Abstract

Total knee replacement is the most effective treatment to relief pain and restore normal function in a diseased knee joint. The aim of this research was to develop a patient-specific knee implant which can be fabricated using 3D Printing also called as additive manufacturing techniques. 3D printing is an emerging technology and its use in orthopaedics is slowly gaining acceptance. This technique makes it easy to manufacture patient specific devices/guides and instrumentation of any shape and size.

The patient-specific technology improves on conventional of the shelf process by allowing to consider each patients anatomical structure, shape and size. In this study patient specific knee implant design , simulation and 3D print is discussed. In particular we want to highlight the role of computer simulations in testing and optimising patient specific device.

Patient knee CT scan data was modeled in ImageSim software and 3D model was generated. This model was used as the base model to capture the outer shape of distal femur and proximal tibia. Full set of J curves of condyles were captured and then exported. These set of J curves along with other landmarks were imported in Solidworks and full implant for femur , tibia components and insert were designed.

A detailed total knee-joint FE model was created in order to predict stress and strain at various flexion angles. Results from these simulations highlighted some initial stress riser sites especially in femur component. The design was accordingly changed and simulations were run again to make sure that design changes were correctly done. Finally, the patient-specific knee implant was successfully built using additive manufacturing techniques.

1.0. Introduction

The knee joint is the largest synovial joint in the human body and carries very high loads. It bears the weight of the body during sitting, standing and climbing. It is one of the major joints of the human body that is highly susceptible to osteoarthritis (OA).

Total knee arthroplasty (TKA) is the most effective and an established treatment for relief from pain caused by OA and restore normal function in a diseased knee joint. TKA is considered among the most successful medical procedures worldwide regarding the degree of improvement in functional status and quality of life. A typical full TKR implant has a metal femoral component, a metal tibial tray and a polyethylene insert.

As a result of the success of TKA, the increase in the aging population, and the desire of older adults to remain physically active, the incidence of TKA is increasing rapidly. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually.[1]

Today over 5 million people are living with total knee replacements.9 Therefore, millions are likely dissatisfied with their knee replacement. This number continues to grow as over 1.2 million knee replacement procedures are done every year worldwide.

Carr and Goswami [2] reviewed knee replacements and biomechanics; they pointed out that issues such as wear and fixation had become more critical with prolonged use of knee implants. Knee implant recipients are more active today than ever; therefore, designing implants that mimic the natural knee is essential to the patients' long-term satisfaction and survival. Thus there is a scope for making implants / devices that can make better fit to patients and improve the quality , rehabilitation and thus satisfaction levels of patients.

2.0 Why Patient Specific Knee Implant:

Although with current technique implant survivorship has been excellent, reported patient satisfaction has lagged substantially behind other orthopedics procedures such as total hip arthroplasty, with upward of 20% of TKA patients reporting dissatisfaction with regard to implant outcomes [4]. There are a number of reasons why such a large subset of patients report dissatisfied outcomes and the three most recurring reported factors tend to be pain, stiffness, and limited function [4]

Although many implants currently on the market perform well, they still fall short in successfully achieving the kinematics of normal knee [4].

Patient dissatisfaction is due to number of reason[3] , including residual pain that could be attributed to fit and rotation data suggest 27% to internal rotation errors.

Functional limitation and unnatural feel. After TKR patient experience substantial functional impairment compared to their peers without TKR[3]. Even amongst satisfied TKR patients around 20% state their knee does not feel normal.

Early implant Failure - Instability, malalignment and fixation errors contribute to around 50% of early revision TKA[3].

Every patient has a unique anatomical geometry and these geometries can vary because of gender, ethnicity, and body type between patients [4]. There is also substantial variation between individual subjects within these groups, suggesting that a customized implant may be advantageous compared with ethnic and/or gender-specific TKA [4].

The optimal TKR implant should reproduce knee function, maintain bone-implant interface integrity, and resist wear. The kinematics and loads on the TKR implant are very important to the success of TKR. To create a customized TKR implant, an iteration procedure is required to optimise stress, material wear, and knee kinematics. While experimental validation in Laboratory using knee wear simulator testing is invaluable for understanding polyethylene wear mechanisms and pre-clinically evaluating new implant designs and materials [5]. However, the experimental testing is associated with substantial cost and time, as a large number of low frequency gait cycles are required [5], computational wear modeling is an alternative attractive solution [5] can be done iteratively however it has significant cost and time involved. On the contrary finite element analysis can be used to test the implants in an environment that can closely resemble the actual human movement.

