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DESIGN, ANALYSIS, AND FABRICATION OF PATIENT-SPECIFIC IMPLANT FOR MAXILLOFACIAL SURGERY

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Abstract: The design of a Patient-Specific Implant is a challenging task for an engineer as it is a multidisciplinary task which involves both Engineering and Medical fields. Keeping given all the objectives specified by the doctor the implant needs to be designed. The data required to design an implant is the CT scan of the patient. Using the segmentation process the CT scan will be converted into a 3D model. The Segmentation process has been done using Slicer 3D software. The 3D model in the present study is the maxilla of the skull for which an implant is to be designed. A 3D modelling software AUTODESK MESHMIXER has been used to design the implant. All the designed implants which need to Additive Manufactured are exported into STL format. But unfortunately, as STL files have several errors they need to be rectified to improve the quality of the Additive Manufactured product. The error rectification is done using AUTODESK NETFABB software. The static structural analysis is considered to calculate the stress concentration and the displacement induced in the implant when the bite force of 1st molar is considered. From the results, it can be known whether the implant is safe to use for the patient. OPTISTRUCT (Altair Hyperworks) software has been used to perform the static structural analysis. This paper focuses mainly on providing a complete outlook of all the processes that are followed to successfully design, fabricate and analyse the performance of an implant.

Keywords: Patient-specific implant, CT scan, Segmentation, Additive Manufacturing, structural analysis.

1. Introduction:

Subperiosteal Dental Implant is a framework like custom made structure with abutments for support and fixation of dental restorations. This metal frame is attached under your gum tissue but above your jawbone. Protruding from the metal frame of the subperiosteal implant are small metal posts. These are used as the anchors for the replacement teeth that the Oral and Maxillofacial surgeon will attach to the implant. Subperiosteal Dental Implants are made from biocompatible materials, mostly CrCo and 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. If you are considering dental implants, you need to have healthy gums and adequate bone to support the implant. If your bone is too thin or soft and unable to support an implant, you may require a bone graft. Or if there is not enough bone height in the upper jaw or the sinuses are too close to the jaw you may require a sinus lift.

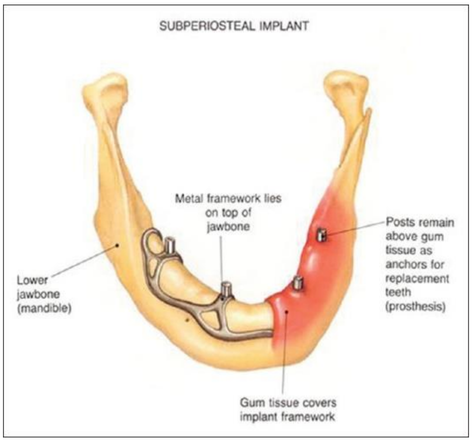

Fig 1: Subperiosteal Implant

1.2 Literature review:

Manufacturing of Subperiosteal Implants can be done in three ways, so depending on the condition the type of manufacturing can be used.

1) **Classic (or) traditional method:** In this type of Implants the surgery needs to 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 CrCo or Titanium alloy. The second surgery is then done to install the Implant to the patient. Though it takes two surgeries this is the most accurate method presently in use.

Fig 2: Impression of the bite (Traditional method)

2) **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 the plastic or some other material and rest of the design process are similar to the classic method. This method helps in preventing two surgeries.

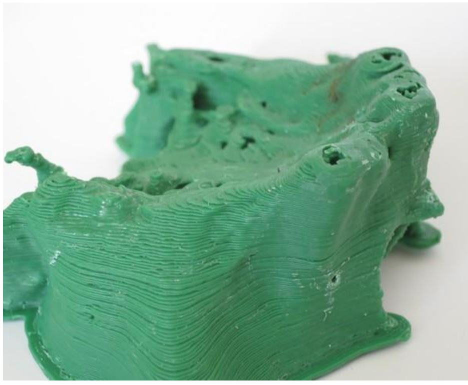

Fig 3: Wax casting (Hybrid Method)

3) **Digital method:** In this 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.

