International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 12s,2025
https://theaspd.com/index.php

Precision In Practice: The Evolution Of Patient-Specific Implants In Modern Surgery"

Dr Roma Goswami[1], Dr Deepesh Saxena[2], Dr Pallavi Kumari[3*]
[1]Professor & Head, Department of Prosthodontics and Crown & Bridge, Subharti Dental College & Hospital, Subharti University, Meerut, U.P, India
[2]Professor, Department of Prosthodontics and Crown & Bridge, Subharti Dental College & Hospital, Subharti University, Meerut, U.P, India
[3]Postgraduate, Department of Prosthodontics and Crown & Bridge, Subharti Dental College & Hospital, Subharti University, Meerut, U.P, India
Email: [1]romagoswami@rediffmail.com,[2]drdeepeshsaxena@ yahoo.com,[3]drdeepeshsaxena@yahoo.in

Abstract
Background: *Patient-specific implants (PSIs), represent an advanced method for reconstructive and aesthetic surgery, especially in complex areas like maxillofacial surgery. These implants are specifically made to match the unique three-dimensional contours of a patient's anatomy, addressing challenges that standard implants may not adequately resolve. Over the last decade, considerable advancements have been made in the development and production of PSIs for maxillofacial applications.* ***Aim***: *This narrative review was conducted to understand the indications of patient specific implants in the rehabilitation of different congenital and acquired maxillofacial defects, along with their benefits, drawbacks, fabrication process, manufacturing method and future perspectives.* ***Methods***: *An electronic search was performed on EBSCO, Medline/Pubmed and Cochrane Library databases for the articles published from April 2012 to February 2024 was used.* ***Results:*** *A total of 22 articles were collected and they were used to formulate this review. Despite constraints, the design of patient-specific implants (PSIs) ensured accurate placement due to their intricate shape matching the anatomy of reconstructed areas and the inclusion of retention features. There were no significant complications during the postoperative phase.* ***Discussion:*** *Craniomaxillofacial reconstruction, essential for treating conditions like tumors and trauma, addresses both functional and aesthetic concerns. It encompasses trauma, pathology, neoplasia, esthetics, gunshot injuries, and congenital anomalies. The alternative options for synthetic reconstruction has grown to facilitate single-stage procedures, avoiding donor site issues. Patient-specific implants (PSI) are pivotal, widely utilized in various oral and maxillofacial surgeries, including TMJ reconstruction, trauma, and orthognathic procedures. The adoption of 3D printed PSIs in craniomaxillofacial surgery has surged recently.* ***Conclusion***: *Maxillofacial surgery is difficult due to intricate anatomy and issues with conventional implants. Yet, patient-specific implants (PSIs) enabled by 3D printing have transformed the discipline. They bypass the need for donor sites, ensuring accurate reconstruction and stability, especially in challenging areas like cranioplasty and orbital fractures. Despite being costly and requiring specialized resources, PSIs reduce adjustments, and optimize results, making them invaluable despite some accessibility challenges.*
Keywords: *Three-dimensional printing, patient specific implants*

INTRODUCTION

Repairing and reconstructing maxillofacial defects, whether they're present from birth or acquired, pose significant challenges for surgeons. The intricate anatomy, diverse patient needs, and individual nature of each defect all contribute to this complexity. Surgeons must skilfully address these issues to ensure patients are both functionally and aesthetically satisfied and maintain their well-being. While autogenous grafts remain the preferred choice for reconstruction, they can sometimes lead to unpredictable resorption and donor site complications.[1]Over the years, implants have undergone significant engineering advancements that have increased their range of use, from securing loose-fitting dentures to full-mouth rehabilitation and maxillofacial prosthesis.[2] The notion of custom implants emerged in 1970, with patient-specific implants first utilized in craniofacial surgery during the 1980s. The application of CAD/CAM technology for creating custom implants for TMJ replacement was introduced in 1993. The inaugural instance of patient-specific implants being employed in orthognathic surgery was documented in the English literature by Philippe in 2013.[3]Patient-specific implants (PSIs) for maxillofacial reconstruction can be made from a range of synthetic materials, including metals, ceramics, polymers, and composites. Among these options, titanium stands out as a favoured metal for such applications, particularly in procedures like orbital reconstruction, mid-face reconstruction, and total mandibular replacement.[4]The widespread adoption of computer-assisted surgery (CAS), which encompasses CAD/CAM (computer-aided design and manufacture) techniques, has accelerated the production of customized implants. These implants can either be entirely customised, created externally after overlaying a mirror image derived from a CT scan of the uninjured side (referred to as patient-specific implants or PSIs), or they can be traditional implants modified and shaped based on patient-specific three-dimensional models generated from CT imaging using stereolithography (referred to as hybrid-PSI).[5]This manuscript primarily aims to investigate the indications of patient specific implants in the rehabilitation of different congenital and acquired maxillofacial deformities.

