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The Realm of Patient Specific Implants (PSI) In Maxillofacial Prosthodontics: A Review

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Abstract: *Reconstruction and augmentation of congenital and acquired maxillofacial defectsare deemed quite a challenge to experienced doctors. Meticulous rehabilitation of the elaborate "three-dimensional" (3D) facial forms necessitates detailed shaping and sculpting of autologous grafts and manufactured implants, and conforming them to the primary skeletal structure to reestablish anatomical facial structures. Inaccurate shaping of off-the-shelf implants could end in suboptimal formed restorations. Nevertheless, recent developments in computer-aided design/computer-aided manufacturing (CAD/ CAM) have devised contemporary alternatives for fabricating patient-specific implants (PSIs), with enhanced accuracy, resulting in restoration with improved contour and outcomes. This article collates available evidence relating to the benefits and limitations of Patient-specific implants, thereby revealing the potentiality of Patient-specific implants (PSI) as a viable option for the rehabilitation of oral and maxillofacial structures in near future.*
Key Word*:Patient-specific implants, Patient-specific dental implants, Custom made implants*

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I. Introduction

Dental implants have been drawing more recognition owing to their benefits of reliability and comfort and it is assessed that at least 10% of people would require dental implants during their life time (1). Reconstruction and augmentation of congenital and acquired maxillofacial defects are deemed quite a challenge to experienced doctors. Meticulous rehabilitation of the elaborate three-dimensional (3D) facial forms necessitates detailed shaping and sculpting of autologous grafts and manufactured implants, and conforming them to the primary skeletal structure to reestablish anatomical facial structures. Inaccurate shaping of off-the-shelf implants could end in suboptimal formed restorations. Nevertheless, recent developments in computer-aided design/computer-aided manufacturing (CAD/ CAM) have devised contemporary alternatives for fabricating patient-specific implants (PSIs), with enhanced accuracy, resulting in restoration with improved contour and outcomes (2).

The invention of PSIs has considerably evolved ever since its introduction in the rehabilitation of oral and maxillofacial defects. As early as the 1980s, 3D images were created utilizing computed tomography (CT) sections. The 3D images were molded into unrefined anatomic models which were utilized in preoperative planning. To fabricate these models, 3D imaging data were fed to the computer-numerical controlled (CNC) milling machines that would slice out of blocks of Styrofoam (Dow Chemical Company, Midland, Michigan, USA) or polyurethane into the concluding model using Subtractive manufacturing techniques. Early Patient-specific implants were also produced using this approach(3). However, subtractive manufacturing" had its limitations, in reproducing the finer anatomical details. With the advent of Additive manufacturing technologies as stereolithography (SLA), polyjet, fused deposition modeling; 3D printing, selective laser melting (SLM), selective laser sintering (SLS) and electron beam melting (EBM) extend themselves to the production of intricate structural portions without any limitations of design restrictions involving structural arrangements(4) thus proving to be valuable in the reconstruction of Patient-specific implants. In AM technology, the prosthesis is fabricated by depositing the material in layer-by-layer fashion, which is carried out by digitally controlled material laying tools (5)

II. Objectives

The purpose of this review is to collate available evidence relating to the benefits and limitations of Patient-specific implants, thereby revealing the potentiality of Patient-specific implants as a viable option for the rehabilitation of oral and maxillofacial structures in near future.

III. Material And Methods

A PubMed and Science Direct bibliographical research was carried out between the year 2014-2020. The following keywords were used to search for articles: “Patient-specific implants”, “Patient-specific dental implants”, “Custom made implants”, “3D modeling”, “Custom made dental implants” The eligibility inclusion criteria” used for article search were: Review, Systematic review, and clinical reports. The title and the abstract were given a preliminary evaluation to ascertain whether they satisfied the inclusion criteria. The chosen articles were completely read and interpreted “considering the purpose of the study.

IV. Discussion

Reconstruction Aspect:

Maxillofacial PSIs have both reconstructive and esthetic indications. Congenital facial syndromes is linked to skeletal insufficiencies and deformities of the face that are remarkably challenging to rebuild. The conventional method opts for methods such as osteotomies, bone distraction, and grafting to enhance facial contour. Results obtained from these procedures are variable relying on factors such as survival of the grafts, and precision of bone movement and healing. PSIs can be manufactured and used as an onlay, to reconstruct the required facial profile. PSIs could also be utilized in the rehabilitation of deformities involving one side of the face, fabricating implants using a mirror image of the opposite healthy front(6). Various reports have been published about the use of Patient-specific in the reconstruction of congenital facial deformities (7,8).

