Patient Specific Implants

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Abstract: Three-dimensional (3D) virtual surgical planning, the creation of anatomical models, and the development of patient-specific implants (PSI) have become well-recognized methodologies within the realm of surgery. Polyetheretherketone (PEEK) is increasingly utilized, particularly in reconstructive procedures, as a dependable substitute for other alloplastic materials in the production of PSI. The application of computer-engineered PSI facilitates more precise reconstruction of maxillofacial defects, mitigating the common complications associated with traditional preformed implants and leading to enhanced patient satisfaction.

Keywords*: Implants, Polyetheretherketone (PEEK), Reconstruction, 3-Dimensional.*

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I. INTRODUCTION

Reconstructive surgeries present significant challenges, even for the most skilled surgeons, primarily due to the intricate nature of human anatomy, the sensitivity of the systems involved, and the distinct characteristics of each defect. [1] The imperative to effectively reconstruct these defects during surgical procedures is vital for enhancing patient outcomes and overall well-being. [2] A patient-specific implant (PSI) may serve as a valuable solution, tailored to fit accurately within the anatomical irregularities or malformations. [3, 4].

The advancement of three-dimensional (3D) design and manufacturing technologies has facilitated the straightforward production of a range of computer-aided, patient-specific instruments. In the maxillofacial area, the management of facial defects, asymmetries, and dental issues can be effectively achieved through the utilization of custom-designed implants.

The integration of Patient Safety Indicators (PSIs) into the treatment protocol can enhance postoperative outcomes for maxillofacial surgeries. This innovative strategy allows for the planning of screw positions during preoperative simulations, thereby preventing any potential harm to anatomical structures. Such preoperative arrangements contribute to a

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reduction in operating room duration. Furthermore, the utilization of customized osteotomy and drill guides facilitates the precise fixation of implants in the intended positions, thereby minimizing the risk of damage to the maxillofacial area and increasing the accuracy of surgical procedures. [5]

II. MATERIALS AND APPLICATIONS

Virtual surgical planning in three dimensions, the creation of anatomical models, and patient-specific instrumentation (PSI) are well-established methodologies within the surgical domain. Polyetheretherketone (PEEK) has emerged as a dependable alternative to other alloplastic materials, particularly in reconstructive surgeries for the production of PSI. Recently, advancements have enabled the fabrication of PEEK PSI utilizing Fused Filament Fabrication (FFF) technology. The 3D printing of PEEK through FFF facilitates the construction of intricate and complex design geometries.

Various alloplastic materials, including metals, ceramics, polymers, and composites, are produced using Additive Manufacturing (AM) technologies and are employed in both reconstructive and orthopedic surgical procedures. The widespread availability of these materials eliminates concerns regarding donor site morbidity. [3, 5].

Polymers present themselves as effective substitutes owing to the constraints associated with metallic and ceramic biomaterials. Numerous polymers, including ultrahigh molecular weight polyethylene (UHMWPE), polymethyl methacrylate (PMMA), polylactide (PLA), polyglycolide (PGA), and polyhydroxybutyrate (PHB), find extensive application across a range of biomedical fields.

The acquired computed tomography (CT) scans, which capture images of the soft tissues, bones, and nerves within the craniofacial region of the patient, are preserved in the Digital Imaging and Communication in Medicine (DICOM) format. Engineers at AMI commence the processing of these DICOM files utilizing "MIMICS" and "3-MATICS," medical modeling software developed by Materialize in Belgium. The MIMICS software organizes the DICOM files, layering the two-dimensional (2D) images to create a comprehensive three-dimensional (3D) model of the face. As shown in “Fig. 1”, full facial 3D model with tumor region on the left side of the mandible.

