

Design and Analysis of Customized Medical Models Using Hybrid Approach

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Abstract: -Customized medical models are well known health care applications for implants and medical devices. The precise application and implementation to the patients, however, is a difficult issue. In the current work, a hybrid approach is employed to develop the patient-specific implant in order to address this issue. Initially the implant is modelled from the computed tomography scan information of the patient oral cavity. Later it is converted into a three-dimensional model using the Slicer 3D. Finite element analysis is performed on the implant to evaluate the stress distribution and deformation. Further, the real time implant is fabricated using the 3D printing and casting technique. Casting technique is more feasible and cost effective when compared to 3D printing. Overall, the fabricated implant using hybrid approach is potential for implant applications and cost effective.

Keywords: Patient specific implants, additive manufacturing, dental applications, FEM

1. Introduction

Anatomical factors such adequate bone density, volume, and thickness are crucial for the success of dental implants [1]. Bone regeneration by grafting is frequently used to create new bone through autografting, utilizing other bone as a scaffold, in weak jawbone regions. However, in cases of severe osteoclastogenesis, the need for extensive bone replacement challenges clinical treatment difficulties that cause patients to hesitate [2]. Maxillofacial surgery work at least in part to help correct skeletal problems such as misaligned jaws. Such an implant is extremely important, especially for senior patients who require a stable dental repair but cannot or may not want to undertake difficult regeneration operations. Maxillofacial surgery oral cavity implants are made from biomaterials like stainless steel, cobalt chromium and titanium alloys [3][4][5]. In contrast to root form implants, masticatory force is spread over a considerable portion around the surface of the bone rather than the majority of the oral cavity area (bone) [6][7]. In general, healthy gums and enough bone are needed for the implant to be supported in order to attach the dental implants to the patient. [8]. When bone density is poor, bone grafting may be necessary [9]. In order to prevent the aforementioned issues that are experienced by different individuals, patient-specific implants are being developed in recent years. Therefore, in recent years, customized medical model implants have been developed to prevent the aforementioned issues that patients of all kinds confront [10]. Customized medical model implants are fixing the dental restoration and eliminating regeneration procedures for people in the elderly age group people [11].

Maxillary and jawbone restoration are used to treat bone defects brought on by tumors, injuries, or diseases in addition to dental implant [12]. However, such repair poses significant engineering and medical problems [13]. The hybrid approach uses the patient's Computed tomography data to create a three-dimensional model of the jaw, which is then duplicated in thermoplastic or another material. The rest of the design process is carried out similarly to the traditional method [14]. By using this approach, two procedures are avoided. The entire process

is carried out digitally in the digital technique. A prototype model is created from the patient's Computed tomography data, then the implant is evaluated and made utilizing a variety of fabrication procedures employing finite element analysis software. With this approach, two operations are avoided, and the implant's quality is also improved [15].

Numerous studies have investigated on various load conditions and the several kind of materials utilized [16]. Additionally, the architecture of the implant may be a key factor in deciding how much distribution of stress and deformation of the designed implants would experience. and drawbacks of their activities [17]. The current researchers therefore concentrated on the feasibility of the material used, fabrication method, cost of implants and topological aspects of the implants [18]. Further, Researchers frequently use the finite element technique (FEM) to examine how stress is distributed across dental implants and the bone around them [19]. FEM is a powerful tool that can be used to simulate a complicated mechanical issue by breaking down the 3D geometry that is problematic into a number of incredibly small simpler elements [20][21]. The image data is obtained using computed tomography, and the matching FEM model is produced with the use of a 3-D scanner or magnetic resonance imaging [22]. The deformation and developed stress brought on by loading may be efficiently estimated at every node by using the right mix of components and preset boundary conditions in the mesh model.

Recently, several research on the FEA of dental implants have been published, although it is still unclear how accurate the results [23][24]. Due to the fact that each implant serves a specific purpose and has unique boundary conditions, a number of factors might alter the analysis's findings [25]. Additionally, verifying the correctness of the FEA findings is an extremely time-consuming operation. There has been relatively little study done on the FEA analysis of dental implants since the use of the computerized technique for implant design is still in its early phases [26]. Subperiosteal implants required extensive technical manufacture since it was essential to take a tangible impression of the remaining, precision machined bone during a prior medical operation that was very uncomfortable for the patient [27]. Then, during the clinical procedure to locate them, these replacements were not precisely placed, posing the danger of unexpected patient outcomes. In fact, the requirement to modify these implants during operation might result in drawn-out operations with a higher risk of infections and problems [28].

