



The Role of Patient-Specific Implants in craniomaxillofacial reconstructive surgery: A Scoping Review

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Abstract: Most surgeons consider reconstructing maxillofacial deformities complicated due to the region's complex anatomy and cosmetic and functional impacts on patients. Resorption, infection, and displacement are frequently associated with the use of prefabricated alloplastic implants and autogenous grafts. In reconstructive surgery, recent technological advancements have led to the establishment of customized computer-designed patient-specific implants (PSIs). Using biomaterials such as polymethylmethacrylate (PMMA), Polyetheretherketone (PEEK) and titanium mesh, additive manufacturing methods have enabled the production of customized implants for craniomaxillofacial purposes. The advent of additive manufacturing and three-dimensional (3D) printing, as well as recent advancements in the technologies, had a positive influence on the biomedical area, resulting in the use of patient-specific implants (PSIs) in the surgical repair of maxillofacial abnormalities. Due to advancements in computing power, 3D modeling software, and manufacturing technology, craniomaxillofacial implants are now digitally designed and directly fabricated without the requirement of physical anatomical models or prosthetists. This paper describes the various applications, advantages and disadvantages of patient-specific implants in craniomaxillofacial reconstruction.

Keywords: Additive manufacturing, Patient-specific implants, Titanium mesh, PEEK, Craniomaxillofacial, Reconstruction.

I. INTRODUCTION

Craniomaxillofacial reconstruction is a common surgical technique that has been widely used in the treatment of tumor removal and trauma care. Craniofacial abnormalities often have significant functional and esthetic effects.¹ The scope for the reconstruction of craniomaxillofacial surgery involves trauma, pathology, neoplasia, esthetics, gunshot injuries and congenital anomalies. The need for reconstruction alternatives with synthetic availability that allows single-stage procedures and avoids donor site morbidity is crucial to the evolution of patient-specific implants.² Patient-specific implants are currently used in various fields of oral and maxillofacial surgery, such as total joint replacement in TMJ reconstruction,^{3,4} reconstruction of the maxillofacial skeleton after ablative surgeries, trauma⁴ and orthognathic surgery.⁵ The production of 3 D printed patient-specific implants (PSI) in craniomaxillofacial surgery has rapidly increased in recent years. Especially complex three-dimensional (3D) structures such as orbital walls and maxillary sections have been successfully treated with titanium PSI.⁶

The first record of 3D printing with the additive process was by Hideo Kodama in 1981.² He used ultraviolet light to stabilize polymers and create solids. This was a prelude to stereolithography (SLA). Charles Hull patented stereolithography, a process similar to 3D printing that uses technology to create smaller versions of objects. Material is printed layer-by-layer, solvent-soluble and solidified with ultraviolet light. The process uses computer-aided designs (CAD) to create the 3D models.⁷ In the late 1980s, computer-controlled milling was used to produce prostheses using three-dimensional (3D) imaging data from computed tomography (CT). With the development of CAD/CAM technology, there have been increasing cases of reconstruction of craniomaxillofacial

defects to improve appearance and function with more accurate surgery and shorter operation times. With CAD/CAM software, accurate pre-operative planning can be established, and surgeons can perform virtual ablation, and reconstruction procedures, plan osteotomy and create PSIs. The advantages of CAD/CAM technology include improved accuracy of aesthetic results, restoration of large and geometrically complex anatomical defects, reduction of operative times, more accurate fitting of implants, and overcoming the disadvantages of autogenous bone grafts.⁸

Patient-specific implants are also useful in maxillary, malar and orbital defect reconstruction, resulting from trauma and neoplasms. Nasal bone structure can be reconstructed by using dynamic titanium mesh which otherwise is challenging especially if it is affecting the cartilaginous component.^{9, 10}

PSI prostheses have been made of titanium, polyetheretherketone (PEEK), PEEK-Optima, polymethylmethacrylate (PMMA), and porous polyethylene. Recently even bioresorbable implants using poly-D-Lactic acid have been used in paediatric craniofacial surgery.¹¹

Titanium is considered to be the most biocompatible metal due to its resistance to corrosion due to body fluids, bio-inertness, capacity for osseointegration and high fatigue limits. It has high strength, good malleability, is resistant to inflammation and demonstrates a low risk of infection. Disadvantages today include cost, possible sharp edges that may be encountered if these meshes have not been properly trimmed and increased production time. PMMA material has high porosity (30%), is radiolucent and has compression strength comparable to bone (5000 psi). The combination of high porosity and hydrophilicity allows for vascular ingrowth. Polyetheretherketone (PEEK) is a semicrystalline polyaromatic linear polymer with excellent biocompatibility, good mechanical strength, radiographic translucency and is nonmagnetic.¹²