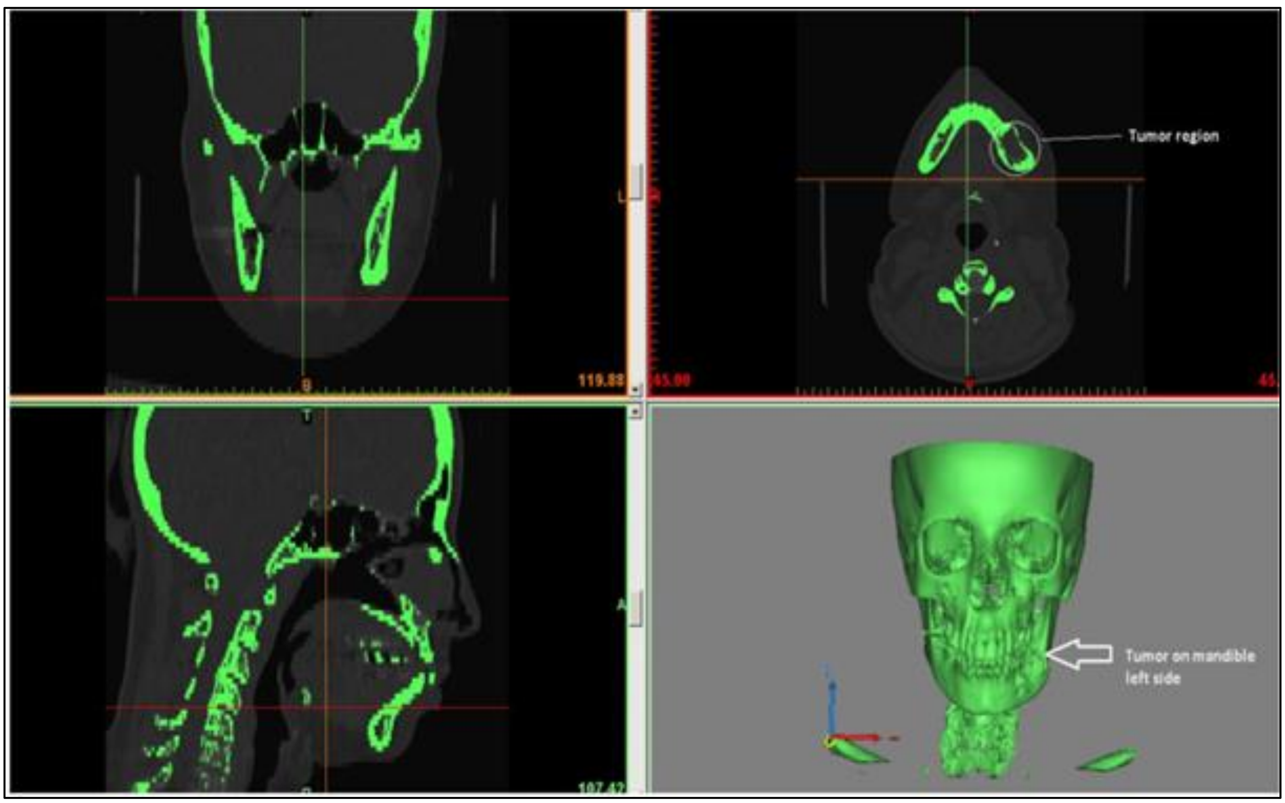

Fig 1 - 3D Image of the Patient’s Craniofacial Bone using Mimics

Different segmentation techniques, including thresholding, region growing, and 3D reconstruction from masks, are employed to isolate the mandible region from the complete 3D facial model, as illustrated in the accompanying figure 2 (A-G)”.