To this end, stainless steel (SS316 alloy) is used to fabricate due to its mechanical properties and corrosion resistance. In particular, to fabricate customized model implants, the casting techniques are adopted and 3D printing technique is used to fabricate the pattern of the implant to provide accurate results [29]. The application of existing manufacturing processes prompted researchers to investigate traditional technologies, like as casting techniques, to lower the cost of the implants. This can be extremely useful in the reducing the cost of the implants and limited financial resources. The current investigation develops a novel hybrid approach for manufacturing the customized model implant using sand casting and 3D printing. Further, investigated the lifespan and complication levels experienced when using the present fabricated implant.

2. Objectives

2.1 Materials and methods

Initially the data is collected from the patient computerized tomography (CT) scan. The experimental methodology used in present investigation was reported in a prior work of authors [30].

The three-dimensional model is created using the slicer 3D software with the assistance of the patient CT scan. The errors occurred during the extraction of the 3D model is adjusted by the design criteria limits. Following that, CT scan is converted to Standard Tessellation Language format from the three dimensional model. Further, to modify or develop 3D model, an Autodesk meshmixer software is used. Based on the errors observed from the software, the issues are resolved for 3D model according to design principles followed by the medical clinicians. Also, the design of surgical implant is designed using same software. After, design of implant, the initial design of the implant is tested with patient oral scan data. Later, depending upon the trial and error method, the final 3D model of the implant is fabricated into prototype model. Finally, the model is fabricated using sand-casting and 3D printing techniques.

2.2 Design of implant

The autologous bone density is an important factor when developing the implant. If a patient has reduced bone density, an implant cannot be utilized. The implant has to be supported by a bone transplant. The implant has been engineered to be strong while being light. If the patient's bone density at that specific moment is poor, some of the screw holes won't be utilized to make holes. These holes can therefore help to spread out the stress on the implant.

As shown in Figure 1, segmentation is the process of separating a particular 3D model from a collection of images. It is used to identify things in each slice that match the tissue boundaries. Volumetric data is progressively built up as it is done slice by slice. It may be used to construct specialized medical models as well as extremely accurate simulations of tissues, organs, and pathologies. The significant degree of variability in image segmentation is a major problem. The human body itself reveals substantial variety to predict the type of the failures. The segmentation's output can then be used to get more diagnostic information.

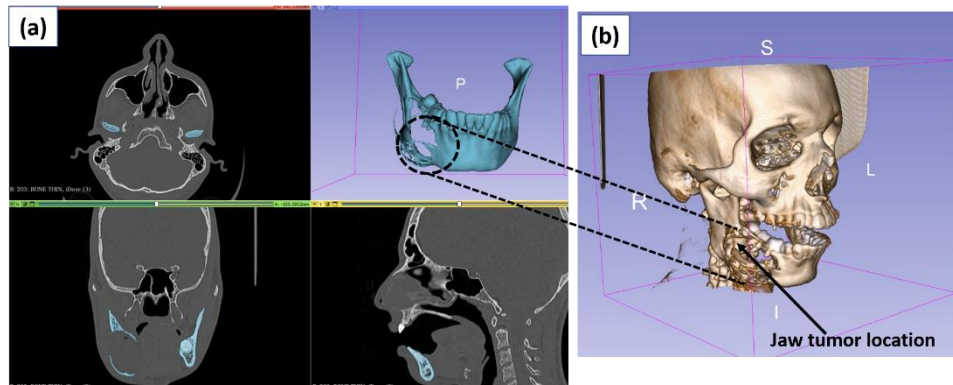


Figure 1(a) Patient scan data for segmentation and (b) Three-dimensional model of patient

The patients three-dimensional model, created from the DICOM data, will be used to design the implant. The patients cranial vault portion of the three-dimensional model that was created for this investigation is depicted in Figure 1 (b).

