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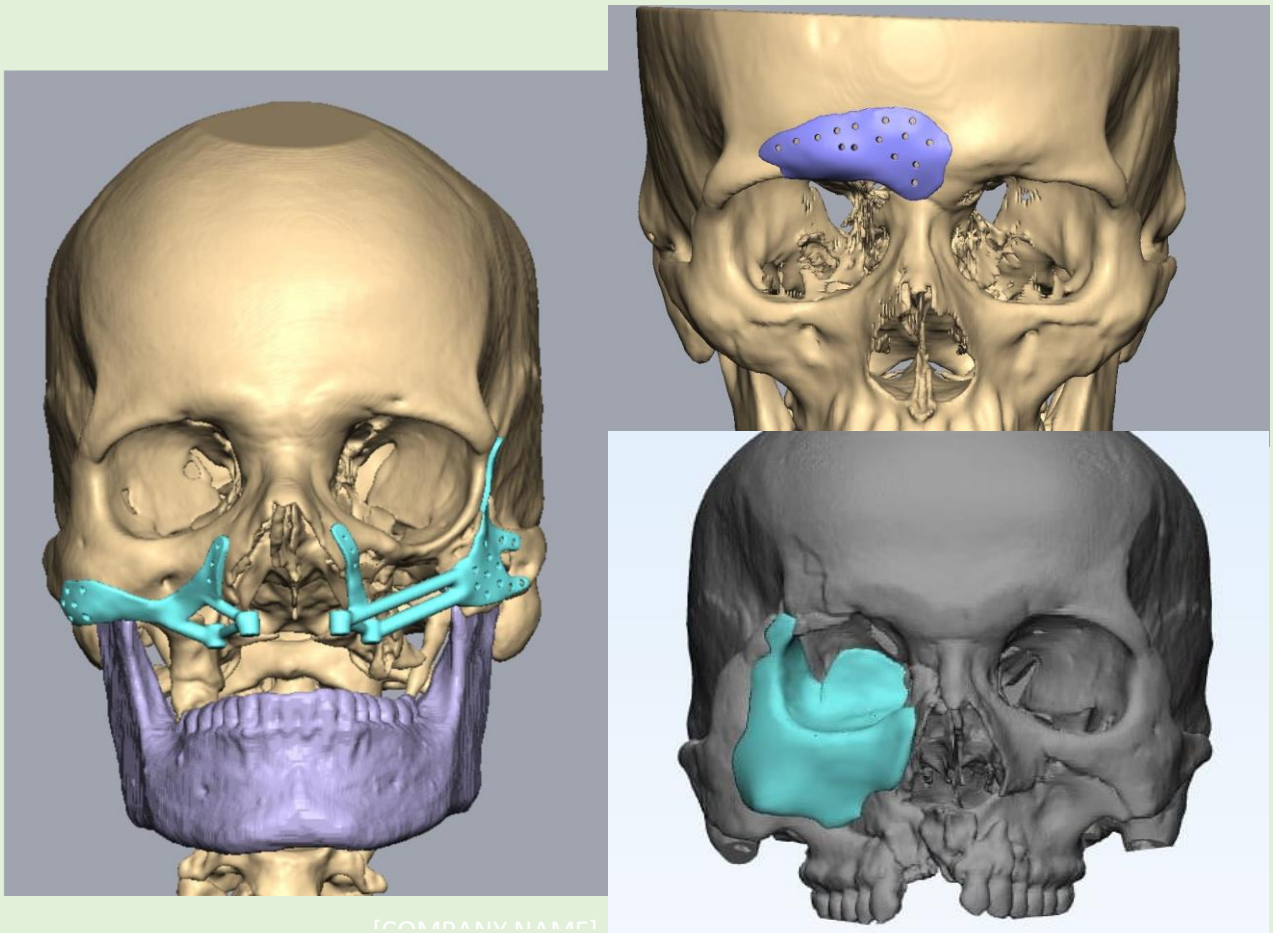
Vyomika Bansal, Akhilesh Kumar Singh, Naresh Kumar Sharma, Arjun Mahajan



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INTRODUCTION

In today's era, "*Personalized Medicine*" term has gained momentum, as it uses information about a patient's gene, proteins, and environment to prevent, diagnose, and treat disease. The meticulous surgeons of 21st century in need of better outcome have gotten a major shift from the "**One-Size-Fits-All**" approach designed for the average patient, toward **treatments tailored for the individual**.