3.0 Methodology: Patient Specific knee Implant design

a) Patient CT scan to 3D CAD model.

The method used in this study was to obtain CT scan data of the patient knee that required the implant. The ImageSim software was then used to segment the data using image processing algorithms to create a mask and capture the required area/volume of interest. Segmentation was performed to detect the bones and hard tissue and then generate a three-dimensional knee model as shown in figure[1]. This model was then used as a reference to create the implant.

Segmentation –

Computed tomography data of a patient suffering from a osteoarthritis was used. The CT file was then processed through the ImageSim software (From VOLMO LTD) that used each slice of the scan to create a three-dimensional mode. Basic image processing techniques (cropping, filtering , contrast enhancement etc) were used to obtained the best quality and most accurate model. The total number of slices were 699. An anisotropic gradient filter was applied for smoothing this helped to preserve the boundary of the object to be segmented. The masks that differentiated the bone from the rest of the scans were identified using thresholds and connected threshold filters. The masks were merged using the Boolean OR operations. Figure 1 shows the CT scan data views in ImageSim, in axial, coronal and sagittal views and mask being created.

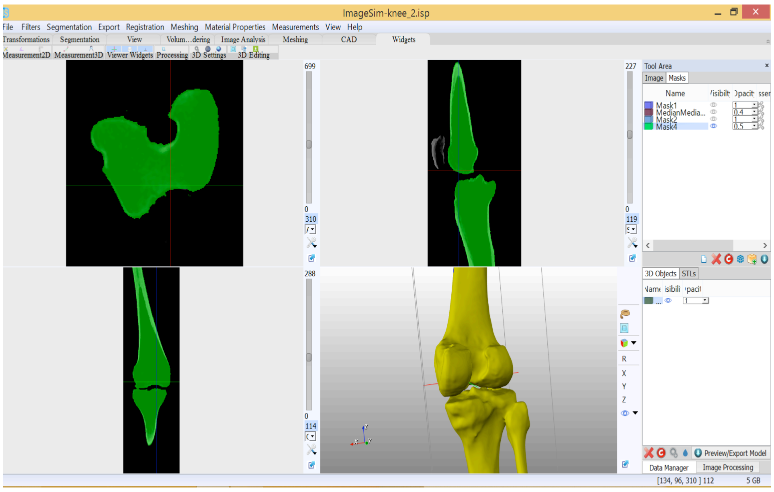


Figure [1]

In addition to femur and tibia STL models full set of J Curves of medial and lateral condyles were captured and exported separately. Also the distance between the two condyle profiles and other landmarks were accurately captured and exported. This helped to recreate femur condyle surfaces that matched closely to patients articulating joint surface.

b) CAD model to Implant Design

STL models of Femur and Tibia along with cross sectional planes of distal femur and proximal tibia were imported into Solidworks. Full 3d knee model was created in Solidworks. Both femur and tibia bones were then resected , femur bone was resected with five sectional cuts and tibia with one horrizontal cut as shown below in figure (2)

