3 and a tensile strength of 97 MPa. The 3D scanning system used in the research is Medit T710. All patients underwent a CT scan, under the condition of providing a large number of slices (more than 200 slices) per axis, and the thickness of each slice to be less than 1 mm with a 64-bit resolution. Representative models of the patient anatomical data were created based on the radiated raw data of the patient obtained via Digital Imaging and Communications in Medicine (DICOM) from the CT scan. The DICOM format is 0.3–0.6 mm thick, depending on the anatomical region. The medical modeling software (EXoCad3.0) was used to compile DICOM data at the axial, sagittal, and coronal planes and then to create a 3D virtual model of the anatomical region (Fig. 1). The surgeon and the manufacturing technician then approved

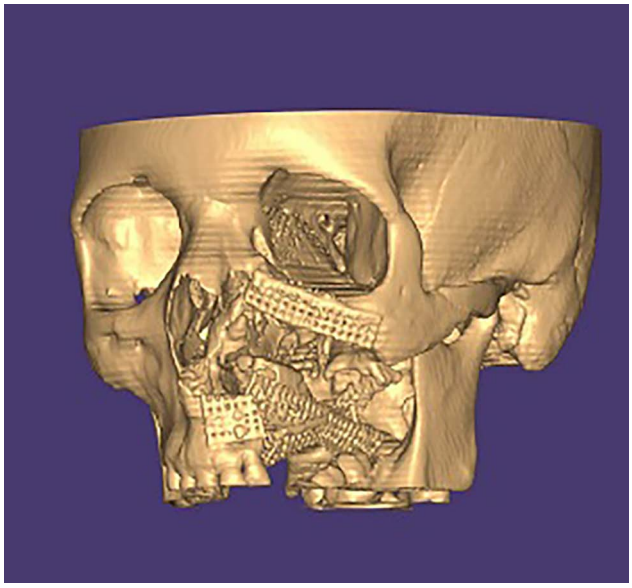

Fig. 1. A 3D CT scan.

the design format and any modifications required, with the proposed areas for placing the titanium screws for the installation of the facial implant (Fig. 2). After completing the final design of the facial implant according to the requirements of each disease case within the research, the 3D soft tissues were reconstructed using the ExoCad 3.0 program based on the CT scan of the area available to us, where the soft tissues in the facial implant area were displaced at a fixed value equal to the maximum value. Commonly, there is a thickening of the soft tissue in that area that is proportional to the shape and size of the facial implant (Fig. 3). The final virtual model of the facial implant was exported as a stereolithography file and sent to the 3D printer, which was eventually printed for the patient (Fig. 4). The printer used in this study is a prototype of OO-Kuma Katana HT PEEK 3D Printer. After the process of printing, the facial implant is steamed using an autoclave sterilizer at 134 °C under a pressure of 311 kPa for 3 minutes and then encapsulated. The surgical work on the patients was performed under general anesthesia at the Tishreen University Hospital, at an appropriate surgical entrance depending on the size and location of the deformity. The facial implant was checked to be suitable before stabilization, and any necessary modifications were made during the surgical process. The PSI was fixed in place using 1.5–2.0 mm sized titanium screws, and all patients received ceftriaxone 1 g IV and 0.5 g IV of metronidazole during the procedure (Fig. 5). After the surgery, patients received two doses of amoxicillin/clavulanic acid, and metronidazole 0.5 g per day for a week was given. We asked patients not to put pressure on the surgical area and to stop smoking for 2 weeks, especially in cases having an intraoral incision. The sutures were removed after 10 days post surgery. The patients were followed up after 6 months (Fig. 6) (a three-axis CT scan of the skull was performed with the same standard specifications as the basic image). To evaluate the deviations and the accuracy of the preoperative soft tissue simulation, a 3D partial comparison analysis was performed using 3-Matic Medical 13.0 software. The software's built-in comparison analysis feature uses the iterative closest point algorithm to calculate the closed point distance between surface triangles of 3D surface meshes of the patient's facial soft tissue in the facial implant placement area (presumptive expected outcome and final postoperative outcome) which are modeled based on multislice CT images. A color-coded surface distance map was created, which defined measurements as mean, mean differences (positive and negative deviations), SD, and root mean square (RMS). These different color images were used to qualitatively examine the congruence or discrepancy between the planned outcome