2.3 Analysis of the implant

In the present investigation, ANSYS is used for analyzing the implant displacement and stress distribution. To enhance the precision fine grid size is maintained as shown in Figure 2. The 2 mm diameter cylindrical C beam components have a cylindrical cross section are used in the present analysis. SS316L stainless steel was selected as the material for investigation. Static structural analysis is performed to evaluate the stresses and deformation generated by the implant. The material properties of SS316L stainless steel are taken for analyzing the stress distribution. Computer aided design converter is used to translate the multifaceted topology from its original STL format into a STEP file that can be inserted into the ANSYS software. Then, nodes and elements are discretized from the CAD file. The discretization function generates 13814 elements and 25666 nodes in total. Tetrahedral components are discretized from the whole body. In Finite Element Analysis, the following Boundary and Loading conditions are used:

Loading and boundary conditions:

- The implant's top and bottom are fixed, and
- A downward force of 40, 60 and 120 N is applied during mastication

Table 1 Mechanical properties of SS316

Properties	Values
Density(gcm^3)	7.99
Youngs modulus, (Pa)	2e11

ShearModulus,(Pa)	7.75×10^{10}
BulkModulus,(Pa)	1.58×10^{10}
Poisson'sRatio	0.29
TensileYield Strength,(Pa)	2.5×10^8
UltimateTensile Strength,(Pa)	4.6×10^8
Rockwell Hardness,	80
UniformElongation, %	40

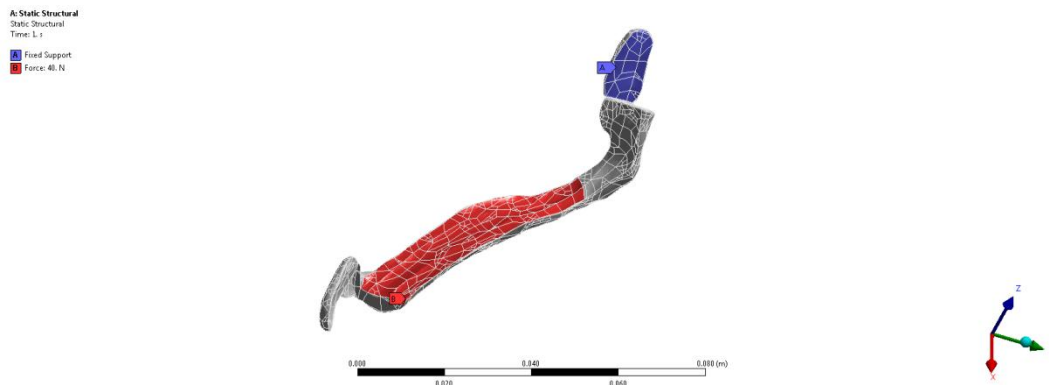


Figure 2 Meshed model of the implant

2.4 Fabrication of customized SS316 implant using hybrid approach

The casting method is chosen to fabricate the implant. Initially, implant is printed using wax as pattern. The wax pattern is placed inside the mould. Later liquid molten metal is poured into the mould, After the solidification process, the pattern is melted due to liquid molten metal reacts with the wax pattern. But the casted part (implant) is not perfectly produced due to the temperature differences and material flow ability could not reach to the extreme locations of the wax pattern. Majorly the problem persists at the heat gun which cannot generate heat more than 950 °C. After this failure the other casting process is considered and the following are sand

casting process is considered.

