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Cohort Study

Evaluating patients' satisfaction level after using 3D printed PEEK facial implants in repairing maxillofacial deformities

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ABSTRACT

Background: it is generally the case in any traumatic accident where a loss in hard tissue occurs to preform restorative plastic surgery, as there are many materials and approaches used to restore the loss, this research sheds the light on the use of one such material and approach being 3D printed facial implants manufactured from PolyEther Ether Ketone (PEEK) and to evaluate the level of patients' satisfaction following the use of said method in repairing maxillofacial deformities.
Materials and methods: a research sample consisting of 10 patients with facial deformities underwent maxillofacial reconstructive surgery between 2020 and 2021 in the Department of Oral and Maxillofacial Surgery in the Tishreen University Hospital - Latakia - Syria. All patients underwent Computed Tomography (CT) scans, then the design of the required facial implant was carried out, the final form of the facial implant was printed from PolyEther Ether Ketone (PEEK), and then surgical work was performed, a check-up after 3 months of the surgical procedure was carried out to evaluate the level of satisfaction on a scale of 1–5.
Results: The results from the 10 patients showed a good level of satisfaction except in one case where the facial implant had to be removed due to recurrent infection where the patient showed no signs of response to medicinal treatment following the surgery.
Conclusions: this research suggests that the use of 3D printed PEEK facial implants to be very agreeable in terms of functionality and aesthetics in treating various facial deformities.

1. Introduction

Bone autograft restoration techniques have been in place since as early as the 1600s, and bone autografts have been considered as the "golden standard" in reconstructive operations due to its advantages of low costs and minimal immune system rejection, but its limited quantity, possible deformations to the graft-donor site, and the difficulty in shaping the graft have prompted the search for new compensatory techniques and materials.

1.2. Importance and objectives of research

The importance of this research stems from the advantages of PEEK Patient Specific Implants (PSI). Being designed prior to surgery, according to the exact shape and size of the deformity, which allows for a shorter operation time and fewer modifications during surgery, thus ensuring stability post-surgery and a good cosmetic result and avoiding infection at the autograft donor site or insufficiency of the autograft, as well as saving time and effort on preparing both the autograft donor site and the surgical site to accept a bone graft. In a country like Syria where complex facial deformities because of war injuries, tumour related injuries and black fungus are frequent such merits cannot be ignored.

The objective of this study is to evaluate the patient satisfaction level after the use of 3D printed PEEK facial implants in repairing maxillofacial deformities.

1.3. Theoretical review

3D printing has been used in various aspects of manufacturing to produce different products spanning from certain parts of aircrafts,

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boats, and food to 3D models of embryos [1].

Physical models of computer-aided digital layouts are created in a layer-by-layer system also known as Rapid Prototyping (RP), Solid Freeform Fabrication (SFF) or Additive Manufacturing (AM) [2], This technique was invented and first introduced by Charles Hull in 1986, and initially used in automotive manufacturing and engineering to manufacture polyurethane structures for various models, pieces, and tools [3].

Originally, Hull used the phrase “stereolithography” in his US Patent No.4575330A, which referred to an “Apparatus for production of three-dimensional objects by stereolithography” published in 1986. The stereolithography technique (SL) involved integrating sublayers on top of each other, by treating photovoltaic polymers with ultraviolet lasers, since 1986, this process began to accelerate and spread globally and affect different fields. The developing market for 3D desktop printers encourages large-scale experiments in all areas. In general, medical indications for these 3D printers is treatment planning, prosthetics manufacturing, and medical training. Due to its use in the weapons industry, the food industry, and in surgical instruments and routers, RP has received considerable attention in the surgical field in the past 10 years [2].

The leading use of 3D printing in oral and maxillofacial surgery was by Brix and Lambrecht in 1985. Later, this technique was used by them to plan treatment in craniofacial surgery [4]. In 1990, 3D printing was used by Mankovich et al. to treat patients with craniofacial deformities [5].

3D printing has recently gained a reputation in medicine and surgery, by helping with complex craniofacial reconstructions. Applications of 3D printing in maxillofacial surgery include, manufacturing of bone graft moulds, manufacturing of dental implants, bone cutting routers, and manufacturing of facial prosthetic implants and occlusal splints for orthopaedic surgeries [6], which in general helps to reduce the duration of the surgery and help the surgeon make quicker decisions during the operation due to more informed planning.