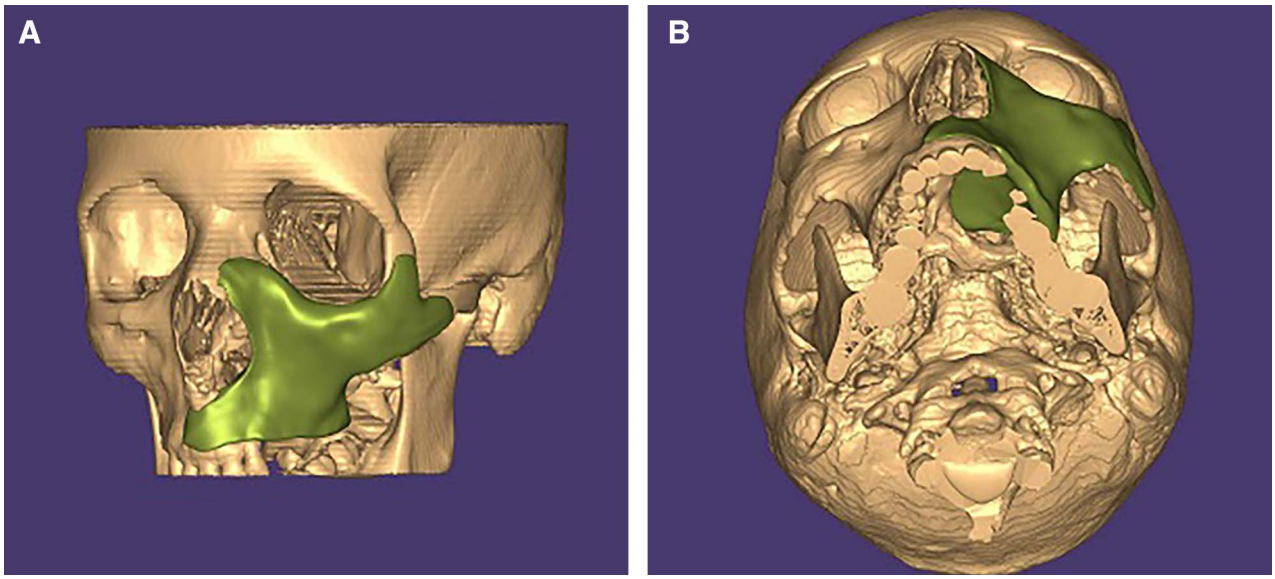

Fig. 2. Virtual 3D design for PSI. A, Front view. B, Sagittal view.

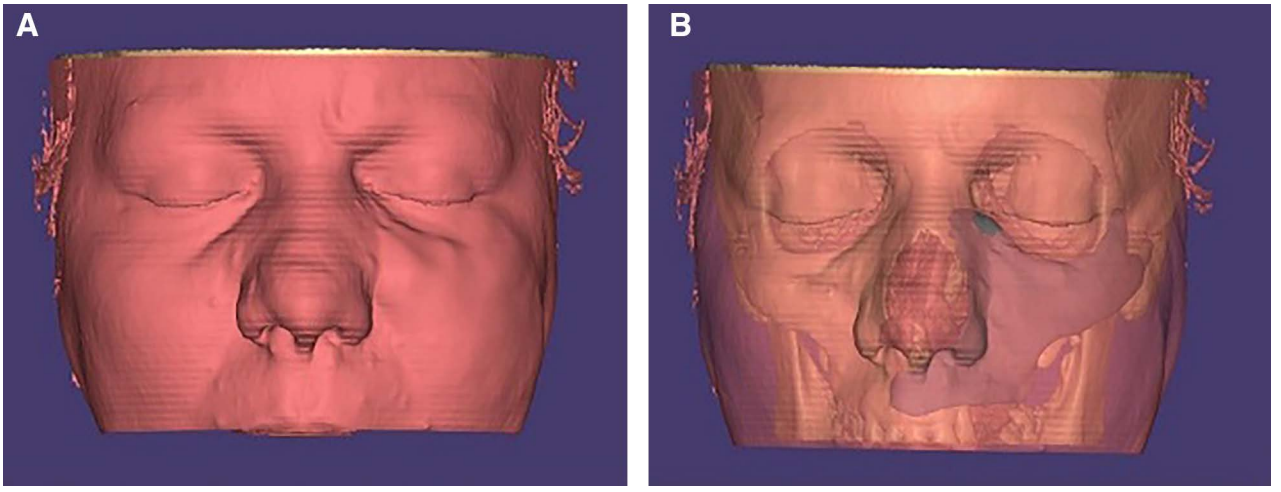

Fig. 3. Virtual 3D design of facial soft tissues. A, Without transparency to show the implant. B, With transparency to show the implant.

