"Structural Design Optimization of Knee Replacement Implants"

[1]Chetan C. Nashte, [2]Dr. M.M. Khot,
[1]Student, [2]Assistant Professor,
[1,2] Mechanical Engineering Department,
[1,2] Walchand College of Engineering, Sangli, 416415, India.

Abstract: The primary aim for this study is to design, develop and analyze of knee implant by using additive manufacturing technique. Recent developments in additive manufacturing give more opportunities in the development and fabrication of surgical implants. Implementation of structural design optimization and additive manufacturing is great way to design and fabricating of lightweight medical implants that biomechanical properties same as original bone. By using topology optimization tried to reduce weight of knee implant. A weight reduction is achieved near about 25% to 30 %. The topological optimized part is fabricated by using 3D printing manufacturing process. For overall analysis stainless steel 316L is used. The prototype of knee implant is made in Poly lactic acid (PLA) material. Comparing finite element analysis results of original designed knee implant with optimized knee implant.

Keywords – *Biomechanical, Topology Optimization, Biomaterials, FEA, 3D Printing, SDO.*

I. INTRODUCTION

Biomechanics involves the application of mechanical principles in the field of medical science. Mainly the mechanical principles are applied related to the bone as it is an important part in the body. Human knee is essential body part which carries the human body weight and provides the support to human body. The human knee joint, which is the largest, most stressed and one of the most complex joint in the human body, consists of: femur, tibia, fibula, patella, cartilages, menisci, different ligaments and muscles. The tibia bone is connected to femur bone of human thigh and ankle joint. At various conditions various type of load act on this bone hence considered as important part and the main focus goes towards this part. Finite Element Method (FEM) is widely accepted as a power tool for biomechanics modelling.

FE model would be advantageous in complementing experimental works. The commonly used biomaterials for implants are stainless steel, pure titanium and its alloys, and cobalt-chromium-based alloys. These materials gives biocompatibility (corrosion resistance and cytotoxicity of corrosion) and bio-functionality (modulus of elasticity, strength, ductility, hardness and toughness). The total replacement or partial replacement of the knee joint is a complicated process but it is essential.

Today topology optimization is more important method for design and development of complicated medical implants like knee replacement implants. Due to complicated shape of medical implant the conventional methods of manufacturing is not to good that's why for manufacturing of complicated medical implants use additive manufacturing techniques in which layer by layer fabrication is done. The main objective of this project is to assess a methodology for the improvement and optimization of customized medical implants in general. Finite Element Analysis (FEA) of this optimized knee implant give clear idea about its behaviour after fixed in body.

1.1 Finite Element Analysis (FEA)

The Finite Element Analysis (FEA) is the simulation of any given physical phenomenon using the numerical technique called Finite Element Method (FEM). Engineers use FEA software to reduce the number of physical prototypes and experiments and optimize components in their design phase to develop better products, faster while saving on expenses.

Finite Element Analysis (FEA) is a computerized method for predicting how a product reacts to real-world forces, vibration, heat, fluid flow, and other physical effects. Finite element analysis shows whether a product will break, wear out or work the way it was designed. It is called analysis, but in the product development process, it is used to predict what's going to happen when the product is used. FEA works by breaking down a real object into a large number (thousands to hundreds of thousands) of finite elements, such as little cubes. Mathematical equations help predict the behaviour of each element. A computer then adds up all the individual behaviours to predict the behaviour of the actual object.

FEA is used by engineers to help simulate physical phenomena and thereby reduce the need for physical prototypes, while allowing for the optimisation of components as part of the design process of a project. FEA uses mathematical models to understand and quantify the effects of real-world conditions on a part or assembly. These simulations, which are conducted via specialised software, allow engineers to locate potential problems in a design, including areas of tension and weak spots. With the use of mathematics it is possible to understand and quantify structural or fluid behaviour, wave propagation, thermal transport and other phenomena. Most of the processes can be described using partial differential equations (PDEs), but these complex equations need to be solved in order for parameters such as stress and strain rates to be estimated. FEA allows for an approximate solution to these problems. FEA is the basis of modern software simulation software, with the results usually shown on a computer-generated colour scale.

1.2 Topology Optimization

Topology optimization is a process that optimizes material layout and structure within a given 3D geometrical design space for a defined set of rules set by the user. The goal is to maximise the performance of the system by mathematically modelling and optimizing for external forces, boundary condition and constraints. Conventional Topology optimization uses the finite element method to evaluate the design performance against defined criteria. Although topology optimization has a wide range of application across engineering product design, currently it's mostly used at the design stage to optimize the size and shape. This is mainly because the free forms that naturally occur through Topology optimization (TO) are often very difficult to manufacture using traditional manufacturing methods. But due to growth and technological advancement in additive manufacturing or so-called 3D printing, the design output by Topology optimization can be fed directly into a 3D printer.