Methods

An electronic search was performed on EBSCO, Medline/Pubmed and Cochrane Library databases for the articles published from April 2012 to February 2024 was used.

Results

Finally, 22 articles were collected and they were used to formulate this review. Despite limitations, the design of patient-specific implants (PSIs) ensured accurate placement due to their intricate shape matching the anatomy of reconstructed areas and the inclusion of retention features. There were no significant complications during the postoperative phase.

Discussion

Craniomaxillofacial reconstruction, essential for treating conditions like tumours and trauma, addresses both functional and aesthetic concerns. It encompasses trauma, pathology, neoplasia, esthetics, gunshot injuries, and congenital anomalies. The alternative option for synthetic reconstruction has grown to facilitate single-stage procedures, avoiding donor site issues. Patient-specific implants (PSI) are pivotal, widely utilized in various oral and maxillofacial surgeries, including TMJ reconstruction, trauma, and orthognathic procedures. The adoption of 3D printed PSIs in craniomaxillofacial surgery has surged recently.

Indications of Patient Specific Implants

Maxillofacial PSIs serve cosmetic and reconstructive needs.

Patients dissatisfied with standard facial implants may benefit from custom PSIs, which can be made and applied as onlays to restore specific facial contours.

In congenital facial deformities affecting one side, a mirror image of the unaffected site can be used to create the implant.[6]

Advantages of Patient Specific Implant

Patient-specific implants simplify surgeries by matching precisely to the patient's anatomy, minimizing the requirement for in-surgery modifications. This precision removes laborious tasks like manually shaping or adjusting generic implants to suit each patient. As a result, surgeons can concentrate more effectively on implant placement and the overall procedure, leading to a reduction in operative time.

Patient-specific implants are tailored to fit large and intricate anatomical defects precisely, ensuring optimal restoration. By utilizing advanced imaging techniques like CT or MRI scans, these implants are custom-designed to replicate the patient's unique anatomy, accommodating even complex shapes and sizes. This personalized approach enables seamless integration of the implant into the defect, providing comprehensive coverage and functional restoration.

Patient-specific implants offer several advantages over autogenous bone grafts, helping to overcome their disadvantages:

Avoiding donor site morbidity : Autogenous bone grafts require harvesting bone from another part of the patient's body, leading to potential donor site complications such as pain, infection, and scarring. Patient-specific implants eliminate the need for donor bone, thus avoiding these associated risks.

Predictable outcomes : The quality and quantity of autogenous bone grafts can vary among individuals, affecting the success of the grafting procedure. Patient-specific implants offer predictable outcomes as they are fabricated to exact specifications based on preoperative imaging, minimizing variability in results.Improved Precision and fit : Autogenous bone grafts may not always precisely match the recipient site, leading to suboptimal fit and potential complications. Patient-specific implants are precisely tailored to match the patient's anatomy accurately, reducing the risk of malposiitioning or instability.