Given the complexity of the facial skeleton, sensitivity of the involved systems, and uniqueness of each defect the surgical repair and reconstruction of defects in the craniomaxillofacial region can be exigent and therefore need to reconstruct the defect in the most precise way for enhancing patient outcomes and well-being.

Development of several recent advancements like computer-aided design and computer-aided manufacturing (CAD/ CAM) technology have allowed the application of personalized prosthesis in oral and maxillofacial surgery in order to improve outcomes. The decreasing cost of this technology has also made it more affordable and accessible to patients.

Several Autogenous and Alloplastic materials are used by the surgeons but precise replication of the details of lost tissues is seldom achieved.

Introduction of 3-dimensional printing in the Biomedical field has led to the utilization of patient-specific implants (PSIs) in the surgical repair of maxillofacial defects, which occur either Congenitally, Post Traumatically, Post Surgically, or various Benign and Malignant maxillofacial pathologies add to the etiology of such defects.

A "NEW ERA" OF PATIENT SPECIFIC IMPLANTS:

The first case report of a patient-specific plate used in mandibular reconstruction was in **2012 by Ciocca** and colleagues, whereby **a titanium alloy plate** was manufactured by direct metal laser sintering using a CAD/CAM to reconstruct a mandibular defect from oral cancer

Today, Digital technology has led to a paradigm shift in the field of oral and maxillofacial surgery and three-dimensional (3D) printers have enabled accurate and rapid surgery. In the case of 3D printers, unlike resin materials that were available in the early days, it is currently possible to print titanium materials that have already been verified for biocompatibility as dental implants.

MATERIAL USED FOR MANUFACTURING PSIs IN FACE:

An ideal maxillofacial implant material must be –

- ✓ Biocompatible
- ✓ Durable
- ✓ Radiolucent
- ✓ Lightweight
- ✓ Inexpensive.

Metals and Polymers are used to manufacture maxillofacial PSIs. Titanium has been established as the material of choice for implant manufacturing because of its **high tensile strength, lightweight, osseointegration property and it resist corrosion.**

Polymers commonly used for maxillofacial PSIs are –

I. silicone
II. polymethylmethacrylate (PMMA)
III. polyetheretherketone (PEEK).

Silicone is a polymerized dimethyl siloxane and is widely used implant materials. Maxillofacial PSIs are made from solid silicone and are used for soft tissue augmentation. These implants can be easily modified intraoperatively as well. For bony defects, **PEEK and PMMA are the most popular polymers**. PEEK has a strong semicrystalline polyaromatic polymer that is needed to withstand repeated stress therefore is manufacturer's choice for maxillofacial implants.

PSI best fits with greater accuracy with added benefit of shorter rehabilitation time in cases of - **Congenital craniofacial deformities** (such as Crouzon or Treacher-Collins syndrome, hemifacial microsomia) or **Acquired defects** due to trauma or Pathological lesions. These congenital deformities are associated with **aesthetic and functional problems**, such as facial disharmony, facial asymmetry, and masticatory problems. In PSI placement, there is no donor site morbidity unlike in Autogenous bone grafting where surgical failure might be more, and subsequent difficulty in reoperation prevails. However, in PSIs, patient may face problem in terms of biocompatibility depending on the material and an increase in the surgical cost accompanying the material cost.