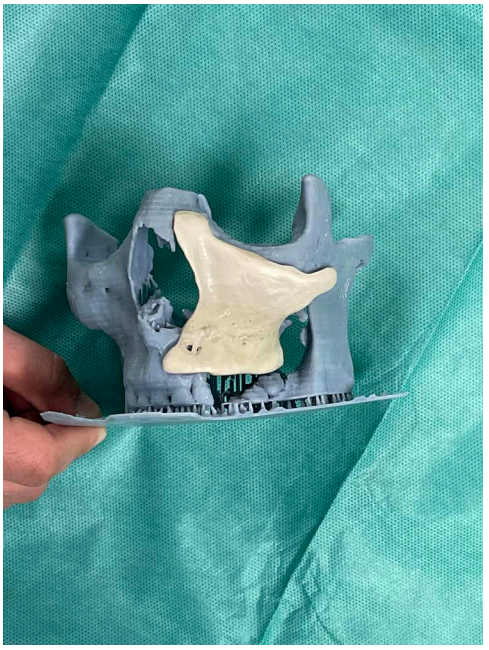

Fig. 4. Photograph of printed PEEK PSI.

before surgery and the outcome after surgery. The software algorithm automatically matched and calculated deviations between closest point pairs. The RMS value was calculated using the following equation: RMS = vt 1 2 Xn i = 1 × 2 (Fig. 7).

The work was carried out in accordance with the STROCSS criteria[15] and was registered in the US National Library of Medicine under the identifier NCT05348434.

Description of the Research Sample

Research Sample by Sex

The majority of the sample were female [seven (70%)] patients, whereas three (30%) were male patients (Tables 1 and 2).

RESULTS

Descriptive Statistics

It was noted that the average difference between the expected hypothetical result and the final result after surgery was −0.12, ranging from −0.28 as a minimum to 0.2 as a maximum, with a very small mean square error of 3.2% (Table 3).

The Hausdorff distance between the expected hypothetical result and the final result after surgery was calculated according to the following relationship. It was found that its value was 0.27 (0.05–0.2), the median value was 0.12, and the interquartile range was 0.08.

Table 4 shows the absolute difference between the hypothetical expected result and the final result after surgery for each implant. If the difference is in favor of the real result, it is shown in red.

It was noted that the absolute difference did not exceed three-tenths for all patients, and that only two of 10 patients had measurements higher than 20%. In general, it can be said that the technique used achieved excellent results, as an absolute difference that does not exceed 0.3 is considered excellent, and therefore, it can be relied upon. This technique, along with the placement of implants, is used to predict the outcome of the surgical procedure in terms of morphological changes in the soft tissue covering the implants.

The results of our research showed that the rate of infection complications after a week was 10% and after a month was 20%. The infection symptoms disappeared after 3 months when they were treated appropriately. One early case of infection was noted after a week for a patient who was diagnosed with a previously treated tumor that was treated with PSI for the jaw. The maxillary, zycomatic, and nasal bones were treated medicinally and then disappeared after 1 and 3 months. It was also noted that there was a case of exposure of the facial implant after a month for a case diagnosed with hemifacial dysplasia syndrome. It was treated with a PSI for the angle of the lower jaw. The exposure was later covered, as well. It was noted that there was a case of exposure of the