Patient-specific implants (PSI) are employed in the rehabilitation of atrophic mandibular ridges seen in elderly patients. Here, custom made subperiosteal implants were fabricatedin titanium utilizing Direct metal laser sintering (DMLS). With regards to the outcomes of the study, the fit of these subperiosteal implants was found to be notably adequate with a median grading of 7 out of 10, and with the survival rate of 100% after a follow-up of one year (9).

The world’s first complete mandible set fabricated using addititive technology, was placed into a patient by Dr. Jules Poukens and team in Belgium (10) (shown in Fig:1)

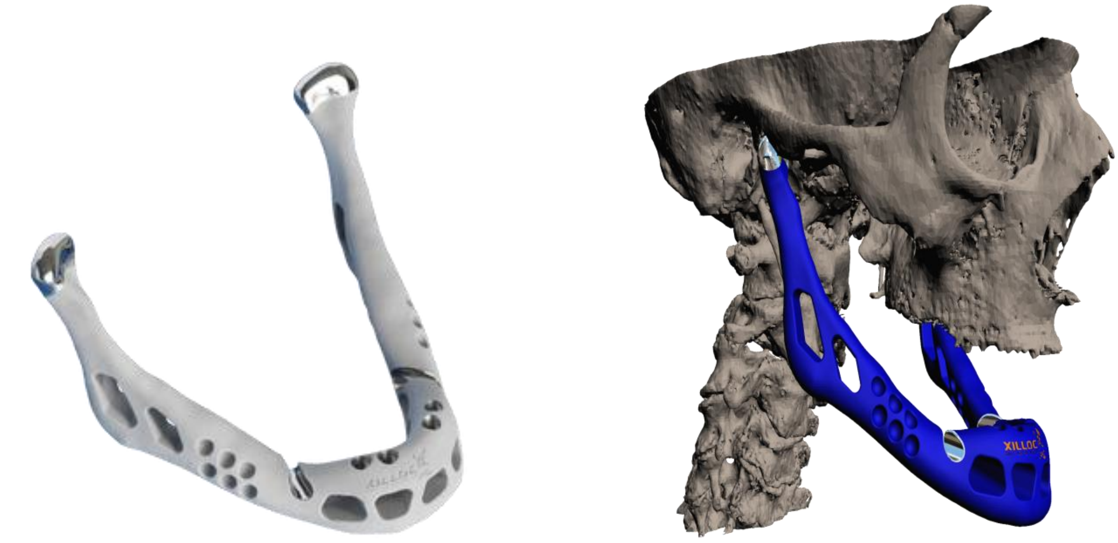

Fig:2 World’s first additive manufactured complete mandible (10)

Reconstruction of complex posttraumatic maxillofacial defects could be managed with Patient-specific implants (PSI) as well. The orbital wall and the floor are typical areas for the fracture of facial bones and could severely impair normal functions (Shin et al, 2013). However, the restoration of these structures is quite complicated, owing to the inadequate intraoperative view and intricacy of the involved anatomical region. Ill-fitting and implants inaccurate surgical techniques often pose the hazard of visual impairment and often yielding unaesthetic results. The use of patient-specific implants in the rebuilding of various facial structures such as fractured orbital walls, the floor of the orbit (11), and in operating other maxillofacial defects have been quite successful(12,13).

Surgically acquired defects post tumor treatment often pose challenges in dental rehabilitation, thereby influencing Oral health-related quality of life (OHR Qol) in such individuals. Jehn et al (14) surveyed 12 individuals that were treated with patient-specific implants for severe bone deficiency and were assessed for Oral Health Impact Profile (OHIP) post dental rehabilitation. Patients- specific dental implants, particularly coupled with fixed dentures lead to positive OHRQoL in patients with severe bone deficiencies linked to tumor therapy.

Material Aspect:

Various implant materials have been perfected in the last 5 decades for the replacement of lost soft and hard bony structures. The implant to be used must be biocompatible with tissues, radiolucent, lightweight, and should possess characteristics that allow ease of modification of the implant. Maxillofacial Patient-specific implants (PSI) are most commonly manufactured from metal, polymers, ceramics using additive manufacturing technologies. Due to the abundance of these materials, there is no problem regarding the morbidity donor site which is one of the disadvantages seen with the use of autologous grafts (15)

The implant materials have been broadly classified as absorbable and non-resorbable materials. Absorbable materials include Poly-DL-lactic acid (PDLLA), polyactide-co-glycolide acid (PLGA), and calcium phosphate, while the non resorbable materials include materials such as Titanium, polyethylene, polyether ether ketone (PEEK) and hydroxyapatite (HA).