USE OF PSIs in MAXILLOFACIAL RECONSTRUCTION:

There are currently various areas of maxillofacial surgery that uses patient-specific implants including -

- **Reconstruction of the maxillofacial skeleton defects i.e., maxilla or mandible post-ablative surgeries (Oral cancer, benign tumors and post covid mucor mycosis)**
- **Correction of post-traumatic secondary facial deformities**
- **Temporomandibular joint (TMJ) total joint replacement**
- **Orthognathic surgery**

❖ Reconstruction of maxillofacial skeleton Defects:

Anatomic diversity and complex movement of maxillofacial skeleton has posed challenges unique to its bony reconstruction. Before the development of custom implants, reconstruction was carried out using rigid fixation plates and locking screws designed to fit the "average" maxilla-mandibular dimension.

- ✓ Protocol for PSI fabrication begins with sending the DICOM data of the preoperative CT scan to the medical engineers at a third-party virtual surgical planning company.
- ✓ After the Web meeting, a report is e-mailed to the surgeon for final design approval before manufacturing.
- ✓ Customized cutting guides, reconstruction plate, an optional sterilizable stereo lithic model, and a detailed report of the surgical plan are sent to the surgeon before surgery.

When used in conjunction with ***Composite flap reconstruction*** (i.e, fibula, iliac crest, and scapula) of complex mandibular defects, patient-specific cutting and drilling guides that correspond to patient specific reconstruction plate allow for accurate 3D orientation of the bony flap segments.

One factor that accounts for the decreased accuracy of fibula reconstruction compared with virtual plan is the fit of fibula cutting guides over an intact periosteum, which is arbitrarily determined to be 0.4 mm during CAD/CAM fabrication of the surgical guide.

The end-osseous implants are placed at the time of primary reconstruction using patient-specific drill guides.

Reconstruction of the maxilla and orbito-zygomatic regions is equally challenging given the complex 3D anatomy as well as its multiple functions, including separation of the oral and nasal cavities, and support for dentition, therefore PSIs allow precise orientation of the vascular segments in order to reconstruct the alveolar portion of the surgical defect.

- **Corrections of Post – traumatic secondary facial deformity:**

Secondary reconstruction of residual skeletal deformities is required in pan facial trauma when no treatment has been provided or when primary surgical treatment has unacceptable outcomes. Inaccurate reduction or remaining defects of the midface, especially of the zygomatic bone, the orbital walls, the maxilla, and mandible can have functional and aesthetic consequences of varying degrees.

Consequences of Post-traumatic deformities –

- ✓ **loss of sagittal projection**
- ✓ **changes in vertical facial height**
- ✓ **widening of the face, or**
- ✓ **facial asymmetry**
- ✓ **Impaired visual function**
- ✓ **masticatory dysfunction**
- ✓ **malocclusion**
- ✓ **temporomandibular joint disorders** (may occur)

Use of patient-specific implants (PSI) appears to be a promising option and has become increasingly important in recent years.

So far, studies regarding secondary reconstruction of post-traumatic midfacial deformities use predominantly navigational systems. The virtual planning technology is transferred into surgery either by means of repositioning guides together with preoperative individually pre bent conventional plates or by use of CAD/CAM fabricated osteotomy guides and PSI.

❖ Temporomandibular Joint -Total Joint Replacement:

In Early 1970s, use of alloplastic material was described for the treatment of severe end-stage TMJ disease or pathologic condition, where replacement of the entire TMJ complex, including fossa and the condyle-ramus unit was advocted. Several different alloplastic materials such as cast Vitallium with a polymethyl methacrylate head, 2 Proplast-Teflon-coated Vitallium,3 and Dacron/ Proplast-Teflon/ultra-high-molecular-weight polyethylene has been used to build these devices.

In **1993**, Patient-specific implants using CAD/ CAM technology for TMJ replacement was introduced. Currently, the only Food and Drug Administration– approved custom-made total joint prosthesis in the United States is one made by TMJ Concepts (Ventura, CA, USA).

