ISSN: 0974-5823 Vol. 7 No. 2 February, 2022

International Journal of Mechanical Engineering

Development of Patient-Specific Implant for Maxillofacial surgery through Direct Metal Laser Sintering

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Abstract. While designing the medical implant, the parameter strength-to-weight ratio always plays an important role. Hence, for achieving a higher strength-to-weight ratio, the present work focuses on optimizing Patient-Specific Maxillofacial Implants. Initially, finite element analysis is carried out to identify the maximum mastication force that an implant can bear by maintaining the stresses and deformation within limits. Later, design iteration is performed to reduce the weight of the implant, which enhances the parameter strength-to-weight ratio. The iterated design is validated using finite element analysis by exercising the same boundary and loading conditions. From the results, it is concluded that the iterated implant design possesses a higher strength-to-weight ratio in comparison to the original design. Since the implant is rough and organic in nature, additive manufacturing technology is suggested to manufacture the designed component. Direct Metal Laser Sintering is used among many additive manufacturing technologies because of its manufacturing capability with high precision and accuracy.

Keywords: Patient-Specific Medical implant, FE analysis, design iteration, strength-to-weight ratio, and Direct Metal Laser Sintering.

1. Introduction

Every human being has a different bone structure in the face. Hence, the dimensions of maxillofacial parts (which comprises of jaws, neck, face, and mouth) vary from person to person. Surgery which is done to reconstruct the maxillofacial structures is highly patient-specific. Hence, they are named as Patient-Specific Implant (PSI). Being patient-specific, adopting traditional technologies like injection molding, casting, or any other similar method will be complicated and expensive. From the literature [1-4], additive manufacturing is best suited for such applications. Design iteration improves a design by making subtle changes to the existing design to achieve the desired objective.

In order to achieve the desired objective following steps are adopted

- Modeling of patient-specific implant based on the raw data obtained from CT scan
- FE analysis to analyze stress and deformation
- Design iteration to reduce the weight by maintaining the value of stress and deformation within the limit.
- Validation for iterated design through FE analysis
- Fabrication of final iterated design using Metal Additive Manufacturing technology, namely Direct Metal Laser Sintering.

2. Materials and Methods

2.1. Modeling

The CAD file of the patient-specific implant is created based on the data obtained from the CT scan. A commercial code is used for modeling the part, which consists of advanced features for 3D printing preparation of CAD models. The resulting file is saved in STL format. The resulting CAD model generated by the black box software is shown in Fig. 1.

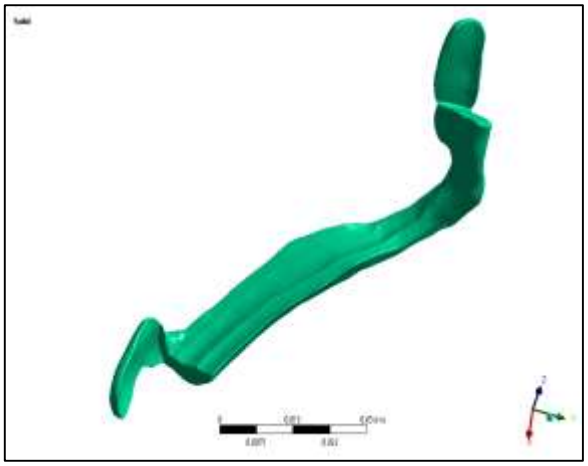


Fig. 1. CAD model

2.2. Material selection

The material model used for manufacturing the component as well as for the finite element analysis is AISI 316L Stainless Steel. Since the material is not undergoing any plastic deformation or failure, a linear elastic model is used for finite element analysis. Material properties of AISI 316L [5] used by the finite element solver are provided in Table 1. The allowable stress in the material is 452 MPa (as provided by the manufacturer). Since the component is not subjected to any dynamic loads, a factor of safety of 1.67 is considered.