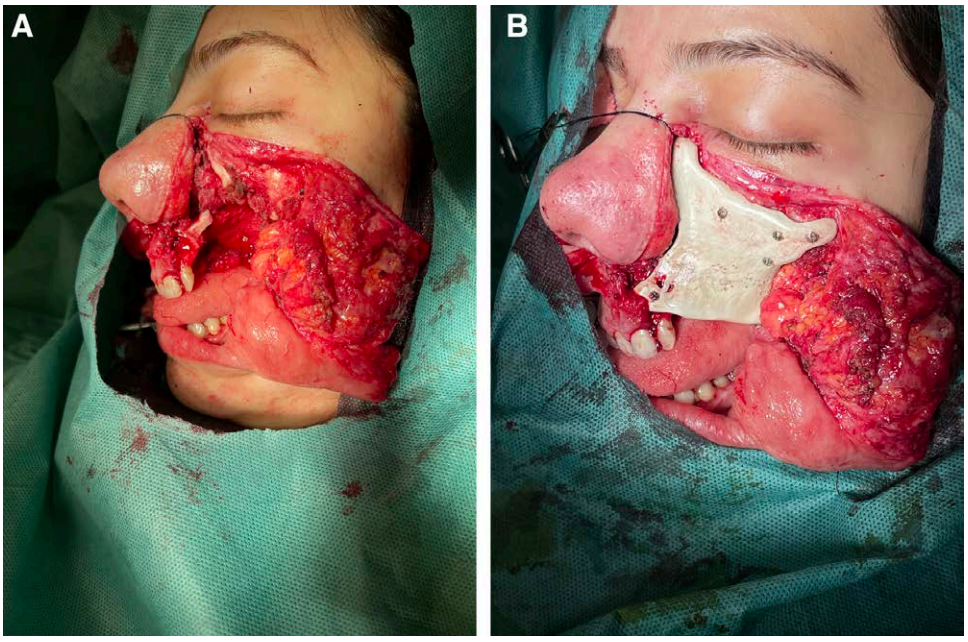

Fig. 5. Surgical stage. A, Photograph of Weber Ferguson approach. B, Photograph of fixed PEEK PSI by titanium screws.

Fig. 6. Photograph of patient after 6 months.

facial implant after a month for a case that was diagnosed, a secondary correction of a congenital cleft of the alveolar and hard palate, which was later covered with displaced flaps. We also concluded that there were no statistically significant differences in the average ranks of the inflammation index during the study periods, and an increase in the inflammation index was noted. After a month, it was decreased by 7.50%, and it again decreased after 3 months from what it was after a month, by 13.95%. It also decreased after 3 months from what it was after a week, by 7.5%.

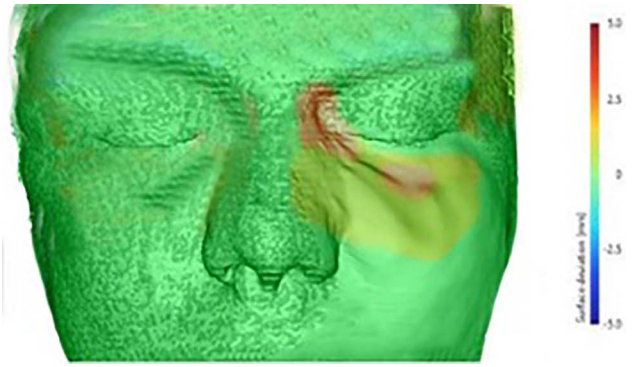

Fig. 7. Map of the mean differences between expected and real changes.

Table 1. Descriptive Statistics on the Age of Patients

Average	SD	Minimum	Maximum
29	4.69	22	37

Table 2. Sample Description according to the Facial Implant Used Results

Implant	Repetition	Percentage, %
Chin implant	4	40
Mandibular angle implant	2	20
Bilateral zygomaticomaxillary implant	1	10
Unilateral zygomaticomaxillary implant	1	10
Nasomaxillary implant	1	10
Lateral margin of orbit implant	1	10

DISCUSSION

Our research results showed that the absolute difference between the expected soft tissue changes result

Table 3. Descriptive Statistics of the Difference between the Hypothetical Expected Result and the Final Result after Surgery

Mse	Maximum	Minimum	SD	Average Difference
0.032	0.2	−0.28	0.14	−0.12

Table 4. Absolute Difference between the Expected Hypothetical Result and the Final Result

Patient	Absolute Difference
1	**0.13**
2	0.08
3	0.10
4	0.13
5	0.21
6	0.28
7	0.18
8	0.19
9	0.14
10	**0.20**

If the absolute difference is in favor of the real result, it is shown in boldface.

and the actual result did not exceed three-tenths for all patients, and that only two of 10 patients had measurements higher than 20%. In general, it can be said that the technique used achieved excellent results, as an absolute difference that does not exceed 0.3 is considered excellent. Therefore, this technique can be relied upon with the placement of implants to predict the outcome of the surgical procedure in terms of morphological changes in the facial soft tissues covering PSI PEEK.

