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Research Article

Design and Fabrication of Patient-Specific Implant for Maxillofacial Surgery Using Additive Manufacturing

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Patient-specific implants are well known for fixing the fracture for bone repairs. However, the exact fixation of the fabricated implant to the patients is a challenging task. To overcome this problem, in the present study two kinds of designs are developed and fabricated. Based on the exact fitting to the patient's oral system, the best design is selected to fabricate. Computed tomography (CT) scan data of the patient oral anatomy is converted into a 3D model using the DICOM Software "Slicer 3D." The patient-specific maxillofacial implant is fabricated using fused filament fabrication (FFF) and direct metal laser sintering (DMLS) techniques. Before fabricating real time product, a prototype is fabricated at the initial stage using FFF. Later, stress distribution and displacement of the implant was investigated using a FEM simulation. The conclusion of the present work results are potential for FFF of patient-specific implants out of Ti-6Al-4V.

1. Introduction

Subperiosteally dental implant is a framework like custom made structure with abutments for support and fixation of dental restorations [1]. Subperiosteal dental implants are made from biocompatible materials like cobalt chromium (CoCr) and [2–4] Titanium alloys. Masticatory force is transferred to and distributed over a large area of the bone surface, rather than the bulk of the bone, as compared to root form implants [5, 6]. In general, for fixing the dental implants to the patient an acceptable bone is required to support the implant and also should contain healthy gums [7]. In some cases, bone grafting is created due to bone density is low. Nevertheless, in the case of severe bone resorption, extensive bone regeneration requirement represents clinical treatment challenges leading to hesitation from patients. Therefore, in recent times patient-specific implants are developing to avoid the above problems faced by various patients [8]. For the age group of 50–60 years, patient-specific implants are avoiding the regenerative surgeries and fixing the dental restoration [9].

Apart from dental restoration, maxillary and jawbone reconstructions find applications in treating bone defects caused by tumors, injuries, or infections [10]. However, such reconstruction represents major challenges from both the engineering and medical aspect. Subperiosteal implants are fabricated by the following three methods: (i) classic/traditional method, (ii) hybrid method, and (iii) digital method [11]. In the traditional method, the surgery needs to be performed twice, where during the first surgery the impression of the bone and the refractory model is made. The implant is designed based on the refractory model in Co Cr or Titanium alloy [12]. The second surgery is then done to install the implant on the patient. Though it takes two surgeries, this is the most accurate method presently in use. In the hybrid method, the CT scan data of the patient is used to develop a 3D model of the jaw and the model duplication is done into plastic or some other material and the rest of the design process is similar to the classic method [13]. This method helps in preventing two surgeries. In the digital method, the entire work is done digitally. From the CT scan data of the patient, the 3D model is developed and using several finite element analysis software the implant is tested and manufactured using several additive manufacturing techniques. Two surgeries are prevented in this technique and the quality of the implant is also better [14].

Several researchers have studied the effect of loads and the type of material used [15]. And, the topology of the implant could play a significant role in determining the stress and displacement of the implants. and their behaviour [16]. Therefore, the present researchers focused on the optimization of the material and topology features of the implants [17]. The application of the finite element method (FEM) has been hugely popular among researchers to analyze the stress distribution of dental implants and the bone surrounding them [18]. FEM is an effective tool which can be used to simulate a complex mechanical problem by disintegrating the 3D problematic geometry into a collection of very small simpler elements [19, 20]. Computed tomography is used to obtain the image data, and the corresponding FEM model is generated by the help of a 3D scanner or magnetic resonance imaging [21]. On applying the proper combination of elements, predefined boundary conditions in the meshed model the displacement and stresses caused by loading can be calculated effectively at each node.

Several studies have been published recently regarding the FEA of dental implants, but the accuracy of the studies is still a question [22, 23]. Several factors affect the results of the analysis as every implant has its function and every implant has different Boundary conditions [24]. And, checking of the accuracy of the results of the FEA is also a very tedious task. The usage of the digital method for designing the implants is also in its initial stages, so the research work carried out on the FEA analysis of the dental implants is also very little [25].