Topology optimization1 is an advanced structural design method which can obtain the optimal structure configuration via reasonable material distribution satisfying specified load conditions, performance and constraints. Compared to sizing and shape optimization, topology optimization is independent of the initial configuration and has a broader design space. Consequently, it has been developed as a mainstream structural design technique for high-performance, lightweight as well as multifunctional structures and been widely used in aerospace, automotive, architecture, etc. [10].

Topology optimization, which refers to the internal member configuration of a structure, is the most commonly used structural design optimization method. Based on literature findings of the last 25 years, the most popular TO methods are: (a) Evolutionary based algorithms (EA), (b) Solid Isotropic Microstructure with Penalization (SIMP), (c) Evolutionary Structural Optimization (ESO), (d) Soft-Kill Option (SKO), and (e) Level-set methods (LSMs) [4].

1.3 Additive Manufacturing

Additive Manufacturing (AM) is an appropriate name to describe the technologies that build 3D objects by adding layer-upon-layer of material, whether the material is plastic, metal, concrete or one day human tissue. Common to AM technologies is the use of a computer, 3D modeling software (Computer Aided Design or CAD), machine equipment and layering material. Once a CAD sketch is produced, the AM equipment reads in data from the CAD file and lays downs or adds successive layers of liquid, powder, sheet material or other, in a layer-upon-layer fashion to fabricate a 3D object. The term AM encompasses many technologies including subsets like 3D Printing, Rapid Prototyping (RP), Direct Digital Manufacturing (DDM), layered manufacturing and additive fabrication. AM application is limitless. Early use of AM in the form of Rapid Prototyping focused on preproduction visualization models. More recently, AM is being used to fabricate end-use products in aircraft, dental restorations, medical implants, automobiles, and even fashion products.

3D printing involves building a model in a container filled with powder of either starch or plaster based material. An inkjet printer head shuttles applies a small amount of binder to form a layer. Upon application of the binder, a new layer of powder is sweeped over the prior layer with the application of more binder. The process repeats until the model is complete. As the model is supported by loose powder there is no need for support. Additionally, this is the only process that builds in colors. SLA technology Selective Laser Sintering (SLS) utilizes a high powered laser to fuse small particles of plastic, metal, ceramic or glass. During the build cycle, the platform on which the build is repositioned, lowering by a single layer thickness. The process repeats until the build or model is completed. Unlike SLA technology, support material is not needed as the build is supported by unsintered material.

II. HUMAN KNEE AND IMPLANT MATERIALS

2.1 Knee Anatomy

The knee is a complex joint that flexes, extends, and twists slightly from side to side. The knee is the meeting point of the femur (thigh bone) in the upper leg and the tibia (shinbone) in the lower leg. The fibula (calf bone), the other bone in the lower leg, is connected to the joint but is not directly affected by the hinge joint action. Another bone, the patella, is at the center of the knee. Two concave pads of cartilage (strong, flexible tissue) called menisci minimize the friction created at the meeting of the ends of the tibia and femur. There are also several key ligaments, a type of fibrous connective tissue, that connect these bones. The four key ligaments of the knee are: Anterior cruciate ligament (ACL), Medial collateral ligament (MCL), Lateral collateral ligament (LCL), Posterior cruciate ligament (PCL). Knee problems and knee pain are common as the knee is a frequent point of contact during traumatic accidents and is as prone to wear and tear due to its weight-bearing nature. It is also a common site for arthritis pain.

Figure 1 Detailed view of human knee

2.2 Material for tibia intramedullary implant

The most commonly used metallic biomaterials for bone fixation implants are stainless steel (ISO 5832-1), pure titanium (ISO 5832-2) and its alloys, and cobalt-chromium-based alloys (e.g. CoCrMo). However, there are problems associated with the use of metallic implants such as a possible release of metal ions, inflammatory reactions, possible toxicity, and problems related to stress shielding and bone loss.

Stainless Steel 316/316 L

Alloy 316/316L (UNS S31600/ S31603) is a chromium-nickel-molybdenum austenitic stainless steel developed to provide improved corrosion resistance to Alloy 304/304L in moderately corrosive environments. The addition of molybdenum improves general corrosion and chloride pitting resistance. It also provides higher creep, stress-to-rupture and tensile strength at elevated temperatures.