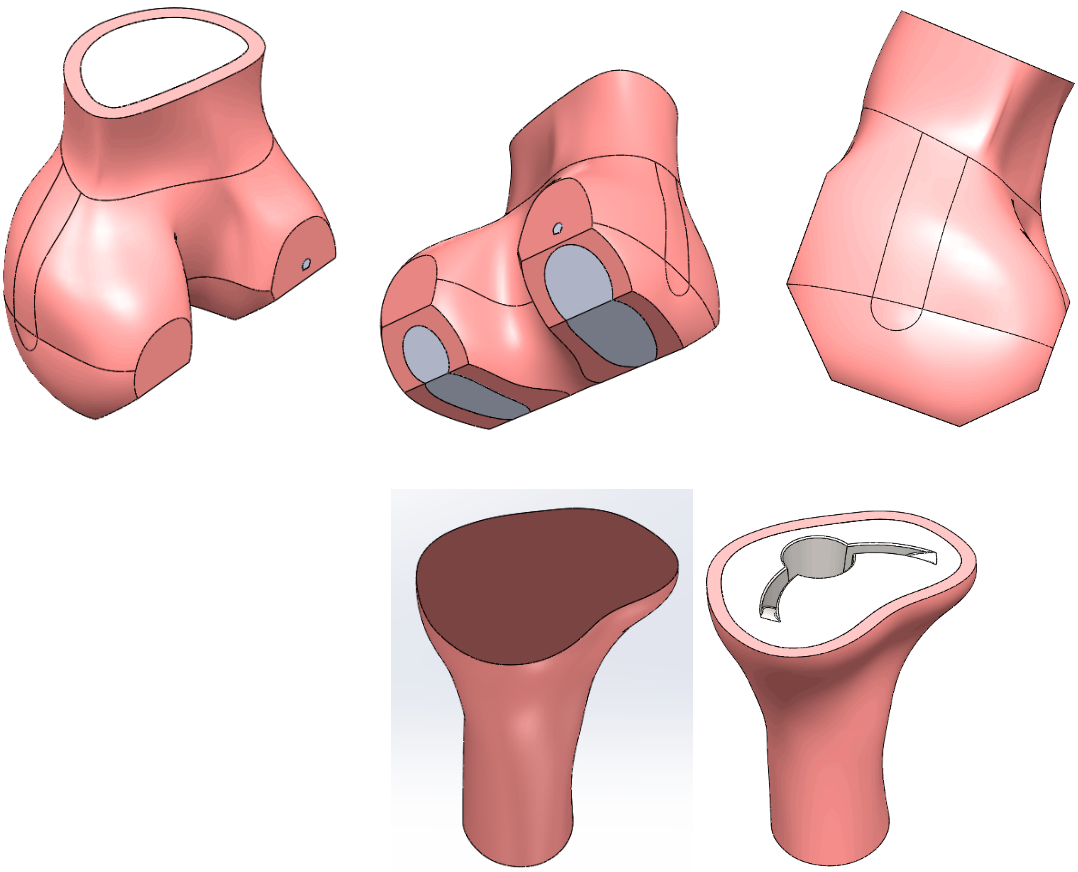


Figure [2]

Femur implant was designed   using the surfaces cut from the femur as shown below in figures [3].