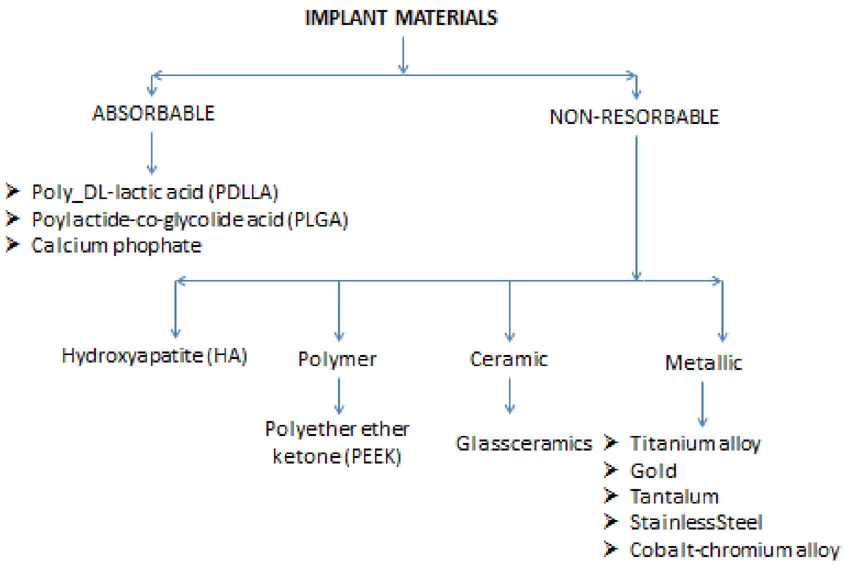

Fig: 3- Schematic of various implant materials

Metallic implants including gold, tantalum, stainless steel, shape memory alloy, titanium alloy, and cobalt-chromium alloy have extensively been utilized for a permanent prosthesis such as dental implants, and even for temporary implants such as pins, screws, fixation rods in the management of various fractures. These implants are said to possess advantageous characteristics such as increased mechanical strength, superior resistance to friction, and are often the chosen "alloplastic material in AM for the manufacturing of orthopedic implants (16,17). Nevertheless, its high strength and elastic modulus does not equate to the normal human bone and thereby causing a stress shielding effect resulting in loosening of the prosthesis.

Titanium has been authenticated as a preferred selection of metal in the reconstruction of patient-specific implants (PSI) in the maxillofacial region such as orbital reconstruction (18,12)mid-face reconstruction (19) and total mandibular replacement (20). Additive techniques on titanium implants include physical vapor deposition or electrochemical methods to chemically alter the surface in a specific environment comprising bioactive materials.

Amongst ceramics, metallic oxides, calcium phosphate, and glass ceramics are often used. The materials used are the least toxic and are highly compatible with body tissues. Yet, their reduced fracture toughness and ductility along with increased modulus of elasticity and brittleness make them unsuitable for load-bearing applications (21)

With recent advancements in technology and material production, Polyether ether ketone (PEEK) has emerged as one of the promising alloplastic materials that could be used as a viable alternative in the production of Patient-specific implants (PSI). "PEEK" exists as semi-crystalline linear polycyclic aromatic thermoplastic associated with a group of linear aromatic polymers containing ether and ketone linkages (22), which is known for its enhanced resilience, endurance to environmental changes, and decreased infection rate (23). Osseous integration of PEEK relies on the factors such as surface composition, surface energy, surface roughness, and topography (24) which can be altered to yield rough or smooth surfaces, with the help of fused filament fabrication (FFF) technology.