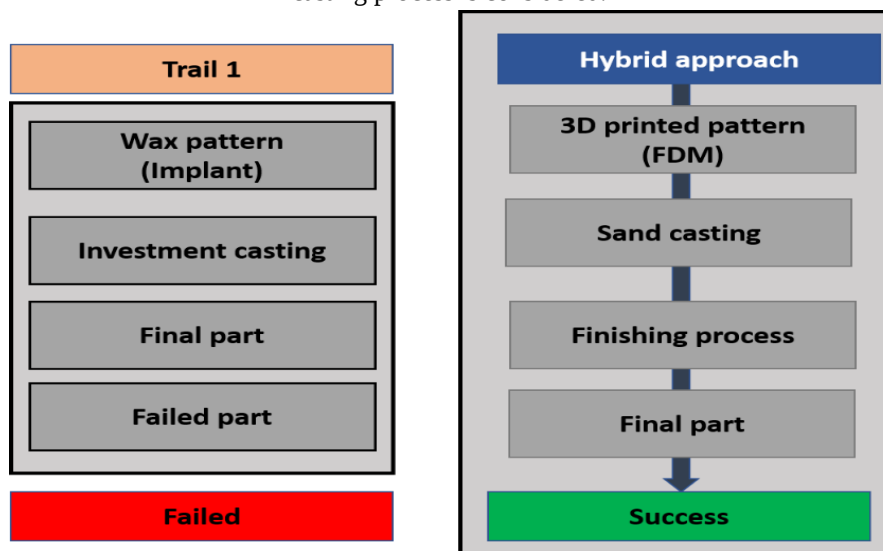


Figure 3 Flow chart for fabrication process of implant

Initially, a prototype model of the pattern (implant) for the patient operations is manufactured using fused deposition modelling (FDM). With this technique, precision within 1 μm is possible. Polymer is the deposition material used for pattern implant. The support should be eliminated from the sample produced by FDM, and any irregular features should also be polished. The design is then manually machined and polished to verify the surface roughness.

Next, the plastic pattern is placed in the sand to form the shape of the implant. The sand-casting technique is used to fabricate the implant. After that, the molten metal is poured into the sand casting. Next, the casting is removed after solidification process.

3. Results

3.1 Finite element analysis for developed model

The geometry of developed implant is modelled using software from CT scan data for FEM analysis. Various combinations of loads (40, 60 and 120 N) considered to fabricate the customized models. The material properties of SS316 alloy is presented in Table 1.

A colour spectrum was displayed in the figure so that the outcomes, such as stress distribution or displacement, could be clearly seen. The order is represented by the colors red, orange, yellow, green, and blue in descending sequence. The lowest stress values are shown by blue, while the greatest stress values are indicated by red (Figure 4). The lower both ends of the dental implant and the complete superficial implant area were examined for displacement. When compared to the ultimate tensile stress of bone, the implant's maximum stress (5.4 Pa) is noticeably lower. The estimated and recorded value of the safety factor is 5.01. As demonstrated in Figure 4 (b), the highest displacement produced by the implant is extremely small (0.496 mm), whereas the smallest displacement is zero. The foregoing outcomes demonstrate that the implant is excellent. This demonstrates how safe the implant is to use and makes it clear that it won't fail under the current loading circumstances. Under the current stress circumstances, the implant experienced the following displacement:

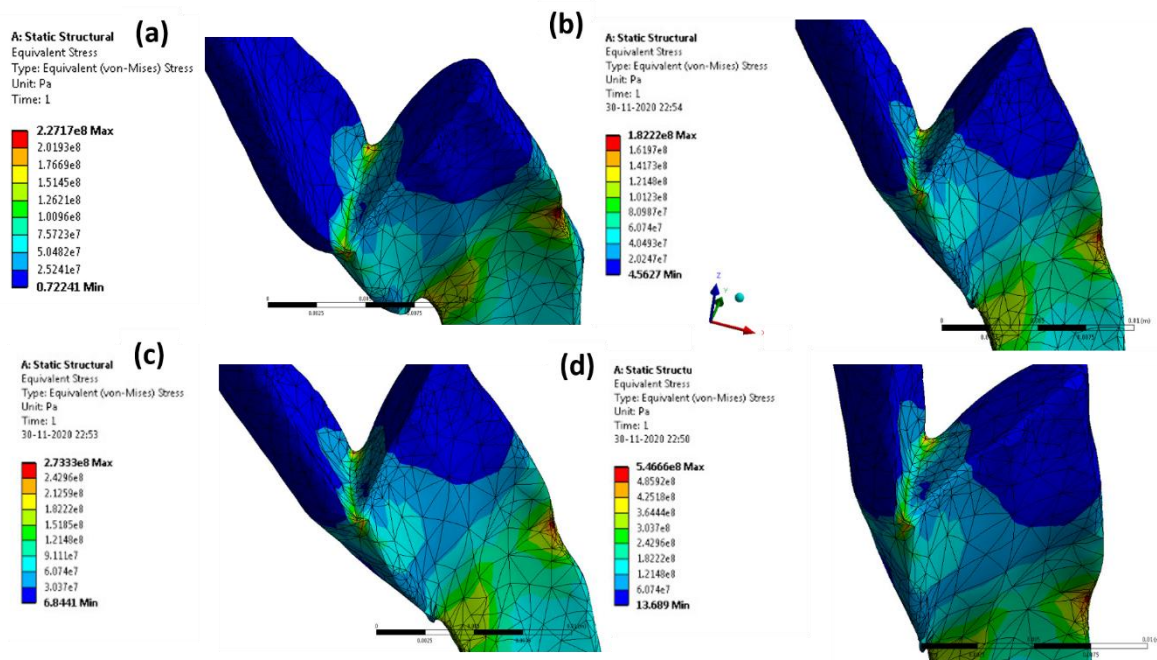


Figure 4 (a) Distribution of stress and (b) Deformation of the implant

The deformation and stress occurred on the implant when the various forces are acting upon the two ends of the implant surfaces is presented in Table 2.