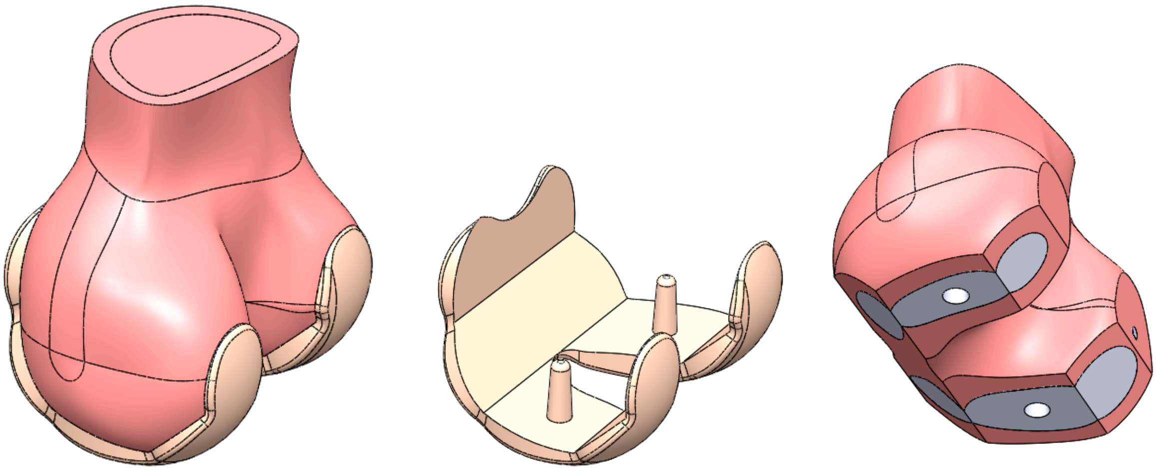
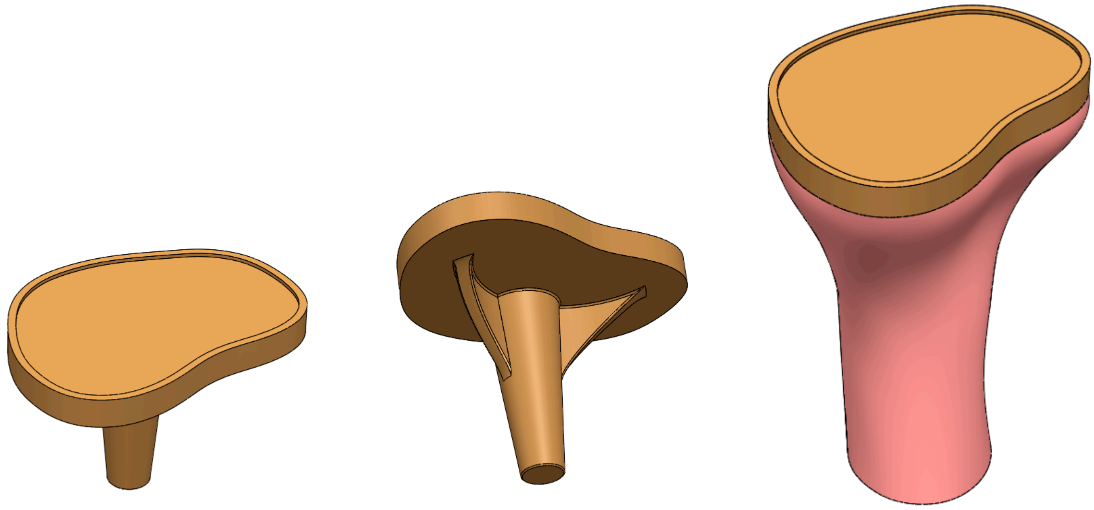
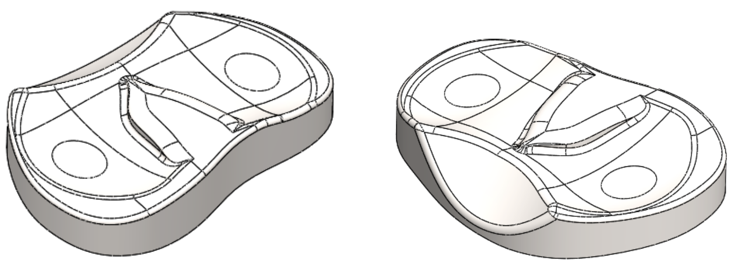


Figure [3]



Figure[4]

Design of middle polyethylene part. This part is very important as it ensures contact and movement between two bones. Lower surface of Polyethylene is simple and fits in tibial implant. Top side is articulating surface and it has to contact with moving femur implant so these surfaces need to be congruent as shown in figure [5]