A case study conducted by Ruggiero et al[16] showed the possibility of predicting soft tissue changes associated with the placement of facial implants made of PEEK material with a 3D design tailored to the patient. Their study included a 13-year-old patient with premature ossification of the cranial suture and the presence of symmetrical atelectasis in the temple area. The patient was admitted to the Maxillofacial Surgery Unit, Great Ormond Children's Hospital, London, and treated with a surgical procedure to insert two facial PEEK implants. This study differs from our study, in which the facial implants were designed based on the required soft tissue changes, as changes were made several times in the 3D design of the implants to reach the approximate shape shown by the soft tissue simulation process. The supervisors of this study also performed a CT scan immediately after the end of surgery to compare the expected design of the soft tissue simulation and the final result of the position of the soft tissue after surgery. In addition, the manufacture of PEEK PSI was carried out by an external company (Cavendish, UK). The entire surgical procedure took 90 minutes, and the patient was discharged from the hospital on the first postoperative day after recovery.[16]

Guevara-Rojas et al[17] performed a cosmetic correction on a 27-year-old woman with severe congenital midfacial hypoplasia, in whom treatment with PEEK PSIs was scheduled to increase zygomatic protrusion. The final design of the facial implants was made based on the desired final shape of the facial soft tissues in the cheek area.

The study showed good results in terms of the ability to simulate the soft tissues of the patient's face in the place where the facial implants were installed, as the average total error was 0.81 ± 1 mm and the spatial deviation was less than 0.7 mm for the vast majority of points. However, this study differs from our study in which the construction of soft tissues after surgery was done using a scanning technique of the patient's face, and the manufacturing of PEEK PSIs in this study was done through the computer numerical control subtraction manufacturing technique.[17]

In another study, the accuracy of immediate computer-aided design and computer-aided manufacturing reconstruction of the temporal region after temporalis muscle surgery was evaluated, using the patient-specific polyetherketoneketone (PEKK) model (PSI). This case series included 10 patients who underwent maxillofacial reconstruction using the temporalis muscle flap. The study involved preoperative planning and fabrication of the temporal implant using virtual surgical planning software. Planning was based on multislice CT, in which DICOM files were used to fabricate a 3D model of the temporalis muscle using PEKK. Patients were followed up for 12 months, to check for any signs of infection or mobilization and to evaluate accuracy. At the end of the follow-up period, all patients showed an acceptable appearance, with no signs of infection or rejection. These custom implants were measured and compared with the original 3D layout before surgery using point-based analysis. This showed a mean difference (±SD) of 0.0373 (±0.3036) mm and a mean difference (Q1–Q3) of 0.0809 (−0.2108 to 0.2769) mm. The study demonstrated that high-precision replication of PSIs can be achieved using this die-forming workflow. The use of PEKK PSIs resulted in uneventful healing and aesthetic acceptance by patients and, therefore, is a suitable treatment option when correcting temporal cavitation.[18]

Regarding the management of complications, in cases accompanied by primary infection, antibiotic coverage must be relied upon. In cases accompanied by secondary infection and exposure of part of the implant, antibiotics are administered and local surgical flaps are used to re-cover the implant. The proposed therapeutic method for treatment in the case of infection and exposure of the implant is surgical. The implant is removed and sterilized in the autoclave; then the implant bed is washed using chlorhexidine, the implant is reinstalled, and the patient is prescribed antibiotics.[19,20]

CONCLUSIONS

This technique can be relied upon with the placement of implants to predict the outcome of the surgical procedure in terms of morphological changes in the facial soft tissues covering PSI PEEK. Therefore, it is possible to make a virtual design based on the cosmetic requirements of the patient.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

PATIENT CONSENT

The patient provided written consent for the use of her image.

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