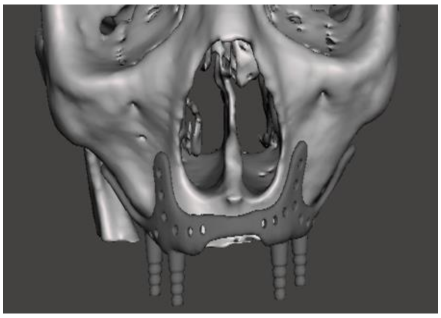

Fig 4: Design of Implant (Digital method)

Finite Element Analysis has become one of the most important tools in both Engineering and Medical field. the behaviour of any structure or tissue can be evaluated using FEA, and biomechanical changes in the tissues can be analysed. Additionally, FEA allows for measurement of the stress distribution inside of the bone and various dental implant designs during mastication. Several studies have been published recently regarding the FEA of dental implants, but the accuracy of the studies is still a question. There are several factors that affect the results of the analysis as every implant has its own function and every implant has different Boundary conditions. And verification of the accuracy of the results of the FEA is also a very challenging 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 less.

2. Design process:

The design of the Subperiosteal dental implant involves several steps.

2.1. Segmentation:

Segmentation, which refers to the extraction of a specific 3D volume from a set of image data/slices. It is used to locate objects and boundaries in each slice that corresponds to the tissue of interest. As it is done slice by slice, a 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 variability in medical images. First and foremost, human anatomy itself shows major modes of 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 the 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.

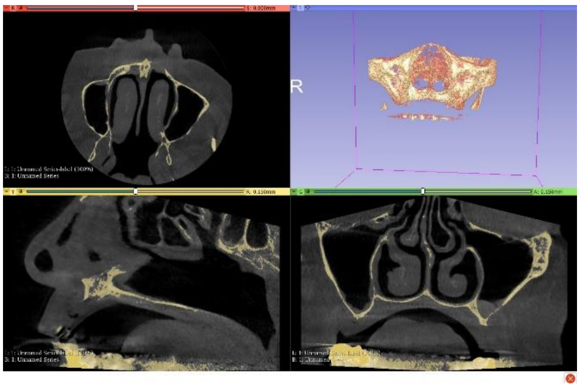

Fig 5: Segmentation of DICOM data

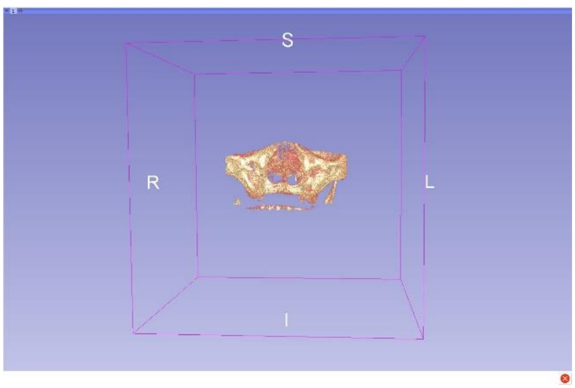

Fig 6: 3D image generated after Segmentation

2.2. Design of the implant:

The 3D model extracted from the DICOM data is of the patient, for which an implant needs to be designed. The 3D model extracted in the present study is the Maxilla of the patient. The 3D model is imported into AUTODESK MESHMIXER, a modelling 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, giving the Oral and Maxillofacial surgeon an opportunity 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 1.5mm diameter. Some of the screw holes will not be used if the bone density of the patient at that particular point is low. And hence these holes can be helpful in reducing the stress concentration on the implant. The Abutments are designed to hold the teeth that will be installed to the patient during the surgery.

2.3. Error rectification:

STL file is the most commonly used type of file in Additive Manufacturing. When a CAD file is Converted into STL file the surface of the model is made up of several triangles, which includes 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 normals, 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 remesh the file, which shows a great impact on the quality of the additive manufactured component.

2.4. Design iterations and design considerations:

he 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.