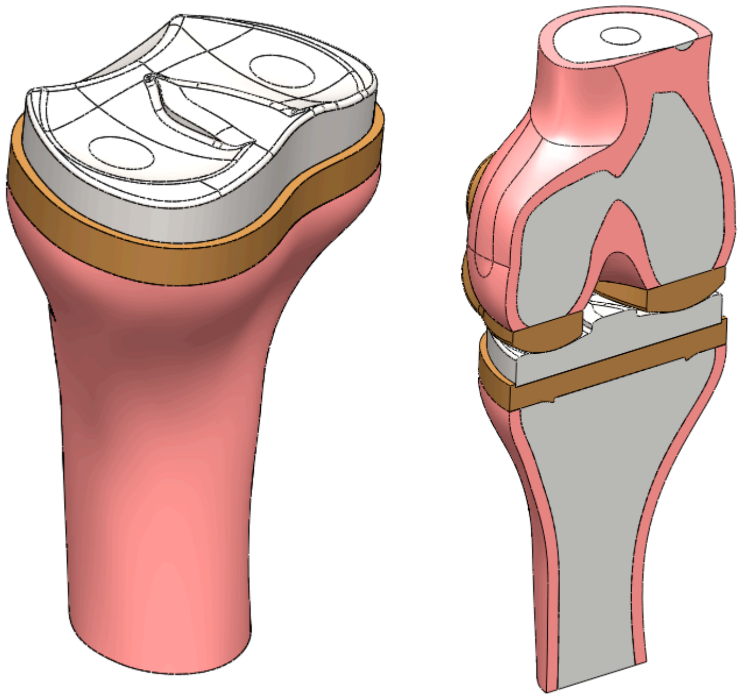
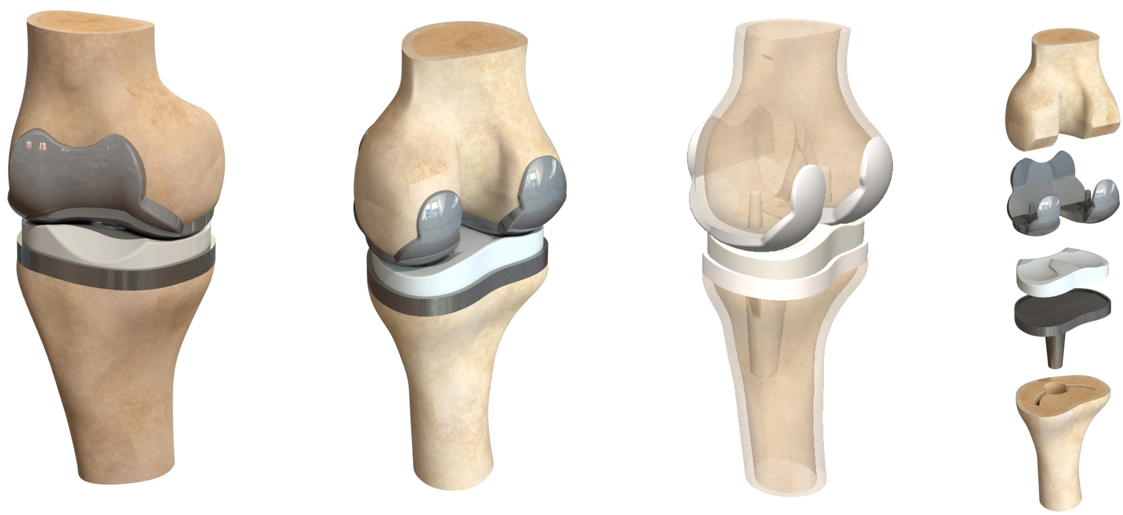
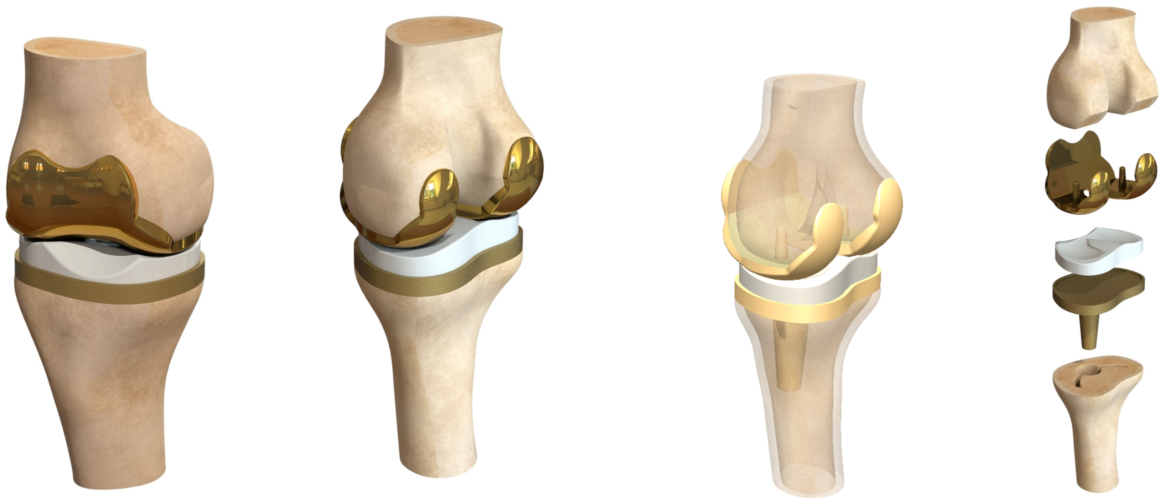


Figure [5]

4.0 Model Assembly:

All the components and bones were assembled in Solidworks and full knee model was created as shown in figure [6].