To this end, Ti6Al4V is one of the widely used Titanium alloys with low density and high corrosion resistance making it one of the perfect choices for biomedical applications (Implants and Prosthetics) [26, 27]. In particular, to fabricate patient-specific implants, the new direct metal laser sintering (DMLS) techniques available today to provide accurate results [28] or even implants [29, 30] that perfectly acclimate to the precise functional requirements of patients. The usage of modern manufacturing methods made the researchers to look into the past techniques, like as such as subperiosteal implants, and re-explain them in a modern and digital way [31, 32]. This can be extremely useful in the case of severe bone atrophy, which does not allow for the placement of end osseous dental implants if a regenerative intervention approach is not followed, particularly in the case of elderly patients with limited financial resources and who do not wish to undergo long and complex regenerative surgeries prior to the insertion of end bony dental implants [33]. The present study develops a new digital technique for the fabrication of patient-specific implant using DMLS subperiosteal implants and investigates the survival and difficulty rates encountered when using these fixtures.

2. Experimental Methodology

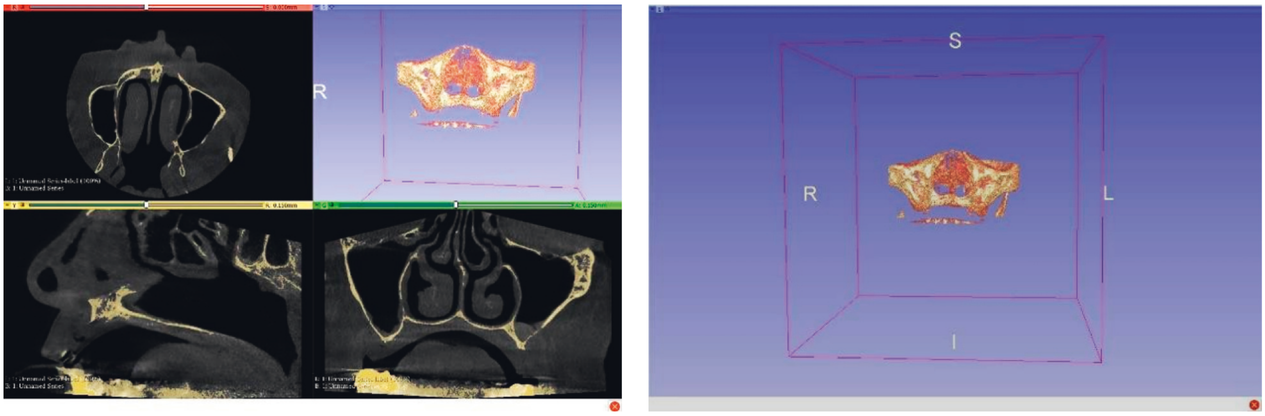
2.1. Materials and Methods. The workflow started with the patient's anatomical data. The DICOM data (CT Scan) of the patient is converted into a 3D model using the DICOM Software "Slicer 3D." The 3D model is extracted by adjusting the minimum and maximum threshold limits. The generated 3D model from the CT scan is exported into STL (Standard Tessellation Language) format. The 3D model is imported into AUTODESK MESHMIXER, a modeling software where one can create and correct the 3D models. The errors in the 3D model are rectified and the implant is designed as per the rules specified by the doctor. The implant is designed using the sculpting tools in the AUTODESK MESHMIXER. Using this input, an initial design of the implant was developed matching the patient's maxilla structure, and 3D CAD of the implant prototypes was generated using modeling software, Using the STL files, implant components were printed by FFF with the filament which has 58% volume of Ti-6Al-4V powder dispersed in a multi-component custom polymer matrix using a desktop printer.

Apart from physical printing, the MF3 printing process was also simulated using a CAE simulation tool, Digimat (MSC Software, Newport Beach, CA, USA), to estimate part deflections and residual stresses. A typical workflow of patient-specific implant fabrication using the MF3 process is presented as the one followed for the case study analyzed.