There are different techniques introduced for 3D printing. Known 3D printing techniques include Binder Jetting (BJ), Electron Beam Melting (EBM), Fused Deposition Modelling (FDM), indirect processes, Laser Melting (LM), Laser Sintering (LS), Material Jetting (MJ), PolyJet (PJ) [7].

3D printing has been used for various purposes including bone synthesis and treatment of craniofacial deformities [8]. Orthopaedic surgery [9] and facial prosthetics [10], it can also be used in surgical education and explaining the patient’s medical condition prior to surgery.

1.4. Polyether ether ketone (PEEK)

A white-coloured synthetic polymer that has been used as a biomaterial in orthopaedic surgery for many years [11]. A semi-crystalline material with a melting point around 335 °C. PEEK can be modified either by adding functional (pre-crystalline) monomers or post-crystalline modifications by chemical reactions such as sulfation, amination, and nitrification. The main useful characteristic of this substance remains its Yong’s modulus of (3–4 GPa) which is close to human bones [12].

PEEK has medical applications, including restorative implants for traumatic facial injuries and the manufacture of facial and orbital bone fracture restorative plates [13], as well as the manufacture of PEEK dental implants [14] and its use in orthopaedic, neuro, and cardiac surgeries [15,16].

2. Research methods and materials

10 patients with maxillofacial deformities (trauma patients, war injuries, patients with pre-existing maxillofacial tumours, and black fungus infected patients) underwent reconstructive surgery using 3D printed facial implants made of PEEK, between 2020 and 2021 in the Department of Oral and maxillofacial Surgery at the Tishreen University Hospital, Latakia, Syria. All patients underwent three-axial CT scan using a Toshiba Slice CT Scanner-Imaging, 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 modelling software (EXoCad) was used to compile DICOM data at the axial, sagittal, and coronal planes and then create a 3D virtual model of the anatomical region.

The surgeon and the manufacturing technician then approved the design format and any modifications required, with the proposed areas for placing the titanium screws for the installation of the facial implant. The final virtual model of the facial implant was exported as a STereo-Lithography (STL) file and sent to the 3D printer, which was eventually printed for the patient. 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 steam sterilized and then encapsulated. The surgical work on the patients was performed under general anaesthesia at the Tishreen University Hospital, Latakia, Syria, 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, all patients received an intravenous 1.2 g Augmentin dose and 0.5 g of Flagyl during the procedure. After the surgery, patients received two doses of Augmentin, after which a prescription of Augmentin 1 g, and Flagyl 0.5 g per day for a week was given. A check-up was carried to evaluate the patient’s level of satisfaction after three months of surgery. Later after the surgery the team asked the patients to assess their own satisfaction with the aesthetic results in the follow up which was 3 months after the surgery on average, the scale we used was a numerical based from 1 to 5: 1 Failure, 2 unsatisfied, 3 Acceptable, 4 satisfied, 5 very satisfied.

The work was carried in accordance with the STROCSS criteria [17] and was registered in the U.S. National Library of Medicine under the identifier: NCT05348434 [18].

Description of the research sample:

1-Research sample by sex:

The majority of the sample was females 7 patients at 70% compared to 30% males 3 patients.

Table 1 shows the descriptive statistics on the age of patients:

Table 2 shows the sample description according to the facial implant used; we note that most of the implants were 4 chin implants, followed by 2 mandibular Angle implants.

3. Results

The following scale was used to investigate patient satisfaction with the aesthetic results. Patient satisfaction was assessed after three months of the surgery on a scale of 1–5: 1 Failure, 2 unsatisfied, 3 Acceptable, 4 satisfied, 5 very satisfied.

Table 3 shows the level of patient satisfaction by facial implant location.

Table 4 summarises the percentage of patient satisfaction on the scale of 1–5.

In order to compare ratios, a Chi-square distribution test was used, and its results are shown in Table 5.

We notice from Table 5 that p value > 0.05 which indicates that there were no meaningful differences in the patient satisfaction levels after 3

Table 1
Descriptive statistics of the research sample by age.

Average	Standard Deviation	Min	Max
29	4.69	22	37

Table 2
Breakdown of research sample by facial implant location.

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%

Table 3
Level of patient satisfaction by implant location.