Table 2 Stress distribution and deformation results

Loads (N)	Von-MisesStress(Pa)	Displacement (mm)
40	2.2	0.326
60	2.7	0.342
120	5.4	0.377

The lifespan of the implant is significantly influenced by the distribution of stress and deformation on the bone during implant implantation. Implant-related problems during and after surgery might emerge from excessive stress or deformation that goes beyond the threshold. Therefore, it is crucial to take these factors into account while placing implants. The maximal primary stress as well as the von Mises stress serve as the gold standard for assessing stress distributed on the bone. Maximum main stresses, which characterize the stress focused in a particular area, are the components of stresses when the basis of other stress tensors is zero. On the other hand, the von Mises stress is a scalar number that is derived from the stresses placed on any structure. In recent research, there has been much discussion on how stress is distributed around dental implants or the soft tissue that is encircled by bone tissue. However, in order to ensure consistent long-term therapeutic effects, physicians and researchers sought to document the long-term effectiveness of certain biological materials. The primary material-related issues with overdentures that are affixed to dental implants appear to be linked to the material's composition and to fatigue during masticatory cycles. One of the best modalities for studying stress distribution and deformation is finite element analysis. It is regarded as a suitable approach for determining the stress placed on the bone during implant implantation. Given the distinct jaw architecture for each clinical instance, the quality of the bone, and the amount of occlusal stress placed on the prosthesis, predicting how bone and implant components will respond necessitates thorough understanding of both mechanical and biologic processes.

A loading of 40 N revealed several troubling difficulties with the implant's two ends. The implant's terminal connectors at both ends will be subject to greater loads. Due to the smaller section in that place, there is a high stress concentration that might cause breaking when loads are extremely inclined. The benefit of having some flexibility is that you "pay dearly" for it, thus caution should be used while utilizing this component. It has only endured in situations when there is only pure strain and compression. When the load was higher (120 N), the von Mises stress was highest in the area surrounding the implant's ends, and it was lowest when the load was lower. In the simulated implant during implant insertion, the right-side area had the lowest von Mises stress values.

3.2 Fabricated implant using hybrid approach

Figure 5 shows the investment casting method was used to fabricate the implant. The wax pattern is shown in Figure 5 (a). The casted part is shown in the Figure 5 (d), It is not casted in well condition. The heat supplied during the investment casting is not sufficient. Further, due to the flowability issues with molten metal also attributed to the damaged casted part. The temperature of the heat gun maintained at 550 °C, even the wax pattern some corners are not adjusted to the molten metal. The final part of the investment casting is failed. So next the authors have chosen a hybrid approach to fabricate the implant. The cost also plays a significant role in the fabrication process, several researchers have manufactured implant using additive manufacturing. However, the cost of the 3D printed implant is very high.