2.2. Design of Implant

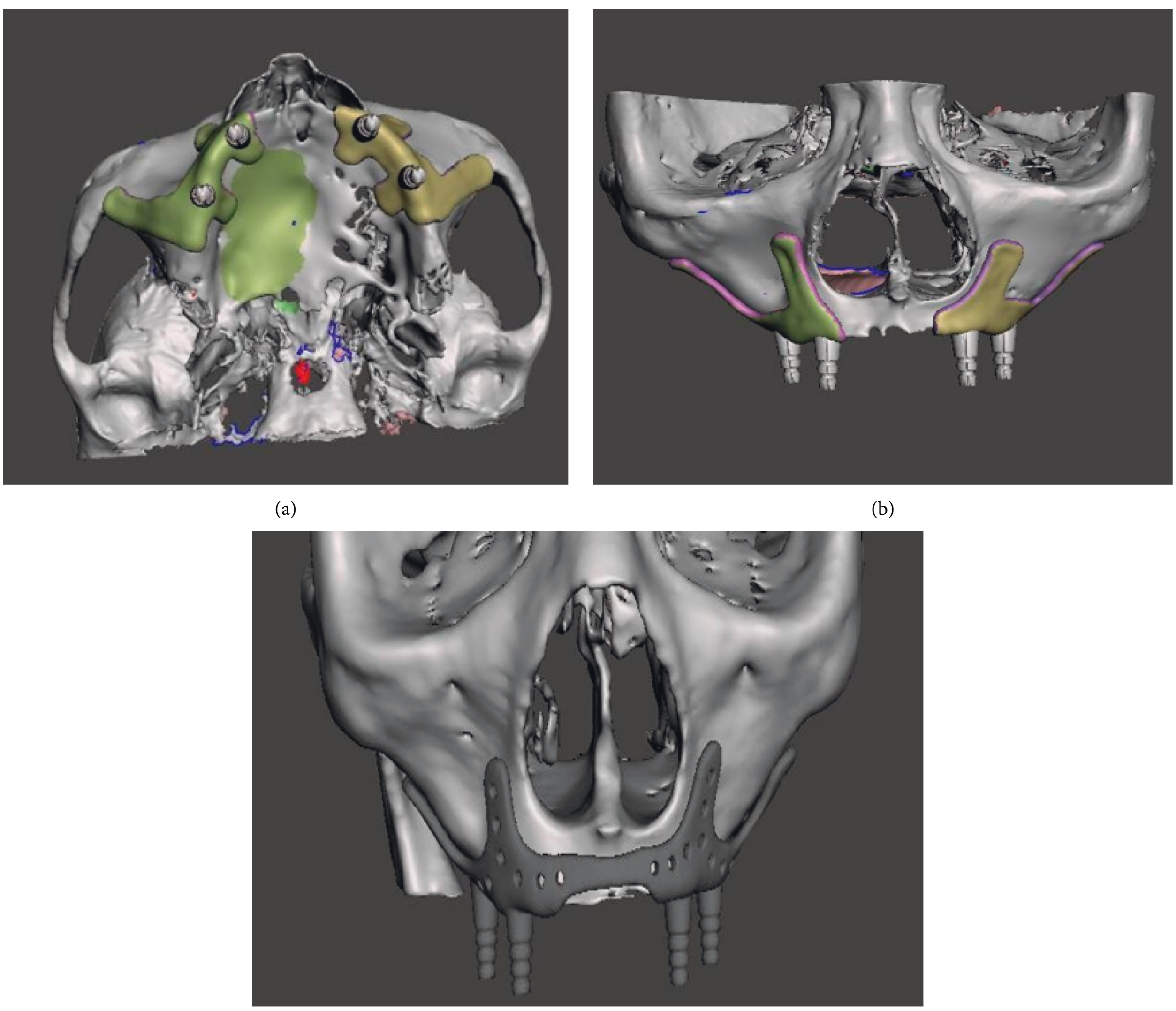
2.2.1. Image Processing and Segmentation. The 3D model is imported into AUTODESK MESHMIXER, a modeling software where one can create and correct the 3D models. The errors in the 3D model are rectified and the implant is designed as per the rules specified by the doctor. The implant is designed using the sculpting tools in the AUTODESK MESHMIXER. Several designs are made for every case, allowing the doctor to choose the best one out of them. The designed implant is then exported into an STL file. The design of the implant is a very challenging task for an Engineer as it requires knowledge of both Engineering and Medical fields. While designing the implant the bone density of the patient also plays a very vital role. An implant cannot be used if the patient's bone density is less. A bone graft needs to be used to support the implant. The implant has been designed with 4 abutments and several screw holes of 1.5 mm diameter. Some of the screw holes will not be used to screw holes if the bone density of the patient at that particular point is low. And, hence these holes can help reduce the stress concentration on the implant. The Abutments are designed to hold the teeth that will be installed on the patient during the surgery.