Implant location	Satisfaction level
Chin implant	4
Chin implant	3
Chin implant	1
Chin implant	3
Mandibular Angle implant	5
Mandibular Angle implant	3
Bilateral Zygomaticomaxillary implant	4
Unilateral Zygomaticomaxillary implant	4
Nasomaxillary implant	5
Lateral margin of orbit implant	3

Table 4
Percentage of patient satisfaction on a scale of 1–5.

rating	Failure	Unsatisfied	Acceptable	Satisfied	Very Satisfied
repetition	1	0	4	3	2
percentage	10%	0%	40%	30%	20%

Table 5
Chi-square distribution.

X^2 value	P value	result
2.00	n.s 0.572	No statistical indication

months of the surgery, noting that there was a relatively acceptable satisfaction level of 3.5 on average following the operation, but due to the low number of samples there was no meaningful differences, but it was still statistically acceptable.

4. Discussion

Reconstructive maxillofacial surgeries are very complex even for an expert surgeon because of the complex autopsy of the head, the "individuality" of each deformity, and the need to restore the deformity in the best possible way, while reducing the time required to perform surgical work, are important factors for surgeons to improve surgical and patient satisfaction outcomes.

PSIs can be a very effective solution in this case as they are designed to accurately suit anatomical deformities or distortions. The need to design PSIs led to many innovations and technological advances in medicine.

Over the past few years, PEEK has attracted a lot of attention from materials scientists and orthopaedists, as it is suitable for surgical uses due to its appropriate biomechanical properties, its radiological transparency, Magnetic Resonance Image (MRI) possibility and being chemically inert [19].

PEEK was initially used in spinal surgery for the manufacturing of intervertebral laminae, and PEEK was also used in a combination with other materials such as Carbon Fiber (CF) in (CF/PEEK) to stabilize fractures and artificial parts (such as artificial hip-joint) [20].

Various studies have been conducted using PEEK to restore complex maxillofacial and craniofacial deformities, and post-surgery observation of those deformities have shown excellent aesthetic and functional results without any complications.

In this study, we relied on PEEK for the printing of the PSIs, and clinical check-ups showed that there was a good level of satisfaction on the part of patients because of the restoration of the cosmetic and functional aspects.

Alasseri and Alasraj [21] conducted a study on PSIs to assess the post-surgery complications for its use as well as the level of patient satisfaction. The study involved six patients with different maxillofacial deformities. Eight PEEK implants were used, with no complications in any patient either immediately after the operation or during the follow-up period which was between 10 and 18 months, and all patients reported a high level of satisfaction of the final aesthetic and functional results [21].

Narciso et al. [22] presented a case report illustrating their experience of using PEEK implants as an innovative means and a solution for restructuring bone and soft tissue in reconstructive and cosmetic facial surgery, as this method is considered reliable by surgeons in order to comply with patient wishes and needs in either reconstructing or simply cosmetic as adding size to the zygomatic area (cheeks).

In Narciso et al. study a 50-year-old patient complaining from a lack of size, and asymmetry on either side of his cheeks, after undergoing three silicone implant and replacement processes, was still dissatisfied with the symmetry, and had an uncomfortable sensation through the skin of the lower eyelids at the edge of the silicone implants - due to the lack of proper contact with the bone -, the authors suggested using bone-fixed PEEK implants, to increase size and reshape the cheek area.

Although no cases have been reported in the medical literature about the use of these substances in plastic facial surgery, this technique seems to offer a safe and effective solution to treat patients who require an increase and adjustment in the appearance of the zygomatic area. Dedicated PEEK implants were already being used in reconstructive craniofacial orthopedic surgeries with good results. No complications have been reported in the case and the results for both authors and patient appear to be satisfactory through the follow up period which lasted till 12 months after the surgery [22].

The study by Pierre et al. [23] showed good patient satisfaction rate of 4.5 on the same scale used in this study. Researchers took a retrospective study of 37 patients who had suffered trauma and then received reconstructive surgery using PEEK-based cranial compensation, which was "patient specific" printed for each patient at the Toulouse University Hospital, France, with an average follow-up period of 4.3 years from 2 moths to 9 years, but no mention was made of the type of printer used in their study [23].