Table 1 Chemical Analysis[9]

Element	Type 316 (%)	Type 316 L (%)
Chromium	16.0 min. – 18.0 max.	16.0 min. – 18.0 max.
Nickel	10.0 min. – 14.0 max.	10.0 min. – 14.0 max.
Molybdenum	2.00 min. – 3.00 max.	2.00 min. – 3.00 max.
Carbon	0.08	0.030
Manganese	2.00	2.00
Phosphorous	0.045	0.045
Sulphur	0.03	0.03
Silicon	0.75	0.75
Nitrogen	0.1	0.1
Iron	Balance	Balance

Table 2 Corrosion Resistance[9]

Alloy	Cr (%)	Mo (%)	N (%)
Type 304	18.0	-	0.06
Type 316	16.5	2.1	0.05
Type 317	18.5	3.1	0.06

Properties of Implant Biomaterial

Bulk Properties: Implant material with modulus of elasticity comparable to bone must be selected to ensure more uniform distribution of stress at implant and to minimize the relative movement at implant bone interface. An implant material should have high tensile and compressive strength to prevent fractures and improve functional stability. Improved stress transfer from the implant to bone is reported interfacial shear strength is increased, and lower stresses in the implant. An implant material should have high yield strength and fatigue strength to prevent brittle fracture under cyclic loading. According to ADA a minimum ductility of 8% is required for dental implant. Ductility in implant is necessary for contouring and shaping of an implant. Increase in hardness decreases the incidence of wear of implant material and increase in toughness prevents fracture of the implants [9].

Surface Properties: Surface tension determines the wettability of implant by wetting fluid (blood) and cleanliness of implant surface. Osteoblasts show improved adhesion on implant surface. Surface energy also affects adsorption of proteins. Alterations in the surface roughness of implants influence the response of cells and tissue by increasing the surface area of the implant adjacent to bone and thereby improving cell attachment to the bone. Implant surfaces have been classified on different criteria, such as roughness, texture and orientation of irregularities: (1) Wennerberg and coworkers have divided implant surfaces according to the surface roughness as: Minimally rough (0.5-1 m), Intermediately rough (1-2 m), Rough (2-3 m); (2) The implant surface can also be classified according to their texture as: concave texture, convex texture; and (3) The implant surface can also be classified according to orientation of surface irregularities: Isotropic surfaces and anisotropic surfaces [9].

Biocompatibility: This is property of implant material to show favorable response in given biological environment in a particular function. It depends on the corrosion resistance and cytotoxicity of corrosion products. Corrosion is the loss of metallic ions from metal surface to the surrounding environment. Types of corrosion are seen: (1) Crevice corrosion; (2) Pitting corrosion; (3) Galvanic corrosion; (4) Electrochemical corrosion.
Implant bio-material should be corrosion resistant. Corrosion can result in roughening of the surface, weakening of the restoration, release of elements from the metal or alloy, toxic reactions. Adjacent tissues may be discolored and allergic reactions in patients may result due to release of elements [9].

III. DESIGN, DEVELOPMENT AND ANALYSIS

3.1 Modeling of tibia intramedullary implant

In Design, Development and Analysis phase of the tibia intramedullary implant at this stage a number of CAD Models were drawn in Solid Edge and their adjustments and structural analysis were followed by FEA using ANSYS/Solid Edge simulation. We developed a model based on previously known models and the work up forth by previous researchers. In development of the CAD Model a number of different models have been drawn and designed based on the measurement of human knee and the data also collected from orthopedic doctor and google also. The lower part of the tibia intramedullary implant is called as stem. By using press fit method the stem is inserted in tibia bone canal (tibia shaft).