I. Computed tomographic (CT) scan is done in order to fabricate a stereo lithic skull model from which the mandibular resection and fossa preparation can be performed.
II. A minimum gap of **13 mm** should be present from the skull base to the mandible after the resection.
III. The post resection stereo lithic skull model is then shipped to for implant design and fabrication that is *specific to the patient's anatomic morphology, surgical defect, and jaw relationship*.
IV. TMJ Concepts' fossa component is made from **Unalloyed titanium mesh bonded to an articulating surface made of ultra-high-molecular-weight polyethylene**. The mandibular component is composed of a condylar head made from *cobalt chromium-molybdenum alloy and a mandibular body made from titanium-aluminium-vanadium extra low interstitial alloy*.
V. A third-party virtual surgical planning software (i.e, 3D Systems, Materialise, or Individual Patient Solutions) can be used to fabricate intraoperative cutting guides in order to replicate the planned resection and joint reconstruction.

❖ Orthognathic Surgery:

3D imaging and CAD/CAM technology has revolutionized orthognathic surgery as the pre-surgical planning that was done traditionally using 2-dimensional cephalometric analysis, facebow transfer, plaster models, and model table has been replaced with digital planning which has saved both patient's and the surgeon's time.

3D surgical planning provides significant foresight into issues that can be encountered intraoperatively by the surgeons, like collision of proximal and distal segment in Sagittal split osteotomy and bony interferences during Le Fort I impaction. Mock surgery is then sent to the operating room using occlusal wafers, and then surgery is carried out using miniplates that are adapted intraoperatively. The use of bone-borne patient-specific guides and patient-specific implants eliminate the need for occlusal wafers.

- Several **ADVANTAGES** of using patient-specific cutting guides and patient-specific implants in orthognathic surgeries-

1) Accurate 3D positioning of the maxilla and mandible, independent of occlusion

2) Elimination of intraoperative plate bending, which is time consuming, weakens the integrity of the bone plates, thus introducing errors

3) Eliminating needs of intermaxillary fixation, which is also time consuming and risk for penetrating injuries.

4) Patient-specific drill guides designed to for placement in thick bone and avoids injury to important structures such as neurovascular bundles, dental root etc.

- **DISADVANTAGES** of patient-specific implants used in orthognathic surgery –

1) Increased cost, some of which may be offset by decreased time in the operating room

2) Lengthen processing time for fabrication of the patient-specific guides and implants;

3) Impromptu intraoperative decisions are difficult to take place when handling PSIs in cases virtual plan is not accurately translated to the patient.

4) Unpredictability of transverse stability in cases of segmental surgery.

PSIs: "SAVIOURS" IN POST-COVID MUCOR

Mucor mycosis, is an invasive fungal infection affecting immunocompromised elderly patients. Up until the second wave of Corona Virus Disease of 2019 (COVID-19) pandemic, India reported an incidence of over 45,000 cases between the months of April and July 2021 with 77.6% cases being of **Rhino-cerebral type**. The most common etiological factors for the COVID patient to infect with Rhizopus Oryza are excessive use of corticosteroids, uncontrolled diabetes, long-term stays in the intensive care unit, patients on dialysis etc.

Oral manifestations of the mucor mycosis –

I. Massive tissue destruction followed by nonhealing ulcers
II. Osseous destruction
III. Formation of oroantral communications etc.

Varied form of mucor mycosis include ***rhino-cerebral variant*** affecting the sinus and brain, pulmonary affecting the lung, gastrointestinal affecting the tract, cutaneous affecting the skin, and disseminated mucor mycosis which spreads through the bloodstream

Surgical debridement of affected tissues, in this debilitating disease involves removal of necrotic bone often requiring total or partial maxillectomy and primary closure with buccal and palatal mucosa. Post debridement tissue / bone defects can be **simple or complex based on tissue loss**.