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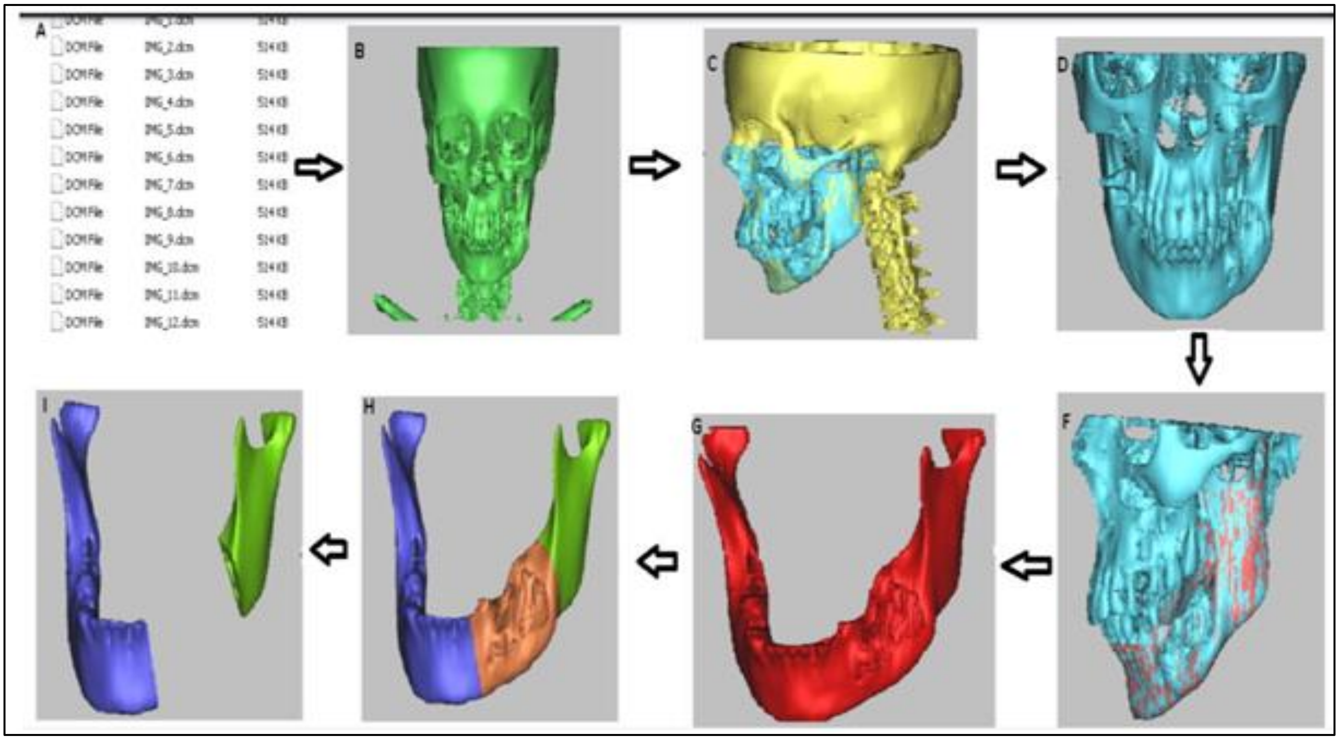

Fig 2 - Flow Process from Dicom Files to Mandible Segmentation.

The tumor is located on the left side of the mandible, while the right side remains healthy and unaffected. To create the reconstruction plate, the healthy portion of the mandible is mirrored to correspond with the affected area on the right side, as illustrated in "Fig. 3 (B)". The customized mandible implant model (yellow) is developed from the right mirror image model (red) through cutting, trimming, and offset operations in 3-matics (refer to "Fig. 3 (D)"). This specially designed reconstruction plate fits seamlessly onto the resected tumor area, as it is derived from the bone's mirror image. The virtual simulation of the implant attachment to the bone with screws has been validated by a dentist. Should any modifications be necessary, the mandible and implant designs will be reprocessed using mimics.