Table 1. Material Properties of AISI 316L Stainless Steel

Property	Value
Density	8000 kg/m^3
Poison's ratio	0.29
Young's modulus	200 GPa

2.3. Design Analysis and Validation of iteration model

In the present work, the design analysis mainly focuses on delineating design concepts, solid modeling, structural analysis, fabrication, and post-processing. For finite element analysis, commercially available software ANSYS 21 is used. Static structural analysis is carried out for evaluating the stresses and deformation induced in the implant. Mechanical properties of AISI 316L Stainless Steel are assigned to the model. Using a CAD translator, the faceted geometry, which is initially in STL format, is imported to the ANSYS environment as a STEP file. The CAD file is then discretized into nodes and elements. A total of 445911 nodes and 306878 elements are generated using the discretization code. The complete body is discretized into tetrahedral elements. Finite element analysis is performed with the following boundary and loading conditions.

Loading and boundary conditions:

1. Top and bottom side of the implant is fixed, and
2. 40 N mastication force is applied in the downward direction.

Fig.2 shows the loading and displacement boundary conditions applied on the model. Once the mathematical model is solved, displacement data is available at the nodes, whereas stresses and strains are calculated at the element centers. Fig. 3 and Fig. 4 show the equivalent stress and deformation respectively in the component. The maximum stress in the component is around 75 MPa and is present at the joints as encircled in Fig. 3. Since the shape of the component is based on the maxillofacial scan of a patient, no structural changes can be done. Also, the factor of safety is higher than 1.67, the model can be taken for implanting. The weight of the component is estimated as 34.678 grams, as shown in Fig. 5.

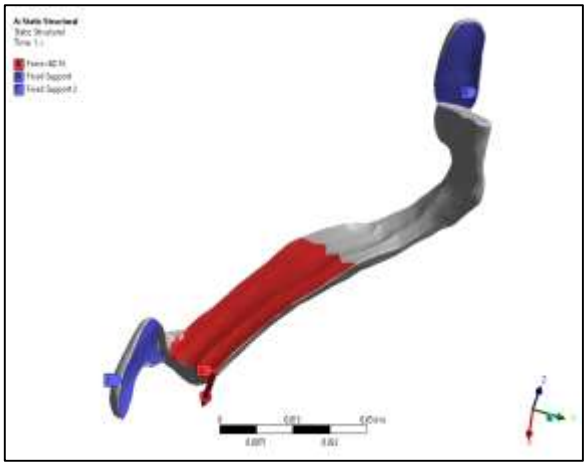


Fig. 2. Loading and Boundary conditions

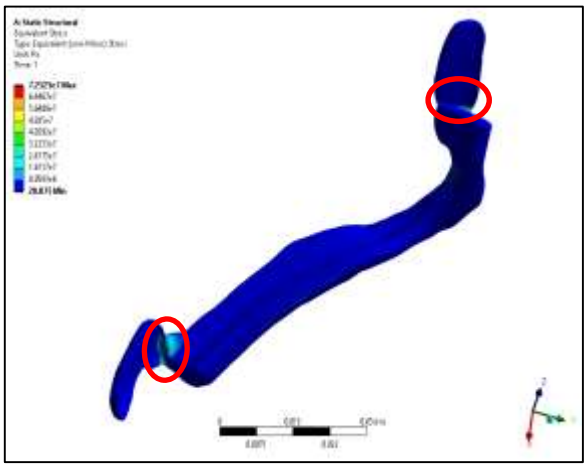


Fig. 3. Equivalent Stress

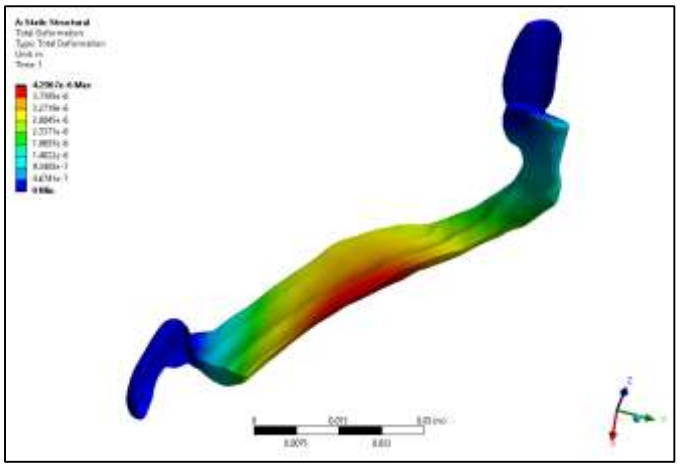


Fig. 4. Deformation

Properties	
Volume	4.3186e-006 m^3
Mass	3.4678e-002 kg
Centroid X	-2.5e-002 m
Centroid Y	9.9575e-002 m
Centroid Z	8.3235e-002 m
Moment of Inertia ...	2.825e-005 $kg \cdot m^2$
Moment of Inertia ...	2.4721e-006 $kg \cdot m^2$
Moment of Inertia ...	2.6522e-005 $kg \cdot m^2$