Disadvantages of Patient Specific Implant

Cost: Patient-specific implants can be more expensive than off-the-shelf implants due to the need for personalized design and fabrication processes.roduction time: Custom fabrication of patient-specific implants typically takes longer than selecting and adapting off-the-shelf implants, which may delay surgical treatment.Dependency on imaging: The accuracy of patient-specific implants relies heavily on the quality and interpretation of preoperative imaging. Inaccuracies in imaging can lead to errors in implant design and fit.Limited adjustability: Once fabricated, patient-specific implants cannot be easily modified during surgery. If there are unexpected changes or complications intraoperatively, adapting the implant may be challenging.Limited availability: Not all medical facilities have the resources or expertise to design and fabricate patient-specific implants, limiting accessibility to this technology for some patients.Potential of errors: Errors in design or fabrication, such as misinterpretation of imaging data or manufacturing defects, can occur and may necessitate revisions or replacements.

Materials for Fabricating Patient Specific Implant

Titanium is favoured due to its strength, lightness, and osseointegration, forming a protective oxide layer against corrosion. Titanium implants, either pure or alloyed, are commonly used in maxillofacial surgeries like orbital[7] and midface reconstruction[8], as well as total mandible replacement.[9]

Maxillofacial PSIs commonly use silicone, PMMA, and PEEK polymers. PEEK and PMMA are favoured for bony defects, with PEEK known for its biocompatibility and strength, and PMMA initially used in orthopaedic implants. [11]PMMA, an acrylic-based polymer with high molecular weight, has been utilized for many years in crafting orthopaedic implants. Recognized for its robustness and rigidity, PMMA serves as an effective substitute for bone. It has found application in the reconstruction of cranial and maxillofacial defects. PMMA is a commonly utilized material in additive manufacturing processes like 3D printing due to its favourable properties such as ease of processing, biocompatibility, and durability. Prototyping with PMMA allows for the evaluation of implant design and fit before final production, facilitating adjustments and improvements as needed.[10]

Manufacturing of Patient Specific Implant

Maxillofacial PSI manufacturing starts with CT or MRI scans, usually CT for better resolution. These scans are then converted into 3D images using CAD software, where implants are precisely designed to fit the defect, sometimes mirroring the normal side for unilateral defects. The design is then sent to CAM software for fabrication. Manufacturing methods include subtractive, where material is carved out using CNC milling machines, and additive, like 3D printing, which builds the implant layer by layer. Both methods have proven successful in producing maxillofacial implants.[12] Additive manufacturing offers advantages such as minimal waste, rapid production, and the capability to create intricate structures, distinguishing it from subtractive manufacturing.

FABRICATION OF PSI[13,14]

The fabrication of patient-specific implants involves six stages. Firstly, patient data, including CT/MRI scans, is gathered and stored in a shared database. Next, the implant is designed using medical modeling software tailored to the patient's anatomy. Subsequently, biomechanical analysis of the finite element (FE) model assesses stress and strain distribution on the PEEK implant. The fourth stage entails 3D printing of the implant. Following this, the implant undergoes quality assurance to ensure proper fitting accuracy. Lastly, the produced PEEK implant is sterilized for surgical use.

1. Image data collection and 3 D model creation

Standard CT scanning procedures provide transverse, sagittal, and coronal data of the skull. These 2D images, stored in DICOM format, depict internal anatomical structures in detail. Using software like Mimics 18.0, the DICOM files are transformed into a digital 3D model, facilitating further analysis and modeling.

2. Implant Design

The implant design process follows a CAD approach. Using softwares like Mimics, 3 D Slicer, Geomagic freeform, Materialise 3 – Matic, CAD software, the 3D model derived from the CT scan undergoes segmentation and region-growing techniques to isolate the desired area on the skull model by removing unwanted regions. The symmetrical plane is determined using data from the patient's CT scan in coronal, axial, and 3D model views.

3. Finite Element Analysis

FE analysis serves as a valuable tool for predicting the biomechanical performance and success of designed implants in clinical conditions. It breaks down complex structures into smaller components, described mathematically as nodes and elements. ABAQUS/CAE software is utilized for FE analysis, aiding in enhancing design models and identifying potential weak spots or areas of instability to prevent future accidents.