Dimensions for CAD model: Height = 210.5 mm
Width = 74.2 mm
Length = 54.7 mm

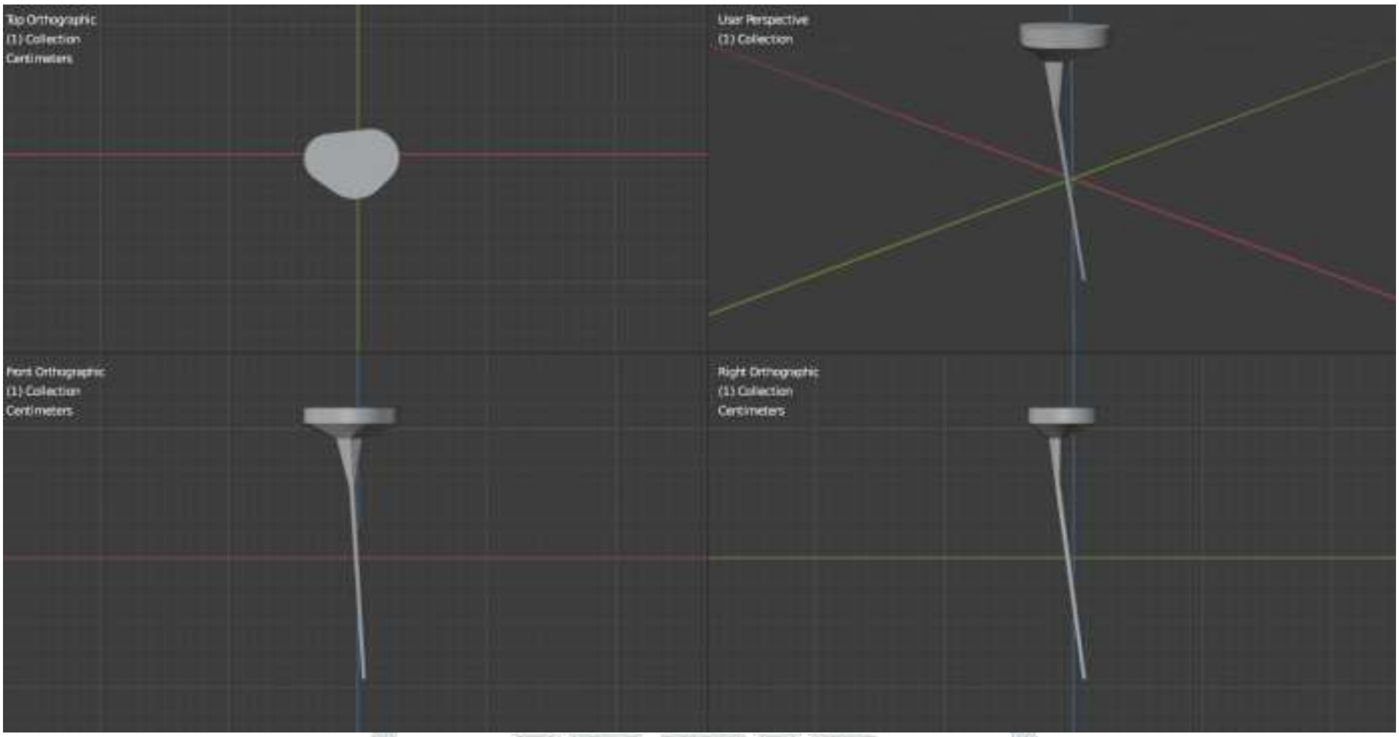


Figure 2 CAD model of tibia intramedullary implant

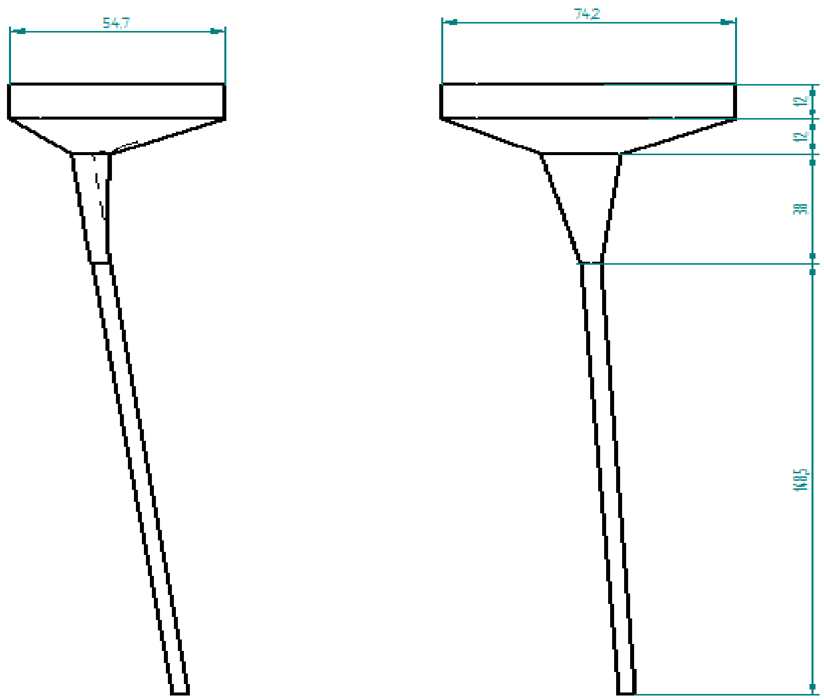


Figure 3 View of tibia intramedullary implant (Dimensions in mm)