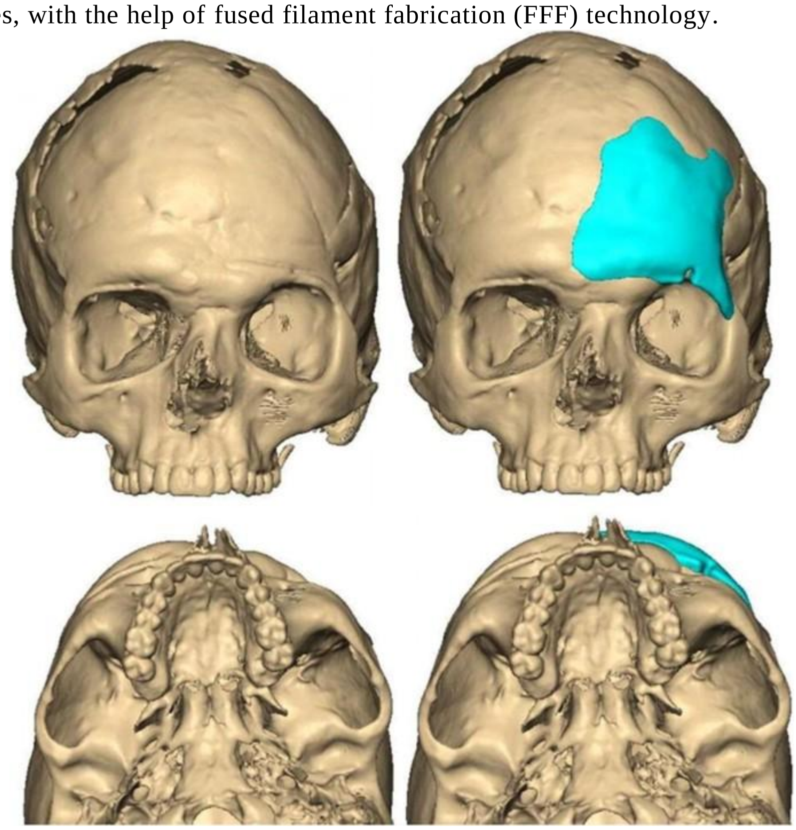

Fig:4 Custom-made Patient specific implant made up of PEEK

Many studies had been conducted regarding the use of PEEK and other materials in the fabrication of cranial prosthesis, reporting the complications faced while using prosthesis made of PEEK. E. Alonso Rodriguez et al (24) and Rosenthal et al (26) printed a study of 65 cases reporting contamination incidence of 7.7%

Nassiriet al (26) reported their experiences with the use of Polymethyl methacrylate (PMMA) CAD/CAM implants in 21 individuals with extensive deformities of the cranium, throughout 3years. A complication of 23.8% was reported, including soft tissue infections and implant exposure, whereas Rosenthal et al reported a contamination incidence of 7.7% among 65 cases in the study he had conducted. (26).

Gerbino et al (28) presented the results of their clinical study comprising of 13 individuals, stating that the form and the fit of the implants used were quite in each case. Minor adjustments were required in 11 cases, while extensive adaptation was required in 1 case. Among the 13 implants that were used for rehabilitation, 11 of those implants restored complex areas with satisfactory esthetic cosmetic results and with no further complications. Jarvinen (29) also added that among 24 cases, 19 of the cases did not require any adjustments in the PEEK made Patient-specific implants. He also added that only 5 cases required contouring or trimming of the bone to achieve a perfect fit.

Poly ethethylene include porous polyethylene (PPE) and ultra-high molecular weight polyethylene(UHMW-PE) are being utilized in the rehabilitation of orbital defects and facial development (30). PPE is durable and simple to model and tissue ingrowth through its pores (31). Nevertheless, the chances of infection are likely to occur (29). UHMW-PE, known for its solid structure, is employed in the restoration of orbit or temporomandibular joints by fabricating PSIs using CAD-CAM technology (32). UHMW-PE is reported to have a lower incidence of infection rate when compared to PPE (33).

Hydroxyapatite (HA) has been utilized as biocompatible scaffolding material towards bone tissue engineering (34). They are osteoconductive in nature and non-resorbable and are widely known for its substantial potential to adhere to the bone and soft tissues. (35).

Absorbable materials- PDLLA and PLGA are generally employed in pediatric craniofacial surgeries (36). Nevertheless, the occurrence of foreign body reactions post-implant therapy is likely to occur and there have also been cases where fracture of the material has been reported (37).

Calcium phosphate which has also been utilized in the rehabilitation of craniofacial defects is known to exhibit satisfactory biocompatibility and biodegradation characteristics. These are quite comparable to the mineral phase of bone and thus, does not induce any artifacts or interferences as witnessed with different alloplastic materials, while taking a CT or MRI. Although calcium phosphate displays inadequate mechanical strength when compared to titanium, it is considered acceptable as a scaffolding for the growth of bones and can be packed with bioactive proteins or antibiotics.