Segmentation refers to the extracting of the specific 3D model from a set of images as shown in Figure 1. It is used to locate objects in each slice that corresponds to the



(a) (b)

Figure 1: (a) Segmentation of DICOM data and (b) 3D image generated after segmentation.



(c)

Figure 2: (a) Implant iteration 1 (bottom view), (b) implant iteration 1 (front view), and (c) implant iteration 2.

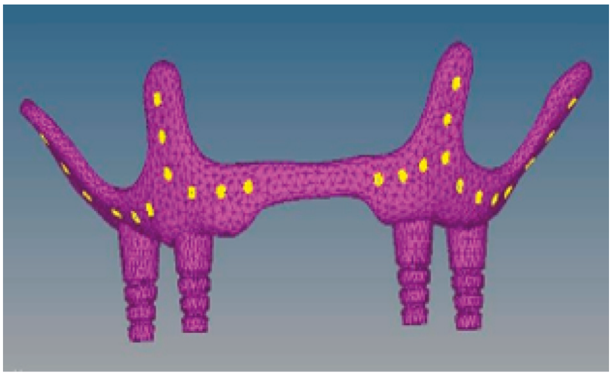


Figure 3: Meshed model of the implant.

Table 1: Calculated muscle, joint reaction, and bite force magnitudes.

Muscles	Force (N)
Masseter	340.0
Temporalis Anterior	264.3
Temporalis Posterior	264.3
Medial pterygoid	191.4
Lateral pterygoid	378.0
Joint reaction force	471.9
Bite force (2nd premolar)	246.3
Bite force (1st molar)	157.4
Openers	155.0

boundaries of tissues. As it is done slice by slice, volumetric data is gradually built up. It can be used to create patient-specific, highly accurate models of organs, tissue, and pathology. A major difficulty of medical image segmentation is the high variations images. First and foremost, the human anatomy itself shows major variation. Furthermore, many different modalities (X-ray, CT, MRI, microscopy, PET, SPECT, Endoscopy, OCT, and many more) are used to create medical images. The result of the segmentation can then be used to obtain further diagnostic insights. Possible applications are an automatic measurement of organs, cell counting, or simulations based on the extracted boundary information. In the present project, the DICOM data (CT Scan) of the patient is converted into a 3D model using the DICOM Software "Slicer 3D." The 3D model is extracted by adjusting the minimum and maximum Threshold limits. The generated 3D model from the CT scan is exported into STL (Standard Tessellation Language) format.

The 3D model extracted from the DICOM data is of the patient, for which an implant needs to be designed Figure 1(b). The 3D model extracted in the present study is the Maxilla portion of the patient.

2.2.2. Error Rectification. STL file is the most commonly used type of file in Additive Manufacturing. When a CAD file is Converted into an STL file the surface of the model is made up of several triangles, which include edges, sides, and faces. There are several chances of occurrence of errors in STL files. The errors generally include holes or gaps in the mesh, flipped normal, intersecting and overlapping triangles, bad edges, and noise shells. All these errors need to rectify for a better output in Additive Manufacturing. So for the rectification of errors in STL files, AUTODESK NETFABB, a very powerful and efficient tool is used. It is extremely necessary to rectify errors in an STL file and mesh the file again, which shows a great impact on the quality of the additive manufactured component.

Table 2: Mechanical properties of Ti-6Al-4V.