Iteration 1:

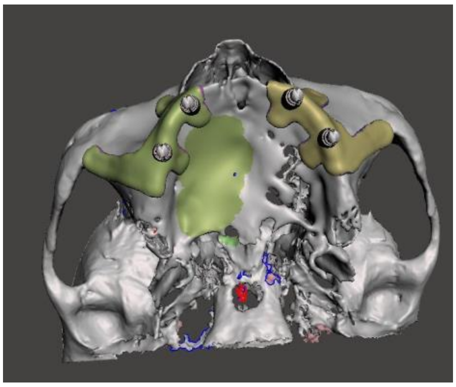

Fig 7: Implant iteration 1

In the present iteration, there are 2 implants designed one for the left half and the other for the right half. The implants contain two abutments each for fixing the teeth. As the doctor was in need of a single implant which can provide support to the center part of the maxilla, the second iteration has been done.

Iteration 2:

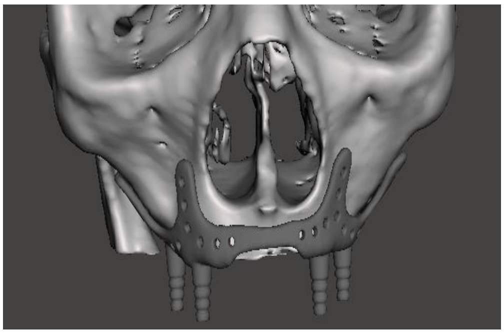

Fig 9: Implant iteration 2

The implant in the second iteration is the modified version of the implant in the first iteration in order to meet the requirements of the doctor. This design of the implant consists of four abutments on the whole to hold the teeth. 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.

2.5. Manufacturing of the implant:

Several Additive Manufacturing techniques are used for the manufacturing of the implant.
Fused Deposition Modelling (FDM) or Stereolithography (SLA) techniques are used to manufacture a prototype of the implant and the maxilla part of the patient to check for the adaptability. If the doctor finds the prototype perfect, the original implant is manufactured using Direct Metal Laser Sintering (DMLS) technique. Accuracy of about 0.1mm can be maintained by using this technique. The original implant is

manufactured using a Titanium alloy (Ti_6Al_4V). Ti_6Al_4V 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). The parts manufactured using DMLS need post-processing also. The post-processing includes heat treatment, support removal, excess powder removal. Machining and polishing can also be done depending on the application. As it is biomedical application post-processing is necessary for a smoother surface.

Fig 10: Checking the Adaptability of the Implant

Fig 11: Implant after Machining and Polishing

2.6. Finite element analysis of the implant:

Finite Element Analysis of the implant is done to analyze the stress and displacement developed in the implant. Based on the results of the analysis if the design fails under applied loads the design can be modified. The material chosen for the static structural analysis is Ti_6Al_4V. The properties of Ti_6Al_4V are as follows:

Property	*Minimum*	*Maximum*
Density g/cm^3	4.429	4.512
Young's 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

Following are the assumptions that have been made to perform the analysis of the implant.

1) The material has been assumed to be Homogenous and Isotropic
2) All the screw holes are fixed.
3) The diameter of the beam element is 1.5mm.
4) The force is considered to be Axial and Compressive in nature.

Several CAE software can be used for the Finite Element Analysis. OPTISTRUCT (Altair Hyperworks Students edition) has been used for the present study. As the initial file is in STL format it has been remeshed to maintain the quality. All the triangular elements in the STL file are converted into second-order tetra 3D elements. The beam elements are C beam elements with cylindrical cross-section and diameter of 1.5mm.

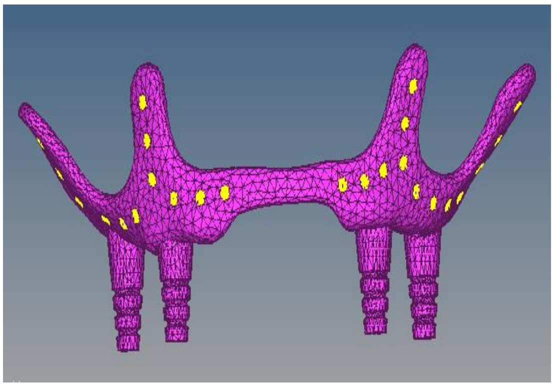

Fig 12: Meshed model of the implant

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 as follows:

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

The force of 157.4N (Axial and Compressive in nature) is applied to the four abutments and Stress and Displacements are calculated. The results obtained will be used to check the efficiency of the design.