In 2015 O'Reilly et al. [24] conducted a 6-year retrospective study of cranioplasty surgeries of 19 patients who underwent 22 cranioplasty surgeries using PEEK implants planned and based on CT scans. The cranial injury was caused by a trauma in 10 patients, from a tumor in 6 patients, from a vascular injury in 2 patients, and from a stroke in a single patient - The PEEK plate implant needed modification in four cases -. Three patients underwent reoperation, following the cranioplasty surgery using PEEK implants. Researchers concluded that the use of PEEK implants manufactured using Computer-Aided Design/-Computer-Aided Manufacturing (CAD/CAM) in cranial reconstruction has many advantages such as: Ease of installation with excellent anatomical accuracy and aesthetic results, potentially saving time during the operation, and the implant can be easily modified in the operating room [24].

Folettia et al. [25] performed surgical restoration of a large cranial deformity using a patient-specific implant printed from PEEK, because of the inability of traditional restoration methods to aesthetically restore the deformity in terms of symmetry, and the results of the surgical work showed satisfactory results for the surgical team and the patient [25].

5. Conclusion

The ideal material for maxillofacial defects has not been precisely specified, but PEEK has shown promising results in both aesthetic and functional terms, at a low complications rate. So, PEEK PSIs are an excellent therapeutic option for war deformity patients, tumor patients and black fungus infected patients. As they conserve both surgery time and effort through proper and precise pre-surgery planning required to use them, but the high cost, lack of the material in the country along with the fact that there are very few engineers capable of manufacturing and later producing the necessary 3D module for printing are the remaining issues facing wider use of PEEK PSIs at least in Syria.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Ethical approval

Board Name: Scientific Research Board Resolution- Tishreen university. Syria.

Board Status: Approved Approval Number: 1430.

Sources of funding

The study had no external sources of funding and therefore was in no way influenced by any sponsorship.

Author contribution

Ahmed Fayez Ahmed: Conceptualisation, methodology, investigation, data curation.

Hekmat Yaakob: Conceptualisation, methodology, investigation, data curation, supervision.

Ali Khalil: Conceptualisation, methodology, investigation, data curation, supervision.

Pierre Georges: writing original draft, reviewing and editing.

Registration of research studies

1. Name of the registry: Evaluation of Using 3D Printed PEEK Facial Implants in Repairing Maxillofacial Deformities. Clinical trails
2. Unique Identifying number or registration ID: NCT05348434
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://clinicaltrials.gov/ct2/show/NCT05348434

Guarantor

Ahmad Fayez Ahmad: dds.ahmad.ahmad@gmail.com.

Consent

Written informed consent was obtained from the patients for publication of this study and accompanying images, a copy of the written consent is available for review by the Editor-in-Chief of Annals of Medicine and Surgery.

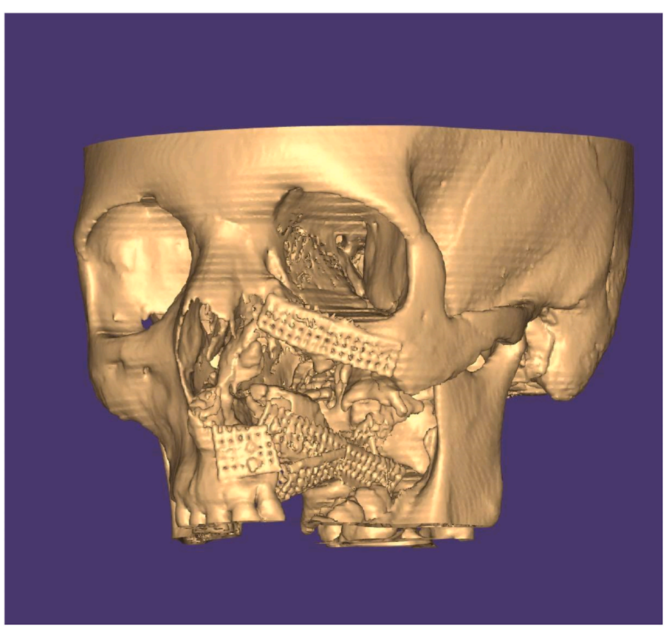
Declaration of competing interest

The authors confirm that there were no conflicts of interest.