Properties	Minimum	Maximum
Density g/cm^3	4.429	4.512
Youngs modulus, GPa	104	113
Shear modulus, GPa	40	45
Bulk modulus, GPa	96.8	153
Poisson's ratio	0.31	0.37
Tensile yield strength, MPa	880	920
Ultimate tensile strength, MPa	900	950
Rockwell hardness C	36 (typical)	—
Uniform elongation, %	5	18

2.2.3. Design Iterations and Design Considerations. The design of an implant is a very challenging task for an engineer. Several implants are needed to be designed for a single case, out of which the doctor will choose the best one depending on the adaptability. For the present case, two iterations have been done.

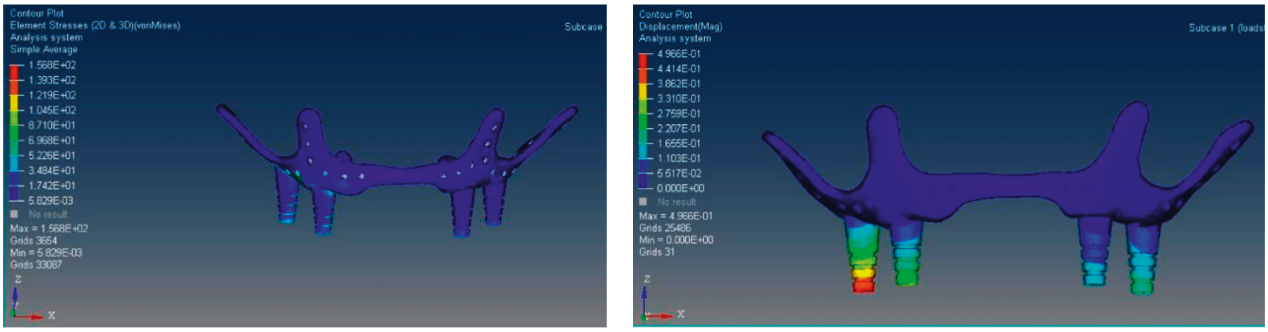
(1) Iteration 1. In the present iteration, there are 2 implants designed one for the left half and the other for the right half as shown in Figure 2(a). The implants contain two abutments each for fixing the teeth. As the doctor required a single implant instead of two implants this design has been modified.

(2) Iteration 2. The implant in the second iteration is the modified version of the implant in the first iteration to meet the requirements of the doctor. This design of the implant consists of four abutments on the whole to hold the teeth (Figure 2(b)). Several holes on the body of the implant are to fix the implant to the patient with the help of screws and also to reduce the stress concentration. After the design is approved by the doctor it has been manufactured using Additive manufacturing techniques.

2.3. Finite Element Analysis of the Implant. In the present work, OPTISTRUCT (Altair Hyperworks) is used. To enhance the quality low mesh is maintained as shown in Figure 3. The beam elements are C beam elements with cylindrical cross-sections and a diameter of 1.5 mm. The material chosen for analysis is Ti-6Al-4V.

The screw holes are considered to be fixed with cylindrical C beam elements. The calculated muscle, joint reaction, and bite force magnitudes acting on the mandible during clenching are presented in Table1.

2.4. Fabrication of Customized Ti-6Al-4V Alloy Implant Using. At the preliminary stage, FFF techniques are used to create a prototype model of the implant to check the adaptability for