During second wave of COVID-19, it was observed that it not only affecting geriatric population, but also younger individuals even without any preexisting medical condition.

Post-COVID Mucor mycosis left individuals with huge maxillofacial defects, heavy financial burden and emotional scars for life. Rehabilitation of such patients has become a tedious task for maxillofacial surgeon, taking into consideration the greater defect size and other anatomical difficulties, therefore need for customized implants that anchor the adjacent residual zygomatic, pterygoid, nasal, and orbital floors provide better results than conventional implants.

The patient-specific zygomatic implant can provide maximum stability and function in post-mucor maxillectomy patients relatively over shorter time period with minimal surgical morbidity.

Challenges for Surgeon and Prosthodontist in rehabilitation of patients with Post – covid rhino-maxillary mucor mycosis:

- Lack of maxillary bone including pterygoid plates sometimes zygomatic bone involvement
- Adherence of nasal and sinus mucosa with palatal mucosa
- Fibrosed palatal mucosa
- Loss of lip support
- Reduced stress bearing area
- Lack of vertical guidance
- Over closure of mandible need to be addressed during rehabilitation.

Points to remember before going for PSI in Mucor mycosis affected patients:

- Patients discharged from the ward with a time gap of 6 months to 1 year between discharge and PSI placement
- Patients with no evidence of disease endoscopically and improved clinical features.
- Patient's remaining bone should be sound to hold PSI

A major advancement to patient-specific implants was the rapid prototyping of ***stereo lithic models*** to scale, first described in oral and maxillofacial surgery by Brix and Lambrecht in 1987. The printed models can be used to manually bend reconstruction plates fitted for a particular defect before the day of surgery, a concept commonly known as "pre-bending." This technique allowed for the accurate adaptation of the reconstruction plate to the patient's anatomy without the patient being under anaesthesia with an open wound. The drawback of plate weakness that occurs with bending however still remains, although at lesser values because of more direct and improved application.

PROCEDURE FOR PSI FABRICATION:

✓ This protocol begins with sending the DICOM data of the pre -operative CT scan to the medical engineers at a third-party virtual surgical planning company.

✓ The recommended slice thickness of the CT scan is less than 1.0 mm in order to have adequate surface detail on which accurate surgical guides and implants can be manufactured.

✓ A Web meeting then takes place between the surgeon and the engineer to plan the resection, design the surgical guides, and design the reconstruction plate.

✓ The surgical guide serves as a cutting guide for the resection as well as a drill guide for the screws used to secure the reconstruction plate.

✓ After the Web meeting, a report is e-mailed to the surgeon for final design approval before manufacturing.

✓ The cutting guides, reconstruction plate, an optional sterilizable stereo-lithic model, and a detailed report of the surgical plan are sent to the surgeon before surgery.

INTRA-OPERATIVELY:

- ✓ The titanium PSI was placed on the desired site of the defect and fixation was done in mesially on bilateral infraorbital rim and bilateral body of zygoma.
- ✓ The site was then irrigated copiously using 10% betadine and normal saline
- ✓ Primary closure was performed using 3-0 vicryl and 2-0 vicryl.

POST OPERATIVE RESULT:

- Good aesthetic results as fullness at the right anterior region could be appreciated.
- No oro- antral communication seen after 4 weeks follow up.
- Patient is on regular follow ups since 3 months.

INDICATION:

1.When simultaneous reconstruction with dental implants is required.

2.A continuity defect of the facial bone limited to hard tissue.

3. Mild or moderate bone defect due to previous excessive bone preparation in a patient with facial osteoplasty.

4. In cases of high aesthetic requirements such as correction of fine skeletal asymmetry.

5. In defects present in functional load bearing areas, such as the mandible.

6.PSIs have aesthetic indications as in Volume loss commonly seen as part of the aging face can result in contour irregularities.