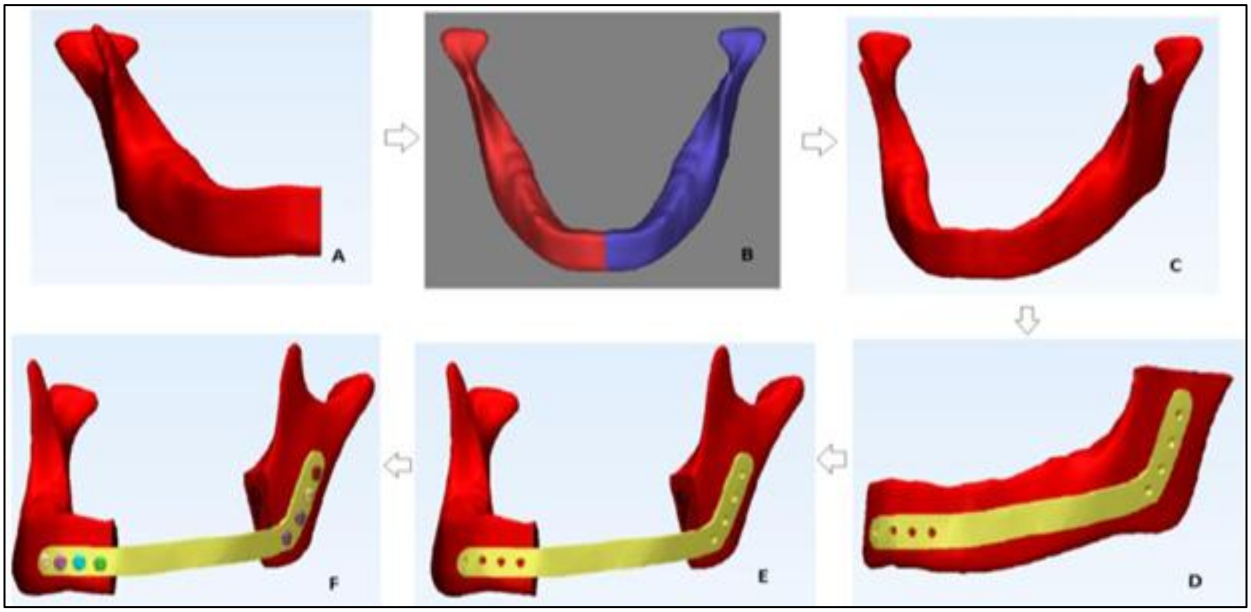

Fig 3 - Design Steps from the Mirroring to the Implant Design

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Upon validation of the Standard Tessellation Language (STL) files for both the implant design and the mandible framework, as illustrated in "Fig. 3 (f)", the physical implants are produced utilizing Fused Deposition Modelling (FDM). The assessment and fitting rehearsal of the physical models are subsequently confirmed by dental professionals prior to the final production of the Titanium implant through Electron Beam Melting (EBM). Should the implant design be deemed unacceptable due to discrepancies between the implant model and the mandible framework, the design process will be reiterated. The creation of the polymer-based mandible framework along with the designed implant and screws is depicted in "Fig. 4 (A, B)".

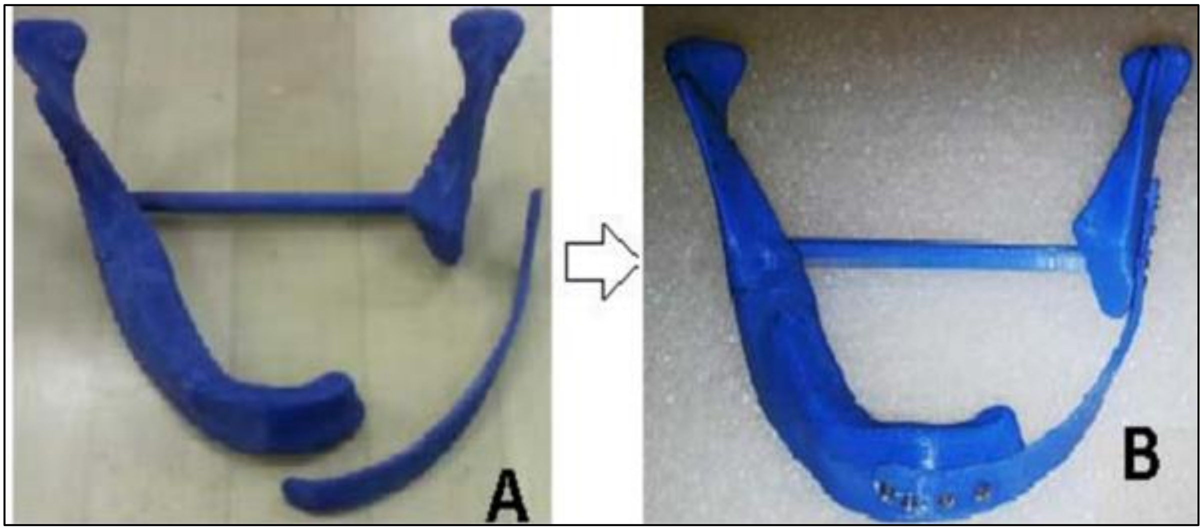

Fig 4 - Customized Polymer Implant for Fitting and Rehearsal on Mandible Framework Fabricated using FDM

Upon the successful conclusion of the design and fitting rehearsal for the polymer-based models, the final titanium implant is manufactured utilizing ARCAM's Electron Beam Melting (EBM) technology. The material employed is Ti6Al4V ELI in powder form, with particle sizes ranging from 50 to 100 microns, processed in the EBM A2 Machine. As illustrated in Figure 5, the titanium implant produced by the EBM process is designed to fit the mandible model. Prior to the surgical procedure, the implant undergoes sterilization.