4.Fabrication Process

Patient-specific implants are manufactured through titanium milling and 3D printing. Titanium alloys pose challenges for machining due to properties like low thermal conductivity, high chemical reactivity, and high hardness and strength at elevated temperatures, which hinder productivity and increase manufacturing costs.

This selective laser melting 3-D Printing procedure consists of 3 parts: Quality control of the powder material, 3 D printing of the implant, Post processing of the implant and quality control of the powder material. During the SLM 3D printing process, titanium powders are melted and solidified layer by layer to create the implant. The quality of the powder greatly influences the geometry, dimensional accuracy, surface quality, and mechanical properties of the final product. Unused powders can be recycled, but reused material may undergo changes due to exposure to heat, oxygen, humidity, and ultraviolet light, affecting its properties.

5. Implant Fitting Analysis

Achieving a precise and comfortable fit for zygomatic restoration is crucial. Particularly when correcting facial malformations like cheek asymmetry, ensuring the accuracy of implant fitting becomes paramount. Therefore, analyzing implant fitting is essential to improve placement and enhance the overall facial aesthetics. Aesthetic results of implant placement were evaluated using a visual analogue score (VAS) ranging from 1 to 5, where 1 represents poor and 5 represents exceptional.

6. Implant Sterilization

Before sterilization, the printed implant undergoes several cleaning procedures to eliminate any undesired organic and inorganic contaminants from its surface. Following steam sterilization, the implant is stored in a temperature-controlled vacuum-sealed package until the surgery.

Applications of Patient Specific Implants

Craniomaxillofacial surgery: Several studies have highlighted the successful use of patient-specific implants (PSI) in craniomaxillofacial surgeries. Various alloplastic materials like PMMA, hydroxyapatite (HA), PEEK, and metallic mesh are suggested as flexible substitutes during cranioplasty procedures. Furthermore, PMMA requires intricate intra-operative processes, such as mixing and shaping, leading to prolonged surgical times and potential cosmetic issues, especially in complex cases.[15] Additionally, contact between PMMA and the dura can trigger exothermic reactions and the release of harmful monomers, leading to tissue damage and systemic reactions. The overall failure rate for patient-specific implants in cranioplasty is approximately 14.3%. Traditional cranioplasty implants may take weeks to produce and sterilize, while 3D printing significantly reduces this time to just a few days. Digital models of cranial plates can be quickly generated and reviewed by surgeons, allowing for prompt manufacturing and delivery. Plates produced through digital workflows exhibit higher accuracy compared to manually manipulated plates, reducing the need for intraoperative adjustments.[15,16]

Orbital Reconstruction: Repairing fractures in the orbital wall and floor is challenging because of the intricate nature of anatomy involved. These fractures account for 10-25% of all facial fractures. Orbital reconstruction aims to correct defects in the orbital wall, restore orbital volume, and reposition the globe. Various implants like titanium, PTFE, and silicone are used for this purpose, but their adaptation to the injured orbit can be complex and time-consuming. Titanium mesh implants are commonly used for stable reconstruction in orbital floor fractures. Patient-specific implants (PSIs) have shown success in facial reconstructions, including orbital repairs. Patient-specific implants provide enhanced dimensional stability in contrast to manually shaped titanium implants. Their rigidity prevents distortion during placement while still permitting small intraoperative modifications.[17]

Nasal reconstruction: Restoring the nasal bone structure is crucial for achieving proper projection and function of the nose. Various methods for reconstructing nasal hard tissues have been discussed, including the use of autogenous grafts like ear cartilage, rib, and cranial bone. However, drawbacks of using autogenous tissue include limited shaping capabilities, potential for bony resorption, necrosis, and infection at the donor site. Conversely, alloplastic grafts, particularly titanium meshes, offer good biocompatibility and osseointegration for midfacial reconstructions. In parasinusal wall reconstruction, titanium mesh can also integrate soft tissue when exposed to the nasal area. Nonetheless, the primary disadvantages of titanium mesh include the potential for exposure and local infection.[18]