Fig. 5. Weight of the model

Though the stresses and deformation are within the limit, a large region in the middle (the blue color region in Fig. 3) is least stressed because of the loading. Hence, some amount of material is removed to reduce the weight of the component and also ensure the factor of safety is below 1.67. Material is removed in the form of cylinders to avoid stress concentration due to material removal.

The resulting model is shown in Fig. 6. Once discretized, it has 5695517 nodes and 1325539 elements. The increase in the number of elements from the initial model is due to the mesh resolution at the curvatures. This model is subjected to the same loading and boundary conditions. Stress distribution and deformation in the model are shown in Fig. 7 and Fig. 8, respectively. The maximum stress is found to be 263.8 MPa which results in a factor of safety of above 1.67. The final weight of the component after modification is approximately 33.2 gms. Comparing the deformations in Fig. 4 and Fig. 8, there is an increase in deformation, but the change is minimal (~ $4x10^{-6}$ m). Since the order of deformations is ~10^{-6} m, any change in the deformation values is negligible. Further, it is observed that there is a weight reduction of 4.2%, maintaining the stresses and deformations within the limit.

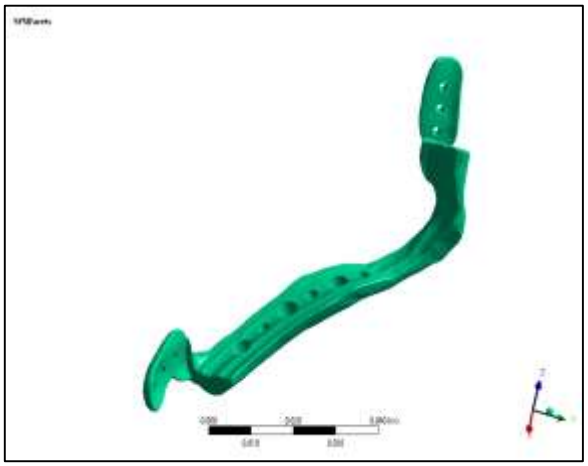


Fig. 6. Modified CAD model

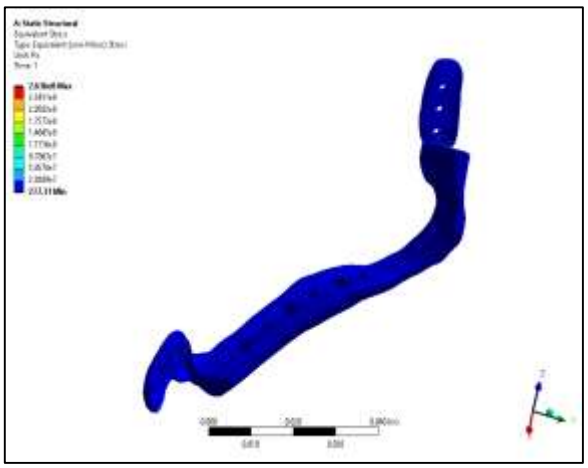


Fig. 7. Equivalent stress for the redesigned model

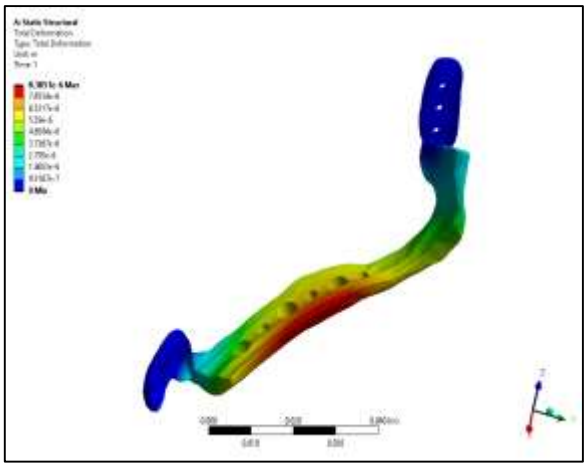


Fig. 8. Deformation of the redesigned model

Properties	
Volume	4.1344e-006 m³
Mass	3.3199e-002 kg
Centroid X	-2.5315e-002 m
Centroid Y	0.1001 m
Centroid Z	8.4127e-002 m
Moment of Inertia ...	2.8863e-005 kg·m²
Moment of Inertia ...	2.5259e-006 kg·m²
Moment of Inertia ...	2.7108e-005 kg·m²