Patient-specific implants can be designed by the following techniques that include: Selective Laser Sintering (SLS), Direct Metal Laser Sintering (DMLS), and Electron Beam Melting (EBM). These patient-specific implants (PSI) are highly precise and offer excellent clinical outcomes, with a significantly lower revision rate. The reported surgical revision rate using traditional orbital plates was described as between 17% and 87.5% compared to an almost 100% success rate using PSI. It gives added value because it almost has no limitations in the realization of one-piece most complex constructions and enables to form trabecular metal surfaces that ensure better secondary fixation of the implant.^{13, 14}

The disadvantages of PSIs are their high cost, preoperative planning and the manufacturing process is time-consuming. Patients with large orbital defects who require surgical treatment with titanium mesh implants are in general at risk of implant malposition. Patients need to have a preoperative MRI or CT scan before the surgical procedure and patients are subjected to the radiation for preoperative imaging. There can be approximately a 3 to 8-weeks delay between patients being listed for surgery until the real-time surgery takes place. It is fair to say that long-term exercise increases the risk of infection as well as the risk of developing normal abnormal anatomy. Prolonged operative time increases the risk of contamination with subsequent risk of infection and vascular complications.^{15, 16} In the present article, the role of the patient-specific implant in craniofacial regions, its manufacturing process, various techniques, materials, advantage and disadvantages have been outlined and discussed.

II. DISCUSSION

Craniofacial anatomy is very complex with regions being subjected to different types of load constraints and reconstruction of complex craniomaxillofacial defects is challenging due to its unique anatomy, the presence of vital structures, and the variability of deficiency.¹ The reconstruction of congenital or acquired craniomaxillofacial defects due to congenital abnormalities, post-trauma, tumor resection and infection requires both functional and aesthetic considerations. Furthermore, reconstruction of the maxilla and mandible requires major consideration of restoration of masticatory functions alongside the restoration of aesthetics. Therefore, proper reconstruction for a craniofacial region requires having a partial morphology of the component to be modified, besides including mechanical properties and a weight equal to that of the native structure.¹⁷

The design of PSI craniomaxillofacial reconstruction implants start with CT scan data. Two-dimensional DICOM files are converted into 3-D (STL) files and the PSI is designed using 3-D software. The skull and the implant are printed as an STL model in resin using a 3-D printer for the verification of the fit of the implant. The titanium implant is then printed using a laser sintering 3-D printer. The systematic approach for making 3D printed PSI for craniomaxillofacial reconstruction consists mainly of three

parts. First, the implant design, second the computer simulation, based on which the design can be optimized and the design of the supporting structure.¹⁸

SLS is another, more advanced form of 3D printing. It uses additional production and powder polymer usually nylon to create objects. SLS uses a laser to fuse the powder, layer by layer, into more complex shapes than SLA is capable of creating.⁷

FDM developed by Scott Crump¹⁹ is the most common form of 3D printing today. To form an object, the printer heats a cable of thermoplastic material into liquid form and extrudes it layer by layer. In the year 2010 Espalin et al²⁰ explored the use of biocompatible polymethylmethacrylate in FDM to produce spongy customized freeform structures such as craniofacial reconstruction and orthopaedic inserts. The introduction of Electron Beam Melting (EBM) for the processing of titanium has led to the possibility of a one-step fabrication of porous custom titanium implants with controlled porosity to meet the requirements of the anatomy of implantation.²¹

Over the ages, various materials have been used for the reconstruction of craniomaxillofacial defects. Materials include autogenous, allogenic, alloplastic and xenogenic bone grafts. Autogenous grafts are still considered the gold standard for craniomaxillofacial reconstruction. However, they are usually associated with donor site morbidity, time-consuming harvest leading to a longer operative time, graft infection, fragmentation and an unpredictable bone resorption rate resulting in a poor long-term aesthetic result. Autogenous bone grafts can work well if the defect is small and the contours are simple; however, in the presence of larger and more complex shape defects, alloplastic materials are preferable to autogenous bone grafts. Several implant materials have been developed over the past 50 years for both soft tissue and bone replacement.²² The ideal implant material must be inexpensive, durable, radiolucent, lightweight and biocompatible. Within craniofacial reconstruction, three materials that have appeared to be the most widely utilized are titanium, PMMA and PEEK. Maxillofacial PSIs are usually produced in metals and polymers. Synthetic materials such as titanium, hydroxyapatite, alumina ceramics, methyl methacrylate and porous polyethylene among others, have been reported as alternatives for maxillofacial reconstruction. However, the most suitable material remains controversial.²³