3.2 Static Structural Analysis

The static structural analysis of the model showing equivalent (Von-Mises) Stress results and displacement results from the downward loading applied on them. Due to different daily life physical activities, the peak forces acting on the tibia plateau vary significantly. Previous studies have found, from measuring forces in distal femur replacement and transforming to the knee joint, that during typical normal level walking a resultant joint reaction force is equivalent to approximately three times the body weight (BW). According to their in vivo experiments it was reported that the average peak resultant forces in terms of body weight (BW) from the highest to the lowest are:

Table 3 Human knee daily activities[4]

Phase	Multiply Factor
Stair descending	3.46 BW
Stair ascending	3.16 BW
Level walking	2.61 BW
One legged stance	2.59 BW
Knee bending	2.53 BW
Standing up	2.46 BW
Sitting down	2.25 BW
Two legged stance	1.07 BW

Normal walking task consists of two main phases: stance phase and the swing phase. During the normal gait approximately 60% of the time is compromised by stance phase and 40% by the swing phase. The highest joint loading occurs during the stance phase only. There are six sub-phases in the stance phase which are: heel strike, foot flat, mid-stance, heel off, and toe off.

By taking three body weights calculate the displacement and Von-Misses Stress. In Solid Edge simulation module calculate displacement and Von-Misses Stress counter plot. In that fixing the stem of the tibia intramedullary implant and force is applied on top surface of the implant. The applied force is equally divided into two parts and applied vertically on equally spaced areas.

Case 1:
Body Weight (BW) = 60 kg
Force = 9.81 * 60 = 588.6 N
Applied Force = 3 * 588.6 = 1765.8 N

The displacement and Von-Misses Stress counter plot is as follows:

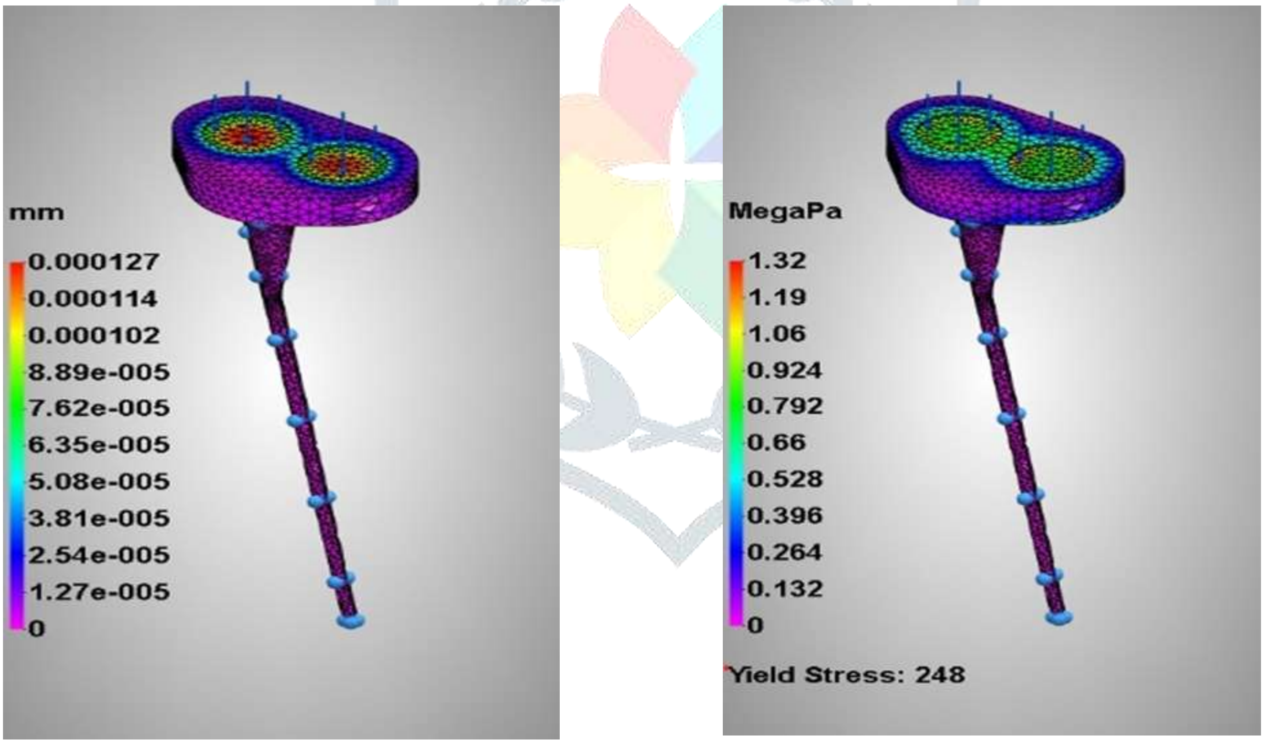
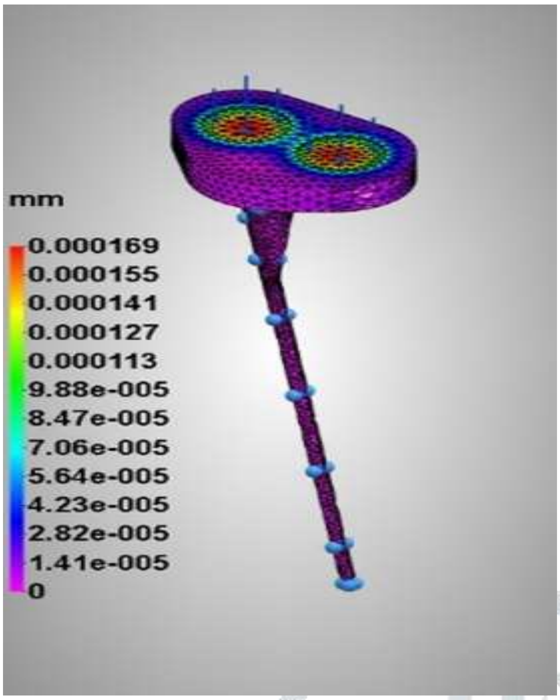