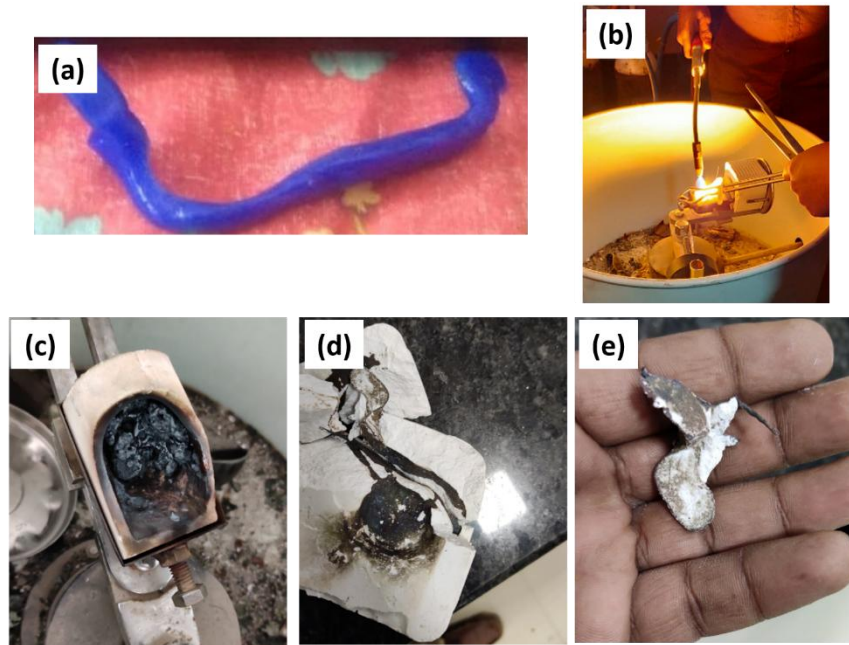


Figure 5 (a) wax pattern, (b) investment casting, (c) image after molten metal pouring into cavity (d) opening of cavity (e) final failed part

Therefore, in the present study the sand-casting technique is used to fabricate the real time implant. First, to replicate the implant, a pattern is fabricated using the FDM process. The plastic material used as pattern material. The plastic pattern is shown in the Figure 6. The plastic pattern is surface finished and clear without any damages. The sand-casting process is used and fabricated the final implant and shown in the Figure 6 (e). After the casting process, the implant is cleaned and finishing process to obtain smooth surface.

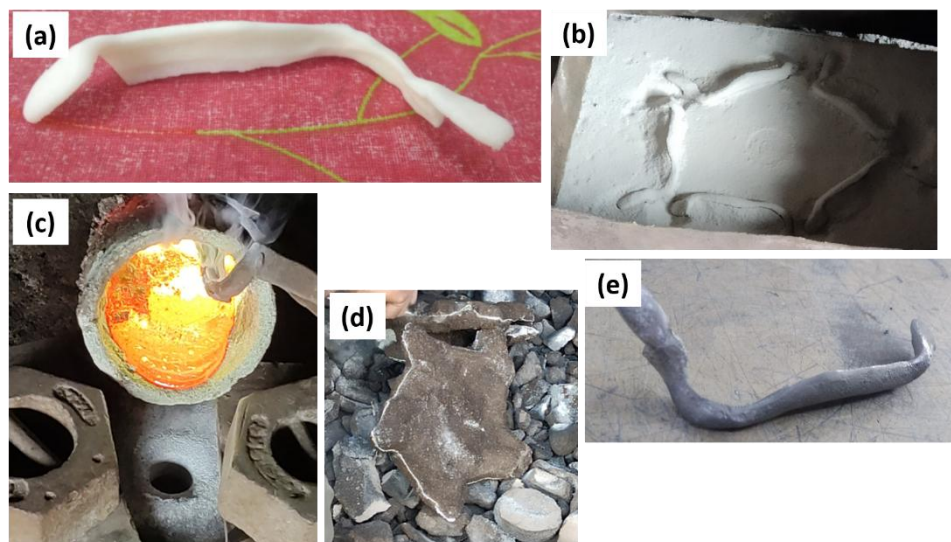


Figure 6 Hybrid approach fabrication (a) 3D printed pattern, (b) shape of pattern in sand casting mould, (c) molten metal pouring into cavity, (d) casted part and (e) final part

Figure 7 shows the fabricated implant for patient surgery. The weight of the implant is another problem arises while the surgery to patient. Therefore, the ensure the stress distribution and loading conditions, the weight of the implant also reduced by creating holes on the fabricated implant as shown in the Figure 7 (c). The final fabricated implant after the surface finishing and polishing is shown in the Figure 7 (d).