Fig. 9. Weight of redesigned model

3. Fabrication using DMLS technology

3.1. Introduction and fabrication

Direct Metal Laser Sintering (DMLS) is a technology that helps in the manufacturing of complex geometries with high accuracy, which is difficult with other manufacturing methods. Parts made using DMLS are comparatively stronger and denser than the parts manufactured using investment casting. Also, the manufacturing times are minimal.

Direct Metal Laser Sintering, also referred to as selective sintering, is a laser-based additive manufacturing technique. In DMLS, a precise and high-wattage laser is used to micro-weld metals and alloys in the powdered form resulting in a fully functional metal component from the CAD model [6]. It integrates the metal into solid elements according to the CAD model in a layer-by-layer fashion. Due to advantages like acceptance of wide range in various materials, appreciable functionality, less production cost, the process more generous. Hence, this is widely used for the fabrication of medical implants. From the literature, it is observed that DMLS is the technology one that shows promising results in the field of medical implants [7-11].

Table 2. DMLS Machine specification [12]

Build volume	250 x 250 x 325 mm
Laser type	Yb-fiber laser; 400 W
Precision Optics	F-theta lens; high-speed scanner
scanning speed	up to 7.0 m/s (23 ft./sec)
Focus diameter	100 µm
Power Supply	32 A / 400 V
Power Consumption	max. 8.5 kW/ average 2.4 kW/with platform heating up to 3.2 kW
compressed air supply	7,000 hPa; 20 m³/h
Machine Dimensions (W x D x H)	2,500 x 1,300 x 2,190 mm (98.4 x 51.2 x 86.2 in)

Fig. 10 shows the part preparation in a commercial code. The. stl file obtained from the modelling software is used as input for the DLMS Machine. The DMLS machines consists of a hopper which is filled with desired powder material. The laser will pass on to the material and heats the powder to the temperature near to sintering point of the material used. The path of laser follows layer-by-layer method [13, 14] according to the CAD model till the entire part completes [15, 16]. Once the part is cool down, the excess material is removed using post processing technique. Fig. 11 (a) and (b) show the part during the manufacturing process.

The designed implant is fabricated using DLMS machine which is as shown in the Fig. 12. DLMS machine used is a EOSM290 model of EOS GmbH. The technical specifications of machine used are given in the Table 2.

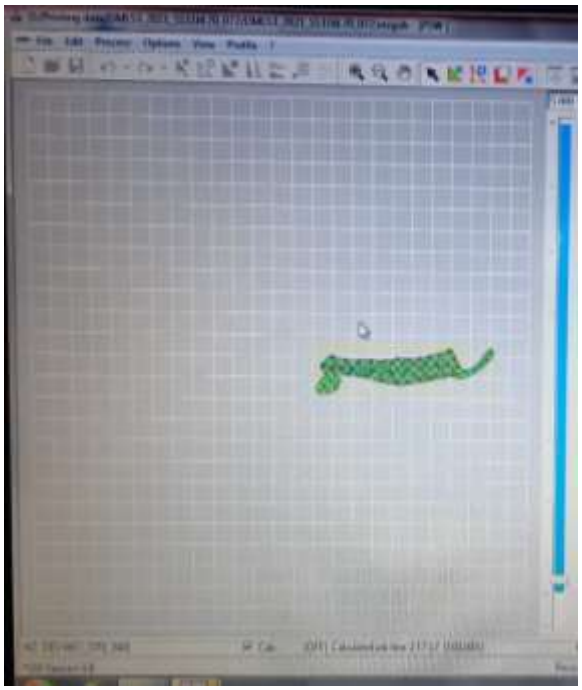
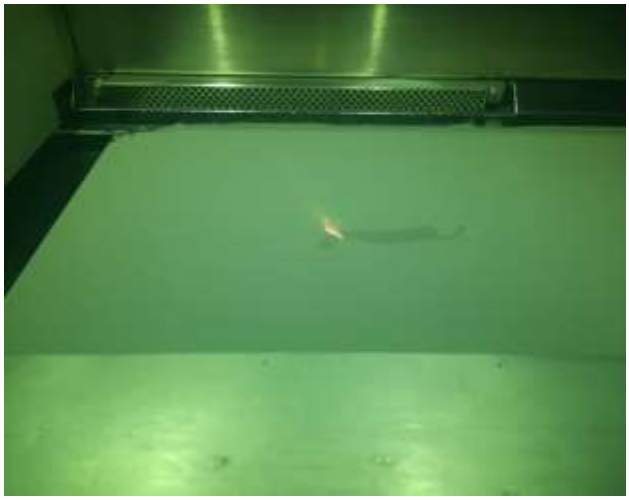