3.Results:

The stress developed in the implant when the Bite force of the 1st molar is applied on the abutments is as follows:

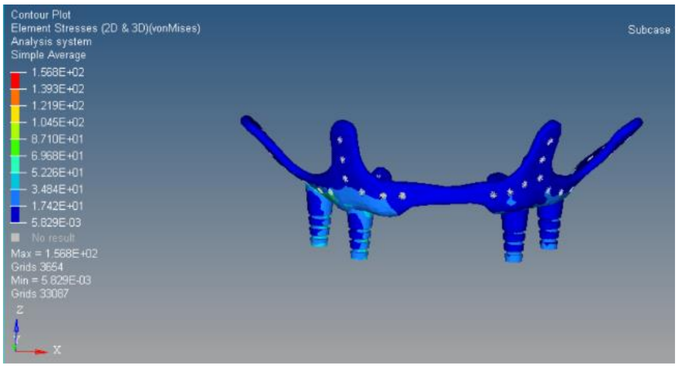

Fig 13: Stress distribution in the implant

Stress (2D &3D vonMises)	*Value*
Maximum stress	156.8 MPa
Minimum stress	0.005829 MPa

The maximum stress(156.8MPa) generated in the implant is very less when compared to the ultimate tensile stress (950MPa). The Factor of safety is calculated to be 6.09. This proves that the implant is very safe to use making it quite evident that the implant will never fail under the present loading conditions.

The displacement occurred in the implant under the present loading conditions is as follows:

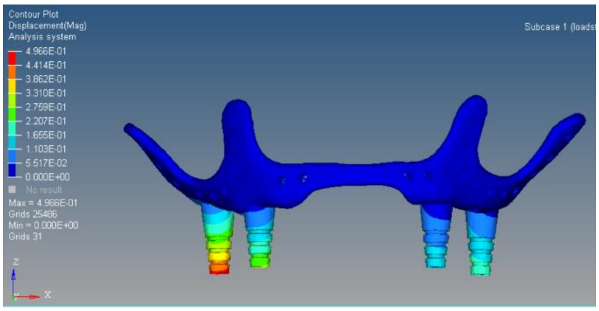

Fig 14: Displacement in the implant

Displacement	*Value*
Maximum	0.496mm
Minimum	0mm

The maximum displacement generated in the implant is very minute, i.e. 0.496mm and the minimum displacement is nil. From the above results, it can be proved that the implant is exemplary.

4. Discussion:

The type of analysis done in the present study is static structural analysis. When it comes to the practical scenario, the masticatory force comes into play. So, for more accurate results the dynamic analysis can also be done. The load is considered to axial and compressive in the present study, a study can also be made by considering an oblique load also. Several materials like gold, tantalum, stainless steel, shape memory alloy, titanium alloy, and cobalt-chromium alloy are being used for manufacturing implants. A new material Apium PEEK (Polyether Ether Ketone) 450 Natural 1.75 mm filament produced from medical grade PEEK granules can be used. This filament is a semi-crystalline polymer with a density of 1.30 g/cm^3 and tensile strength of 97 MPa. With excellent chemical resistance, it is a perfect combination of strength, toughness, and stiffness. Additionally, it is very tolerant to gamma radiation, is extremely stable against hydrolysis, and is suitable for sterilization. Implants with PEEK material must be manufactured using Fused Filament Fabrication technique. Several such changes can be made and new studies can be produced.

5. Conclusion:

Designing an implant is a challenging task for an engineer. All the medical challenges are to be kept in mind while designing the implant. The manufacture of the implant also takes a few days. The quality of the implant is always a point of concern which must never be neglected in this case. It would be advised to keep the factor of safety above 2 to ensure that the implant doesn't fail in the long run. The goal of this study is to find the stress concentration and the displacement occurred in the implant under the mentioned loading conditions. This study can be used to certify whether the implant designed is safe to use.

6. Acknowledgment:

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