Fig 5 - Customized Titanium Implant Fabricated using EBM

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III. APPLICATIONS

- Temporomandibular Joint Total Joint Replacement
- Reconstruction of a mandibular ramus-condyle
- Parry-Romberg syndrome case
- Hemifacial microsomia
- Craniotomy
- Zygoma defect
- orthognathic surgeries
- Post-Traumatic Orbital Defects and Deformities

IV. DISCUSSION

Maxillofacial defects present significant treatment challenges due to their critical functional, aesthetic, and psychological implications. The intricate anatomy of this region adds to the difficulties faced by all surgeons, regardless of their experience level. Conventional pre-fabricated alloplastic implants often result in less than ideal outcomes due to the need for modifications. However, advancements in 3D imaging and additive manufacturing (AM) technology facilitate the creation of custom patient-specific implants (PSIs) that offer improved accuracy, enhanced stability, predictable results, and superior refinement of facial contours. Unlike standard alloplastic implants, custom PSIs reduce the risk of complications such as infections, foreign body reactions, and displacements. [6] This aligns with our clinical experience, where none of these complications were observed. Utilizing AM technology, we successfully treated six patients with various maxillofacial defects, employing a total of eight PEEK implants and two titanium PSIs. Initially, we encountered difficulties in obtaining the appropriate pre-operative CT scans for effective 3D planning. This issue was resolved by consistently requesting 1-mm-thick CT scans for all PSI cases. In the design of custom PSIs, engineers typically position fixation screw holes in areas of the densest bone, often overlooking nearby vital structures. Nevertheless, it is straightforward to modify the drilling locations in the final implant, allowing for greater flexibility compared to pre-fabricated alloplastic implants like silicone.

Drilling screw holes outside of the predetermined locations poses a risk of implant failure. One of the difficulties in addressing the fixation of the mandibular angle PSI is the discrepancy between the extension of the superior border for fixation and the anatomical structure of the corresponding healthy side. To address this issue, we suggest standardizing the PSI design by incorporating an extended superior border with a minimum thickness to ensure secure fixation.

The application of PEEK in reconstructive surgery is extensively recorded in the literature, attributed to its remarkable biocompatibility, adaptability, stability, chemical inertness, radiolucency, and mechanical characteristics [7, 8]. In addressing the secondary deformity associated with the zygoma and orbit, a custom-made titanium implant was utilized in the orbital region rather than PEEK, as it is more cost-effective and does not require additional modifications. The reconstruction of the zygoma was accomplished using a distinct PEEK patient-specific implant.

The Patient-Specific Instrumentation (PSI) utilized necessitated only minor modifications, which were easily implemented during the surgical procedure. Nevertheless, challenges associated with the insertion of larger implants could be alleviated through a modular design featuring connectors. In the case of post-traumatic secondary deformity, a custom cutting guide was employed to create the zygomatic osteotomy, thereby facilitating the repositioning of the zygoma prior to the placement of the PSI. The design of custom nasal implants presented difficulties due to the involvement of bilateral bone structures. We addressed this issue by utilizing an average healthy nasal bone template. However, the final implant proved to be excessively bulky, necessitating additional adjustments during the operation. [9, 10]

In each of our cases, we focused solely on the reconstruction of bony hard tissues. Nevertheless, assessments of soft tissues remained essential to guarantee the achievement of optimal outcomes. Looking ahead, we advocate for the integration of soft-tissue defects into PSI designs to appropriately plan for PSI thickness. The infection rate associated with maxillofacial reconstruction using PSI was minimal (7.7–14.3%) to nonexistent [11, 12, 13].

The primary issue associated with PSI reconstruction is the risk of postoperative infection [12]. Drawing from our extensive experience with non-custom implants, including silicone and porous polyethylene, we have observed that postoperative infections typically occur within the initial weeks and are rarely encountered after one month. Although the high cost of PSI presents a notable disadvantage, its benefits surpass the financial implications. [14, 15, 16]

V. CONCLUSION

This research assesses the safety of implants by conducting stress analysis, thereby guaranteeing both durability and patient satisfaction through the use of computer-aided patient-specific implant design for the reconstruction of maxillofacial defects.

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