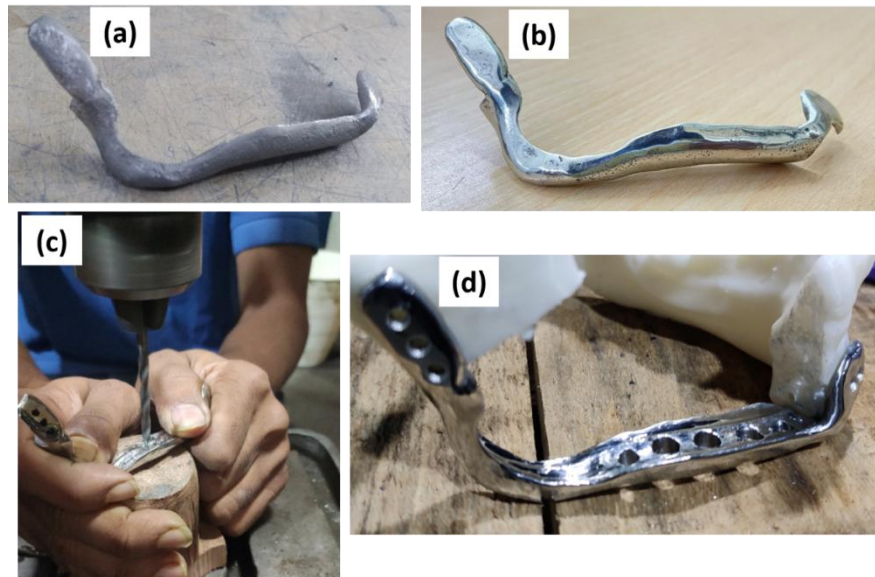


Figure 7 (a) casted implant, (b) implant after surface finishing, (c) drilling holes and (d) final implant with holes

3.3 Surgical procedure

Figure 8 shows the implantation of the fabricated dental implant for maxillofacial surgery. Before going to the surgery, the doctors have given general anesthesia to the patient under sterile and aseptic conditions to ensure the painless procedure for the patient. Figure 8 (a) shows the removing the right side of the lower jaw region. Initially the doctors have cut the portion of the lower jaw top portion of the skin using the medical devices. Later, the fabricated implant is adjusted to the patient lower jaw bone, aligned properly and fixed the implant using medical devices as shown in Figure 8 (b).

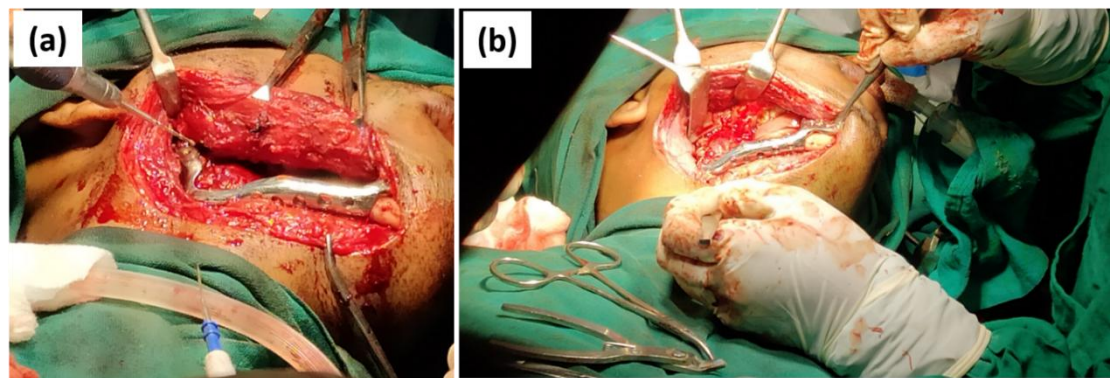


Figure 8 Surgery for patient (a) placing implant at lower jaw and (b) fixing the implant to lower jaw

4. Discussion

In conclusion, the findings about how finite element analysis and dental implant fabricated using hybrid approach (3D printing and sand casting) affected mechanical behaviour and cost of implant.

The following conclusions are drawn from the present study:

- The finite element analysis results reveal that, the stress distribution and displacement under the three loadings conditions (40, 60, 120 N) are under considerable range. The maximum stress developed for 120 N load condition was 5.4 Pa.
- The fabricated implant using investment casting is failed due to the temperature distribution to the each and every corner of the wax pattern. Further it effected the flow of the molten metal into the mould cavity.

- The hybrid approach of fabricating the dental implant is successfully fabricated using the 3D printing and sand-casting techniques. The pattern produced using 3D printing was smooth and perfect polished. The sand-casting technique is very feasible and cost-effective process when compare to other fabricating techniques. The implant fabricated using this hybrid approach is perfectly implanted to the patient.
- Finally, the surgery for the patient was successfully performed and implant is properly fixed.

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