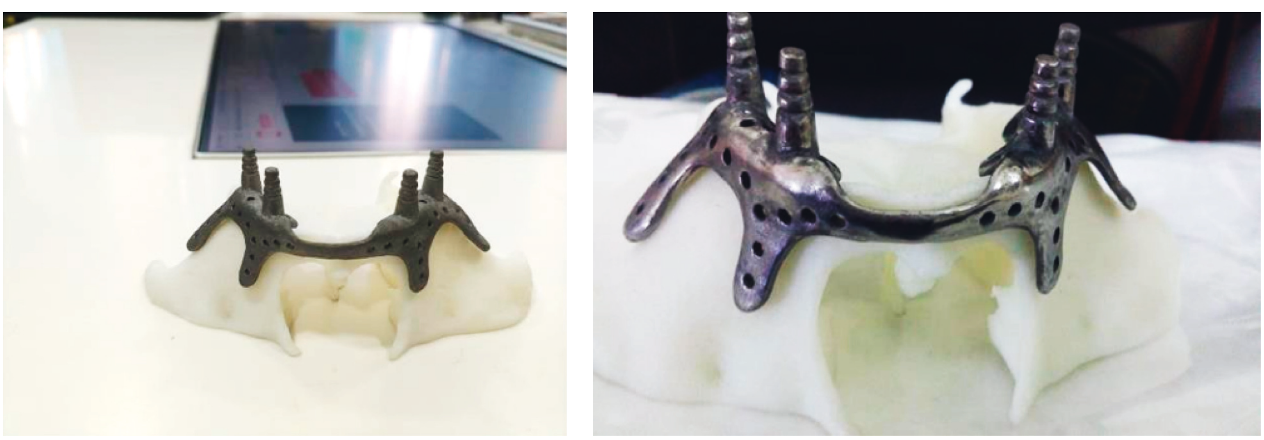


(a) (b)

Figure 4: (a) Stress distribution in the implant (b) displacement in the implant.

Table 3: Von-mises stress and displacement results.

Von mises stress	Value
(Max) MPa	156.8
(Min) MPa	0.005829
Displacement (max) mm	0.496
(Min) mm	0



(a) (b)

Figure 5: (a) Checking the adaptability of the implant, (b) implant after machining and polishing.

the patient maxillofacial surgery. After, based on the doctor decision the original implant is fabricated using the DMLS technique. In this method, 0.1 mm of accuracy can be maintained. The material used of deposition for the original implant is Ti-6Al-4V. The printed model from DMLS should require postprocessing process which includes the support removal and machining of the uneven surfaces. After which, manual machining and polishing are carried out to the fabricated part to confirm the surface roughness.

3. Results and Discussions

3.1. FEM Analysis. The geometry of the subperiosteal implant is modelled using software from CT scan data for FEM analysis. Firstly, normal analysis is done then a dental implant is placed into that molar region and the analysis are carried out using finite element software Altair Hyperworks. Various combinations of implant loads were considered to prepare the implant models. Ti-6Al-4V alloy is considered as the material and the properties are presented in Table 2.

To visualize the results such as stress distribution or displacement with good clarity a color spectrum was shown in Figure 4. The colors from red-orange-yellow-green-blue represent the descending order. The red color indicates the highest stress and blue denotes the lowest stress values Figure 4. The displacement was evaluated in the bottom region of four abutments and the entire superficial implant region. The maximum stress (156.8 MPa) generated in the implant is significantly less when compared to the ultimate tensile stress (950 MPa). The factor of safety is calculated and noted as 6.09. The maximum displacement generated in the implant is very minute, i.e., 0.496 mm and the minimum displacement is nil as shown in Figure 4(b). From the above-given results, it is proved that the implant is exemplary. This proves that the implant is very safe to use and makes it quite evident that the implant will not fail under the present loading conditions. The displacement that occurred in the implant under the present loading conditions is as follows.

The stress and displacement developed in the implant when the bite force of the 1st molar is applied on the abutments is presented in Table 3.

3.2. 3D Printed Implant. Figure 5 shows the printed green parts of all three components (RH, Middle, and LH) of the maxillofacial implant. The support structure of each part was generated by the slicing software depending on part geometry and orientation on the print bed. Postprinting, this support was further kept intact to retain part geometry and minimize potential damage in the green stage. Moreover, the removal of the support structure at this stage had associated risks of part damage. Hence, support structures were not removed in the green stage. The geometric fidelity of printed parts was evaluated using an optical surface profiler, as shown in Figure 5(b).

4. Conclusion

Designing an implant is a challenging task for an engineer, which needs more attention while designing the implant. The quality of the implant is always a point of concern that must never be neglected in this type of case, even though the time takes for manufacture is more. Always, it is advised to keep the better factor of safety preferably above 2 to ensure that the implant does not fail in the long run. The goal of this study is to find the stress concentration and the displacement that occurred in the implant under the mentioned loading conditions. This study can be used to certify whether the implant designed is safe to use.

Data Availability

The data used to support the findings of this study are included within the article.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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