Zygomatic Bone: Reconstructing the zygomatic bone and maxilla is crucial for both functional and aesthetic reasons. Achieving accurate restoration of normal anatomy, symmetry, facial projection, and width are essential in orbito-zygomatic reconstruction. Various surgical techniques have been described for zygomatic complex reconstruction. Alloplastic implants, including metals, silicone, polymers, and hydroxyapatite-based products, have been used as alternatives to autologous bone grafts. However, finding the ideal alloplastic material remains a challenge. Off-the-shelf implants come in various sizes but often fail to precisely fit defects, leading to high revision rates. In contrast, patient-specific implants produced through computer-aided design and manufacturing (CAD/CAM) address these limitations.[19]

Temporomandibular Joint: Patient-specific implants (PSI) offer significant advantages in fabricating temporomandibular joint (TMJ) reconstructions. By leveraging advanced imaging techniques such as CT or MRI scans, PSIs can be precisely tailored to match the patient's unique TMJ anatomy. This customization ensures optimal fit and alignment, which are crucial for restoring proper function and alleviating symptoms associated with TMJ disorders. Additionally, PSIs allow for the incorporation of intricate features such as articulating surfaces and condylar contours, which are essential for mimicking the natural movement of the jaw. Overall, the use of PSIs in TMJ reconstruction helps improve surgical outcomes, reduce operative time, and enhance patient satisfaction. Partial TMJ reconstruction prostheses for the glenoid fossa have been made from materials like cast stainless steel, chrome-cobalt, and silicone rubber. Successful findings have been observed in cases of substituting mandibular condyles with CAD-CAM temporomandibular prostheses linked to custom-made reconstructive plates to aid free fibula flaps in patients with cancer related conditions and TMJ disorders, demonstrating favourable outcomes.[20]

Mandibular reconstruction: Reconstructing mandibular defects post-resection surgery poses significant challenges for surgeons due to factors like diverse anatomical regions involved and complexities in movement of mandible. The benchmark practices for treating segmental defects post-resection surgery typically involve sophisticated microsurgical techniques utilizing fibula-free flaps., along with costochondral rib and iliac bone grafts.[21]Digital reconstruction utilizing additive manufacturing and 3D printing enables precise replication of intricate anatomical models and facilitates the design and production of prostheses and implants that can accurately substitute removed sections.[22]

Orthognathic Surgery: Advancements in 3D imaging and CAD/CAM technology have transformed orthognathic surgery. While 3D surgical planning provides valuable insights into potential surgical challenges, such as proximity to vital structures and risk of bone fractures, the actual surgical process still involves free osteotomies. Patient-specific implants (PSI) offer enhanced accuracy, flexibility, stability, and predictability in achieving refined facial expressions. Utilizing additive manufacturing techniques, PSI and cutting surgical guides have proven beneficial in procedures like Le Fort I osteotomy, ensuring precise fit and requiring minimal adjustments in most orthognathic cases.[23]

Future Directions

Numerous studies focus on advancing materials and techniques to improve the treatment of congenital and acquired orofacial defects. Recent research highlights various aspects for further exploration in evaluating maxillofacial prostheses, including biocompatibility, cleaning methods, pigment integration, and material bonding effectiveness. Engineering, computer-aided design and manufacturing (CAD CAM), and surgical guides are essential to produce these new prostheses.[24]

CONCLUSION

Surgeons find maxillofacial reconstruction challenging due to complex anatomy and potential complications with traditional implants. However, patient-specific implants (PSIs) made possible by 3D printing technology have revolutionized the field. PSIs eliminate the need for donor sites, offer precise reconstruction, and enhance stability. They're particularly beneficial for cranioplasty and orbital fractures, providing near-perfect restoration of appearance and function. Despite their effectiveness, PSIs are expensive, require specialized expertise and equipment, and may have limited availability. Nevertheless, they significantly reduce operative time, minimize adjustments, and improve outcomes.

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