Figure 4 Static structural, Displacement and Von- Misses stress (60 kg)

Case 2:
Body Weight (BW) = 80 kg
Force = 9.81 * 80 = 784.8 N
Applied Force = 3 * 784.8 = 2354.4 N

The displacement and Von-Misses Stress counter plot is as follows:



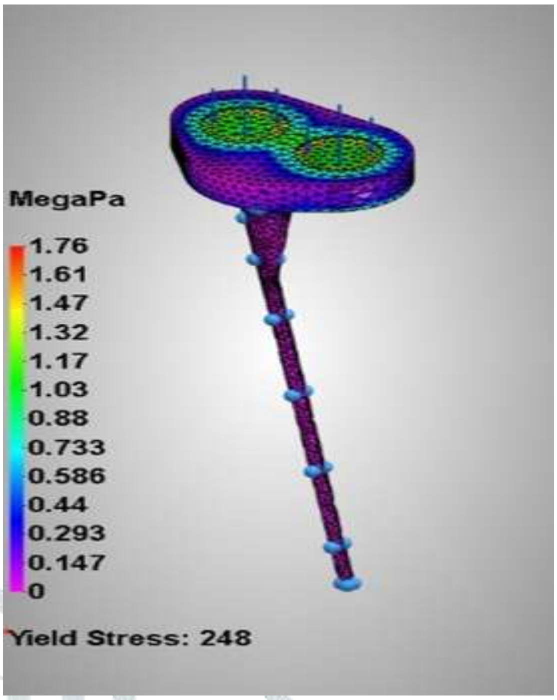
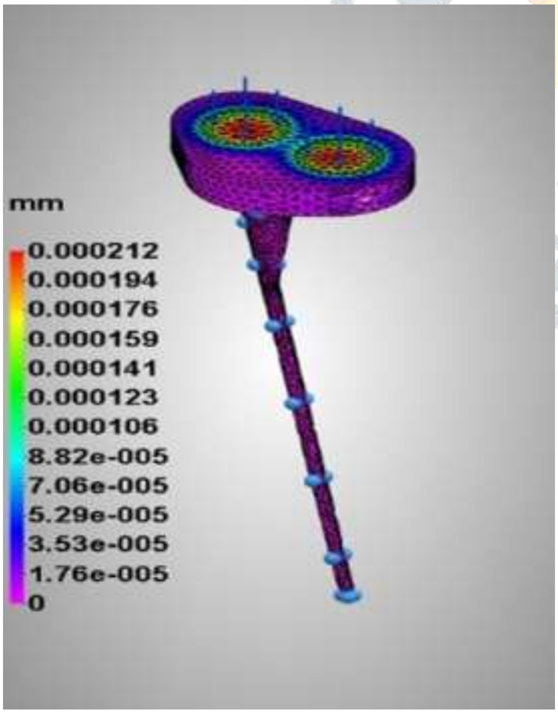


Figure 5 Static structural, Displacement and Von- Misses stress (80 kg)

Case 3:
Body Weight (BW) = 100 kg
Force = 9.81 * 100 = 981 N
Applied Force = 3 * 981 = 2943 N

The displacement and Von-Misses Stress counter plot is as follows:



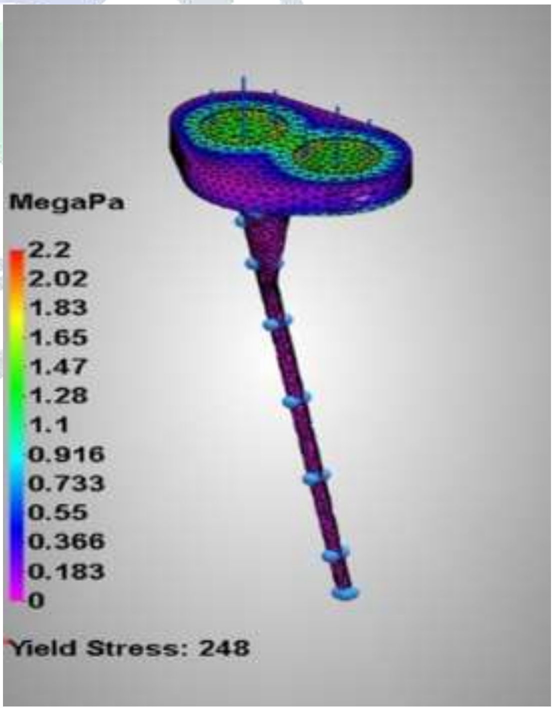


Figure 6 Static structural, Displacement and Von- Misses stress (100 kg)

IV. TOPOLOGY OPTIMIZATION RESULTS

In recent years, many computer-aided methods have been developed to find the most optimum design for a problem. These intelligent techniques have allowed engineers to create designs that were beyond what we could come up with manually. One of these methods is topology optimization. Topology optimization (TO) be a computer-based design method used for creating efficient designs today. Fields such as aerospace, civil engineering, bio-chemical and mechanical engineering use this method proactively to create innovative design solutions that will outperform manual designs. TO was performed only for the top part (not for the stem), and the generated results are shown in Fig. 7. The weight of the implant is reduced by almost 25% to 30%, measuring a value of 245.4 g compared to initial weight of 350.58 g. By using topology optimization module reduction in implant weight is achieved. Due to reduction in weight the material required for manufacturing of implant is less so reduction in material cost. The topological optimized implant manufacturing is done by 3D printing methods.