Titanium has been established as the choice of metal for implant manufacturing because of its high tensile strength, lightweight and osseointegration property. In addition, titanium implants form a protective oxide cover that resists corrosion. The implants can be made of pure titanium or alloy. In the literature, complication rates of titanium PSIs are reported to vary from 4.1% to 29%, with surgical removal rates ranging from 0% to 15.9%. Aesthetic outcomes are good in cranial defects but in facial procedures, it is more difficult to achieve good cosmetic results. Titanium can be used either alone or in conjunction with other synthetic materials, such as porous polyethylene to strengthen the prosthesis. Porous polyethylene is an inert and biocompatible material and is usually used for facial augmentation.²⁴

Since the 1940s, polymethyl methacrylate (PMMA), an easily mouldable and cost-effective synthetic resin, has been employed. PMMA is also one of the most biocompatible alloplastic polymers currently available, with good mechanical qualities. PMMA has the advantage of allowing the surgeon to manually alter the implant during surgery by adding or removing PMMA.

PEEK is a semicrystalline polyaromatic linear polymer with excellent biocompatibility, nonmagnetic, good mechanical strength, and radiographic translucency and has a thickness and elasticity comparable to that of cortical bone.²⁵ Due to statistically significant higher success rates, shorter hospitalization, and lower reoperation and complication rates, PEEK is considered a good alternative to other alloplastic materials. In PEEK Implants complication rates between 0% and 35% have been reported, next to surgical removal rates ranging from 0% to 18.2%. Reconstruction with PEEK and titanium PSIs provide improved quality of life, decreased pain and give aesthetically good results. The installation of Polyether ether ketone, like all computer-generated additives, cannot provide calvarial immediate reconstruction in an emergency. PEEK-PSIs cannot be used in the pediatric population. In patients younger than 2 years, ongoing cranial growth may be affected by a static implant reconstruction.²⁶ PEEK-PSIs do not become revascularized like bone grafts can and therefore may be prone to late complications that are not typically seen with revascularized bone grafts. The various applications of PSIs in craniomaxillofacial reconstruction are as follows:

1. CRANIAL RECONSTRUCTION

Several authors have demonstrated the successful application of PSI in the craniomaxillofacial region. Alloplastic materials including PMMA, hydroxyapatite (HA), PEEK and metallic mesh have been suggested as intra-operative malleable substitutes in cases of cranioplasty. PMMA however, require complex processes, such as intra-operative mixing for the preparation, adaptation and contouring of the implant for the defect, which result in increased surgical time. In addition, the moulding process may lead to poor cosmetic outcomes in patients with large or complicated defects.²⁷

Furthermore, the contouring of PMMA implant by direct contact with the dura can develop exothermic reactions or the release of toxic monomers intraoperatively. It results in focal tissue damage, which implicates local and systemic reactions. The overall failure rate for PSI for cranioplasty is about 14.3%. The reconstruction of neurocranial defects are challenging and is important to restore both form and function of the cranium. The process of producing traditional cranioplasty implants may take up to four weeks, and the plates are usually ordered, produced, and sterilized before the surgery is scheduled. In comparison, it only takes a few days to make an implant using 3D printing. Besides, 3D printing shifts the manufacturing of cranial plates to a later stage in the application process chain. A digital model of the cranial plate can be produced and viewed by surgeons and other clinicians on the same day. Once the date of surgery is confirmed, 3D printing can begin, and the plate can be finished and delivered to sterilize within a week. Most importantly, plates that are manufactured using both fully and semi-automated digital workflows show superior accuracy over conventional hand-manipulated plates, reducing the need for adaption during surgery.²⁸

2. ORBITAL RECONSTRUCTION

Repairs to the orbital wall and floor fractures are difficult due to the complexity of the anatomical region involved. Fractures of the orbital region have an incidence of 10-25% of the total facial fractures.²⁹ The main goals of orbital reconstruction are the elimination of the orbital wall defects with the restoration of the orbital volume and the correction of the globe position. This can be achieved by the use of different implants (titanium, PTFE, silicone, etc.). However, the major problem related to their use is the complex and time-consuming adaptation to the shape of the injured orbit. Titanium mesh implants are routinely applied to achieve stable reconstruction in orbital floor fracture cases. Several authors have demonstrated the successful application of PSI for facial, including orbital reconstructions. PSIs are much more dimensionally stable as compared to manually bent titanium implants. Furthermore, stiffness in PSIs prevents implant deformation during placement, but still allows for minor, intra-operative corrections.³⁰