Appendix A. Images of the planning and surgical work of a 31-year-old patient with fibrous dysplasia in the maxillary and zygomatic bones. Two years prior, the patient had a complete surgical curettage of the lesion, after recovery, she made several attempts at an autograft implant and orthoplast fixation, all of which had failed

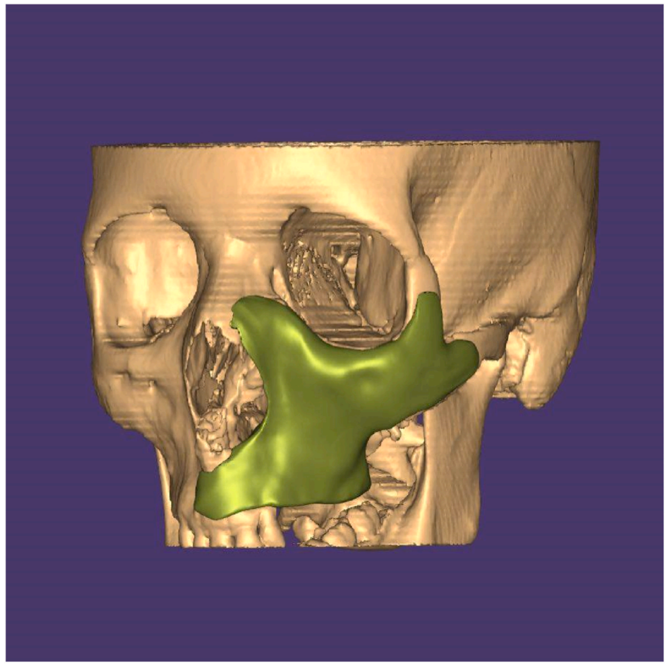
After she checked into the Tishreen university hospital it was decided to perform a reconstructive surgery using a 3D printed PEEK implant.

1. A CT scan was performed, and a 3D model of the patient was made as shown in Pic.1



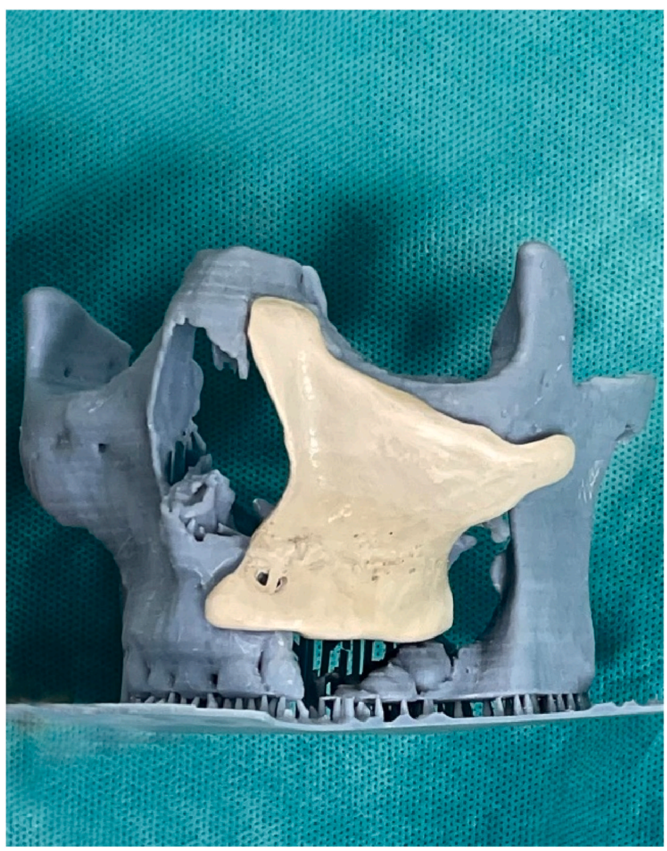
Pic. 1.

2. The plates and metal nets were removed from the model and a proper facial implant which included the maxilla, the hard palate, zygomatic and nasal bones was designed as shown in Pic.2.



Pic.2.

3. Approval of the design and 3D printing the PEEK implant Pic.4.



Pic.3.

4. Preforming the surgical operation under general anaesthesia from an extraoral entrance (Weber Ferguson incision) and the removal of the existing implants and screws from previous operations, then the new implant was tried in place and fixed using screws and orthoplasts as shown in Pic.4.

Pic.4.

5. Surgical incision closure and suturing.
6. The patient after 3 months as seen in pic.5.

Pic.5.

Appendix B. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amsu.2022.104095.

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