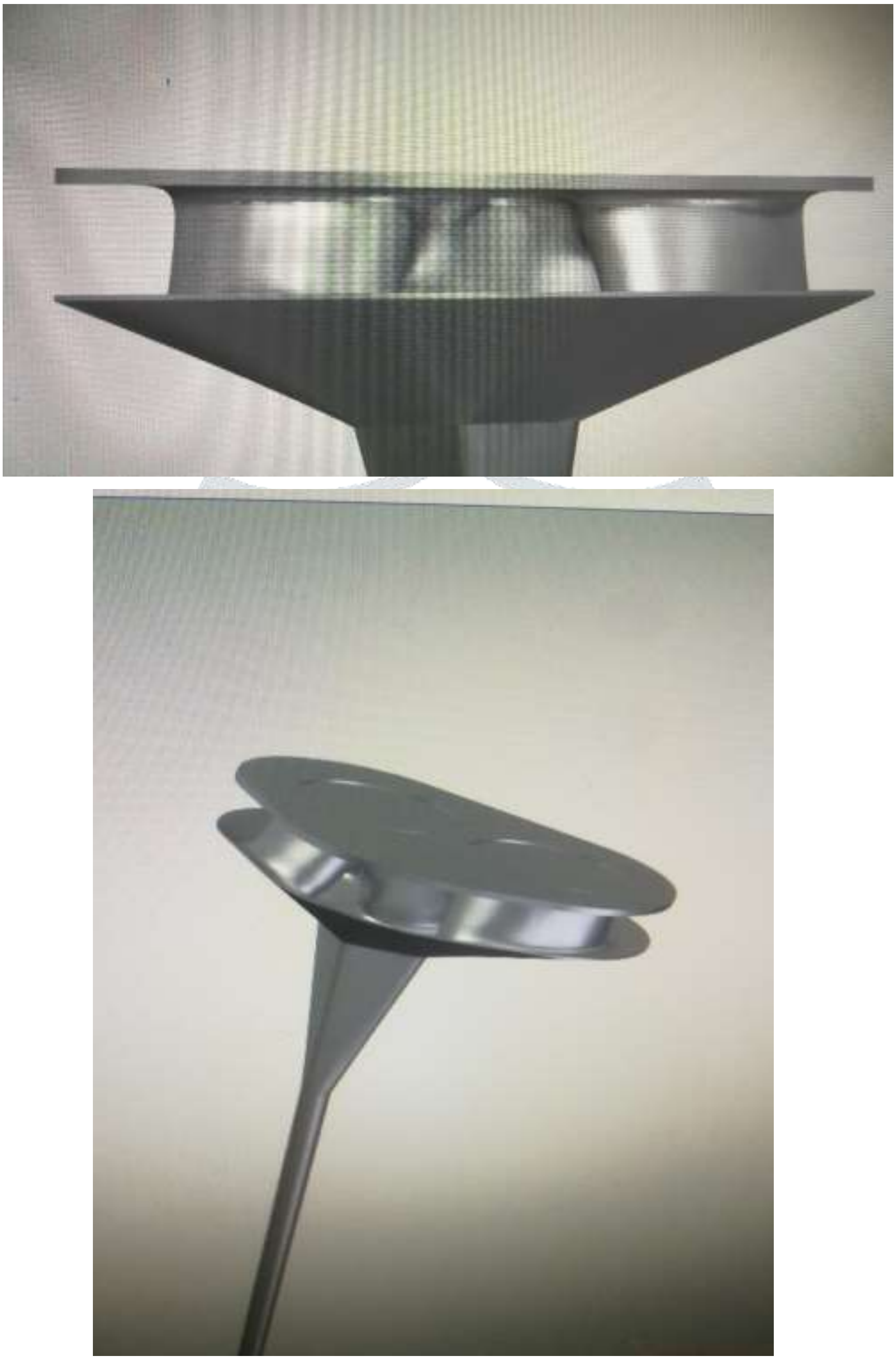


Figure 7 Optimized tibia implant

V. Conclusion

From this study till now we have got some work related results and conclusions. Different analyses are carried out using different body weights of male as well as female on human tibia bone implant. The analysis done on tibia implant by using properties of bio-material Stainless Steel 316L. Based on the properties and characteristics of SS 316L can be selected as a tibia implant material. The FEA method is used on 3D model to check their strength and directional deformation using solid edge simulation. Applied topology optimization on initial designed implant model and calculate how many material removal is possible. According to our study on implant, the weight reduction is achieved 25% to 30% from initial model. The optimized implant will be manufactured by 3D printing methods.

VI. References

[1] Abdulsalam A. Al-Tamimi, Chris Peach, Paulo Rui Fernandesd, Akos Csekea, Paulo JDS Bartolo, "Topology Optimization to reduce the stress shielding effect for orthopaedic applications", Procedia CIRP 65 (2017) 202 – 206.

[2] Sorin Munteanu, Daniel Munteanu, Bogdan Gheorghiu, Tibor Bedo, Camelia Gabor, Patrizio Cremascoli, Fabio Alemani, Mihai Alin Pop, "Additively manufactured femoral stem topology optimization: case study", Materials Today: Proceedings 19 (2019) 1019–1025.

[3] Sudhanshu Nahata, O. Burak Ozdoganlar, "Feasibility of Metal Additive Manufacturing for Fabricating Custom Surgical Instruments for Hip and Knee Implants", Procedia Manufacturing 34 (2019) 772–779.

[4] Marinela Peto, Erick Ramírez-Cedillo, Adriana Hernandez, Hector R. Siller, "Structural design optimization of knee replacement implants for Additive Manufacturing", Procedia Manufacturing 34 (2019) 574–583.

[5] Geoffrey W. Rodgers, Elijah E.W. Van Houten, Rohan Jean Bianco, Romain Besset and Timothy B.F. Woodfield, "Topology Optimization of Porous Lattice Structures for Orthopaedic Implants", August 24-29, 2014.

[6] M. Saini, Implant biomaterials: A comprehensive review, World J. Clin. Cases. 3 (2015) 52.

[7] S.M.P.R. Geoff Richards, Implants and Materials in Fracture Fixation, J. Chem. Inf. Model. 53 (2013) 1689–1699.

[8] Metals for Biomedical Applications by Hendra Hermawan, Dadan Ramdan and Joy R. P. Djuansjah submitted: November 1st 2010 Reviewed: April 22nd 2011 Published: August 29th 2011 DOI: 10.5772/19033.

[9] AZO Materials, Stainless Steel - Grade 316L - Properties, Fabrication and Applications (UNS S31603).

[10] Jihong ZHU, Han ZHOU, Chuang WANG, Lu ZHOU, Shangqin YUAN, and Weihong ZHANG, "A review of topology optimization for additive manufacturing: Status and challenges", Chinese Journal of Aeronautics, (2021), 34(1): 91–110.