Fig. 10. Part preparation for DMLS



(a)

(b)

Fig. 11. (a) and (b) Part during the manufacturing process

Fig. 12. DLMS machine

3.2. Post-processing

After the fabrication, validation of the part in terms of mechanical, biological, and chemical properties is highly essential for the medical implant. Hence, post-processing techniques like buffing, sterilization, and wire EDM are carried out. Fig. 13 shows the component immediately after the machining on the DLMS machine.

Fig. 13. Component after DLMS machining

Processes that are followed are as follows:

1. Wire EDM is used for removing the support material in the holes and build plate
2. Annealing (heat treatment for removal of stresses)
3. Buffing to get the quality finish and removal of uneven, porous material

4. Finally, sterilization of part using sterilization machine.

In wire EDM, the support material is removed using electron discharge by taking component as the anode and tool electrode as the cathode. Dielectric liquid separates the two electrodes. Fig 14. shows the component being subjected to the EDM process.

Annealing is a process of cooling and heating the component with the sole purpose of softening the component. It also increases the ductility and toughness of the material while reducing the inner stress. The structure of the material is improved using annealing.

Fig. 14. EDM process

After, annealing buffing is done to remove the uneven surfaces and sharp edges. Fig. 15 shows the component while subjected to buffing.

Fig. 15. Buffing process

The final stage is sterilization. Sterilization is done to kill the active bacteria or virus by passing UV light. Fig. 16 shows the machine used for sterilization. It is a steam sterilizer of Sterintech type 6 indicator following ISO 11140 NORMS. The Paper used in the sterilization process is BillerudKorsnäs medical grade paper made by Billerudkorsnàs France. Fig. 17(a) and (b) show the component before and after the sterilization.

Fig. 16. Sterilization process

(a)

(b)

Fig. 17. Component (a) before sterilization and (b) after sterilization

Sterilization is done at 120 degrees Celsius. Once the sterilization is done, the indicator changes its color from green to Grey. The sterilization certificate is valid for a period of 6 months from the date of sterilization.

Once all the post-processing steps are completed, the component looks as shown in Fig. 18.

Fig. 18. Finished component

The whole process took a total time of 24.7 hours which is very quick for a medical implant. The division of total process time is mentioned in Table 3:

Table 3. Time taken for each process

Process	Activity	Time Duration in (hours)
DMLS process	build preparation	1.5
	build time	3.7
Wire EDM	Removal from build plate	4.5
	Drilling of holes	1.5
Annealing		9
Buffing		0.5
Sterilization		3
post sterilization		1

4. Conclusion

The primary objective of this work is to design and develop a patient-specific implant by adopting a methodology of iterative design. The iterated design resulted in the lowest possible geometry, leading to significant enhancement of the parameter strength-to-weight ratio. Finally, validation through FE analysis shows that an improved model can withstand the maximum mastication force needed. Thus, it can be concluded that the method of improving the design by removing the material based on the stress field helps to reduce the weight while maintaining the strength, deformation, and stresses within the limit. As the improved model is rough and organic in nature, Additive manufacturing technology is used for the fabrication of the designed implant.

The analysis carried out in this paper is mainly focused on improving the design by removing the material in low-stress areas. However, the parameter strength-to-weight ratio can be examined by various other optimization methods like lattice optimization, gauge optimization, and topography optimization. In addition, fabrication is done using AISI 31L stainless steel material, where analysis can be extended by changing the material to titanium Ti64.

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