7.Congenital facial syndromes can be associated with skeletal deficiencies and facial deformities that are extremely difficult to reconstruct.

8.PSIs can be particularly useful in the reconstruction of complex posttraumatic maxillofacial defects.

9.Patients who suffer severe facial trauma often have life-threatening injuries that may delay facial reconstruction until a time when the patient is deemed stable to undergo surgery.
10.Delayed reconstruction of facial defects can compromise reconstructive outcomes.

CONTRAINDICATION:

1. Cases requiring complex tissue reconstruction of hard and soft tissues.

2. Patients with hypersensitivity to titanium material.

3. Patients who require continuous follow-up through radiographic imaging such as CT or MRI (artifact may occur).

FUTURE IN PSIs

Titanium 3D PSIs hold a promising future for such patients. The use of PSI for the reconstruction of oral and craniomaxillofacial defects should be considered an accurate alternative to non-custom-made implants. Automation allows for the application of safe, time-effective procedures not requiring specialized, and software-specific knowledge. Reconstruction of complex maxillofacial defects is challenging, and favourable outcomes are dependent on precise replacement of the missing or deficient tissue.

Manual carving of autologous grafts and modification of generic implants may lead to suboptimal results. To improve the likelihood of achieving the desired contour results, implants must be customized to fit the particular reconstructive need.

Continuous research in advancement in CAD/CAM technology allow rapid design and fabrication of custom implants bringing us a step closer to achieving the ideal patient specific implant. Use of Titanium-based 3D PSIs during post-covid, provide an innovative solution to ensure the facial deformity does not leave a deep scar on the patient's dignity and self-confidence.

Fig (1,2,3)- Pre- operative pictures of the patient with post covid mucormycosis showing right maxillary defect Fig (4) : Pre – op 3D CT face of the patient

Fig (5,6,7) : Stereo lithic model of the patient fabricating using 3D printing along with the Titanium PSI placed on the patient skull model.

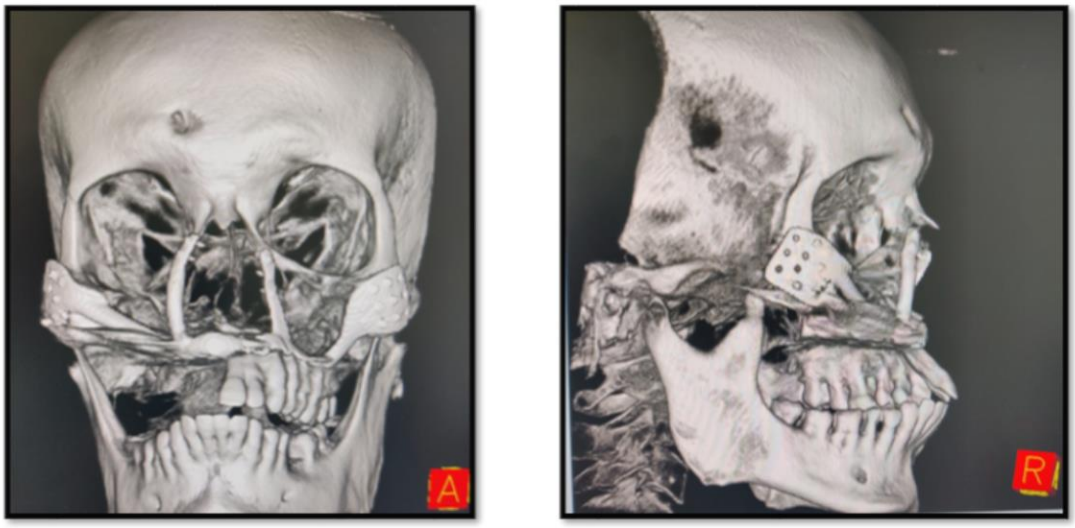

Fig (A,R) : Post operative CBCT of the patient after 2 months follow up

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