3. NASAL RECONSTRUCTION

Restoration of the nasal skeletal framework is of great importance because it is essential for the typical projection contour and optimal nasal functioning. Various approaches to reconstructing the hard tissues of the nose have been described including the use of autogenous grafts such as ear cartilage, rib, and cranial bone. The disadvantages of using autogenous tissue are limited technical capabilities concerning shape, spontaneous bony resorption, necrosis and infections after harvesting the transplant. On the contrary, alloplastic grafts can be used, especially titanium meshes showing high biocompatibility with good osseointegration in case of midfacial reconstructions. In the case of parasinusal wall reconstruction, titanium mesh can incorporate soft tissue when exposed to the nasal area. The major disadvantages of titanium mesh are the risks of exposure and local infection.³¹

4. ZYGOMATIC BONE

The reconstruction of the zygomatic bone and maxilla is essential for the restoration of function and aesthetics. Accurate restoration of the normal anatomy, symmetry, proper facial projection and facial width are the key points in orbito-zygomatic reconstruction. Various surgical procedures for the reconstruction of the zygomatic complex have been described. The various types of alloplastic implants, such as metals, silicone, polymers and hydroxyapatite-based products, have been used to replace autologous bone grafts. The ideal alloplastic material, however, has not yet been discovered. Although stock-made implants are commercially available in different sizes, these implants are of limited value, because such implants fail to accurately fit the defects and hence result in outcomes that are associated with high revision rates. In contrast, PSI that is produced using computer-aided design and manufacturing (CAD/CAM) overcome these drawbacks.^{16,28}

5. TEMPOROMANDIBULAR JOINT

Glenoid fossa prostheses for partial TMJ reconstruction have been constructed from cast stainless steel, chrome-cobalt, and silicone rubber. The outcomes of mandibular condylar replacement using CAD-CAM temporomandibular prostheses connected to customized reconstructive plates to support free fibula flaps in oncological and TMJ pathology patients shows good results.^{32,33}

6. MANDIBULAR RECONSTRUCTION

The reconstruction of mandibular defects after resection surgery has always been challenging for surgeons. A few things need to be considered in the plans for this redesign, including various anatomical regions and the difficulty of mandibular movement. Gold standards of treatment for reconstructing segmental defects after resection surgery include advanced microsurgery with fibula-free flaps, with costochondral rib and iliac bone grafts. Digital reconstruction with additive manufacturing and 3-dimensional (3D) printing allows, accurate reproduction of complex anatomic models and the design and manufacture of prostheses and implants, which can replace resected segments precisely.³³

7. ORTHOGNATHIC SURGERY

The development of 3D imaging and CAD / CAM technology has revolutionized orthognathic surgery. Although 3D surgical planning provides important foresight for problems that may be encountered in surgery (i.e., impacts near the proximal and distal part during sagittal split osteotomy and bone fractures during Le Fort I impaction), surgery does not exactly replicate the surgical process because osteotomies are still free. PSI offers higher accuracy, disability flexibility, improved stability, more predictable results, and better facial expressions refining.²⁹ Patient-specific implants and cutting surgical guides made up of additive manufacturing technique were found to be useful in Le Fort I osteotomy and showed precise fit of the 3D printed implants in most of the orthognathic cases. The PSIs require minimal adjustments.³¹

III. CONCLUSION

Today, PSIs have found their way into routine medical practice. Surgeons performing cranioplasty can now safely and optimally reconstruct the lost part of the cranium without having to create a second donor site. PSIs have a formidable role in the repair of the orbital floor and wall fractures. Anatomic restoration of bony orbital contour and volume can be achieved using PSIs that are clinically more stable and the repair can be compared to that of the uninjured eye. PSIs allow for near to perfect reconstruction enabling the patient to receive their lost facial appearance. The use of PSIs in patients having mandibular defects, including temporomandibular joints has achieved accurate reproduction of complex anatomy, form and function which can replace resected segments precisely. However, PSI is costly, it requires expertise, skill, and special types of equipment for its fabrication and its availability is limited. PSIs have helped the surgeons to shorten the operative time, reduced the need for intraoperative implant adjustment, and achieved higher accuracy and enhanced stability with more predictable outcomes with high cost as the main drawback.

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