Manufacturing Aspect:

The manufacturing process beings with the image acquisition utilizing computed tomography /magnetic resonance imaging (MRI) 2Dimage data as digital imaging and communications in medicine (DICOM) files. These DICOM files are then prepared to employ software (3D Doctor, MIMICS) to devise a 3D model of the anatomical deformity. These 3D models were then fed into design software, where these “3D” models are materialized into the final implant design. The implants are then brought to life by shaping the implant material block (Subtractive manufacturing) or by adding layer by layer and fusion of implant material layers (Additive manufacturing). (6)

Earlier the manufacturing of these patient-specific implants was done using subtractive manufacturing techniques, where pieces of material were sliced off until the final shape was attained. However, it was noted that there was wastage of a lot of material and it failed to replicate complex anatomical shapes using computer numerical control (CNC) in subtractive manufacturing. This paved way for the production of patient-specific implants using Additive manufacturing, also known as Rapid prototyping or 3D printing. This not only overcame the limitations encountered with subtractive manufacturing but also fastened the production of these Patient-specific implants (5). Additive manufacturing included several processes, such as Binder jetting (BJG), Direct metal laser sintering (DMLS), electron beam melting (EBM), laser engineered net shaping (LENS) and Fused deposition modeling (FDM) (6,38,39)

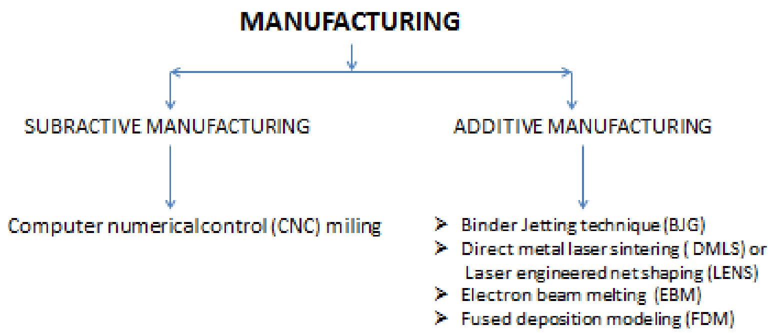

Fig:5 - Schematic of manufacturing processes

Binder jetting (BJG) technique comprised of two components: a powder component that made the prosthetic part and a binder component that bonded the powder materials. Implants that were manufactured using this method did not require any additional support. However, these implants exhibited lower mechanical properties and had rough microstructure, when compared to the ones manufactured by Selective Laser Melting (SLM) or Electron beam melting (EBM) manufacturing technique, owing to the possibility of porosities and heat treatment (38). Apart from this, the cost of production was also increased which was considered another disadvantage.

Direct metal laser sintering (DMLS), also referred to as selective sintering, adopts the highly energized lasers to blend the metal into solid elements based on a 3D CAD file, which is built layer by layer.DMLS possesses advantages such as usage of a large variety of materials, enhanced functionality, the reduced price of production, and the production of ready- made net-shaped elements and, and disadvantages such as size constraints, high power dissipation, and initial large costs. Similar to DMLS is Electron beam melting (EBM) where the metal powder is melted layer by layer using an electron beam. (39)

Laser engineered net shaping (LENS) utilizes metal components straight off CAD solid models and the variation in the alloy particles is interjected in a bath of molten metal formed by a dense highly-powered laser beam (39). The melted metal band quickly sets as the laser beam withdraws, after forming each layer. This is repeated several times until the whole object presented in the 3D CAD model is generated. (40)

In Fused deposition modeling (FDM) [also known as Fused filament fabrication (FFF)], the polymer is liquefied in the printer outlet and is laid down layer by layer. The substance which is dissolved gets placed at a predetermined position, thus creating the first layer, following which the gap between the printing area and the extruder outlet is extended resulting in the deposition of the second layer over the first layer(41). The major advantage of the FDM technique is the reduced cost of production with a short start-up time.

The manufacturing process opted for the fabrication of Patient-specific implants is ideally carried out taken into considerations such as nature of the material, convenient technology, properties, lead time, post-processing accuracy surface, and surface quality. (38)

V. Future Directions

Patient-specific implants that are currently being manufactured takes several days for complete fabrication. With the advent of newer technologies in 3D printing, the production time for the fabrication of these implants could be expected to reduce and could be made more economical. It is also expected to see a combination of alloplastic and autologous materials been used in "the production of Patient-specific implants", paving way for the next generation of craniofacial implants. The usage of "adipose-derived stem cells (ASCs)" in the production of PSIs could be a possibility in the future. Studies have been conducted demonstrating that anatomically correct bone grafts from ASCs were bred and inserted in Yucatan mini-pigs to recreate the ramus-condyle unit(42).

VI. Conclusion

Patient-specific implants have created a niche in personalized medicine, delivering "oral and maxillofacial prosthesis" tailored to one's specific needs. These implants not only yield desirable results but greatly improve the quality of life of the individual in reconstructive cases, making the ideal choice of implants in the rehabilitation of complex post-traumatic maxillofacial defects. Further advancements in the CAD/CAM technology, will permit the fabrication of these Patient-specific implants at a much lesser cost, while simultaneously improving its precision, efficiency, and overall outcome.

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