Figure[6]

5.0 CAD to finite element model generation.

Finite element analysis was done in Ansys. In this study we simulated two different designs . Design were created as discussed above and simulated in different position (0°,60°,90°) as shown in figure [7] .

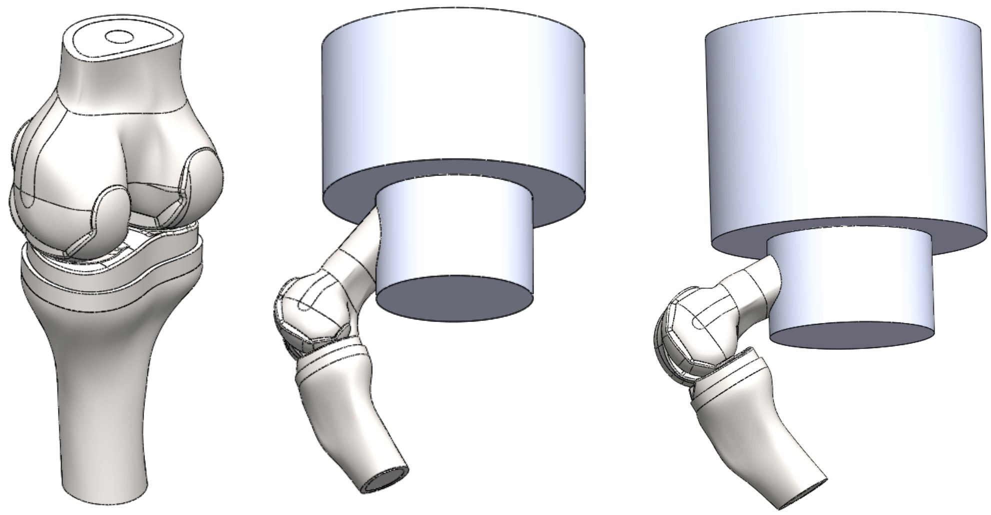


Figure [7]

5.1 Material Properties : Following material properties were assigned to various materials used in the model.

	Cortical bone (Tibia and Femur)	Cancellous bone (Tibia and Femur)	Lower and upper implant (Mild steel)	Middle part (PE High density)
Module of elasticity, GPa	20	1	210	1,1
Poisson ration	0,3	0,12	0,28	0,41
Yield strength, MPa	114	5	220	-
Compresive strength, MPa	141	7,8	-	-
Tensile strength, MPa	-	-	400	22
Density, kg/m>3	1910	127	7800	952

5.2 Contacts : Following contacts were defined in the model. Contacts for bodies were set up as bonded except:

1- Contact between Upper implant and Middle part set as “No penetration”. It allows bodies to move, slide, push each other with friction force under load

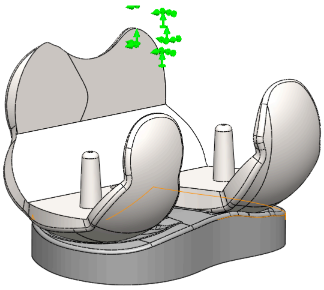
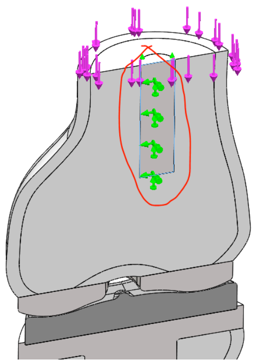


Figure [8]

2- For 0° was added inner cylinder to ensure only vertical movement of Femur bone, cylinder surface of this body is fixed and contact between cylindrical surfaces allows sliding up and down and rotation



Figure[9]

3- For 60° and 90° was added two cylinders with sliding contact to imitate pushing mechanism.

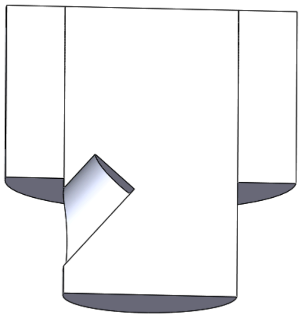


Figure [10]

5.3 Constraints: Bottom of the tibia bone, outer surface of guide cylinder and top/bottom surfaces of outer cylinder were fixed as shown below in the Figure[11]

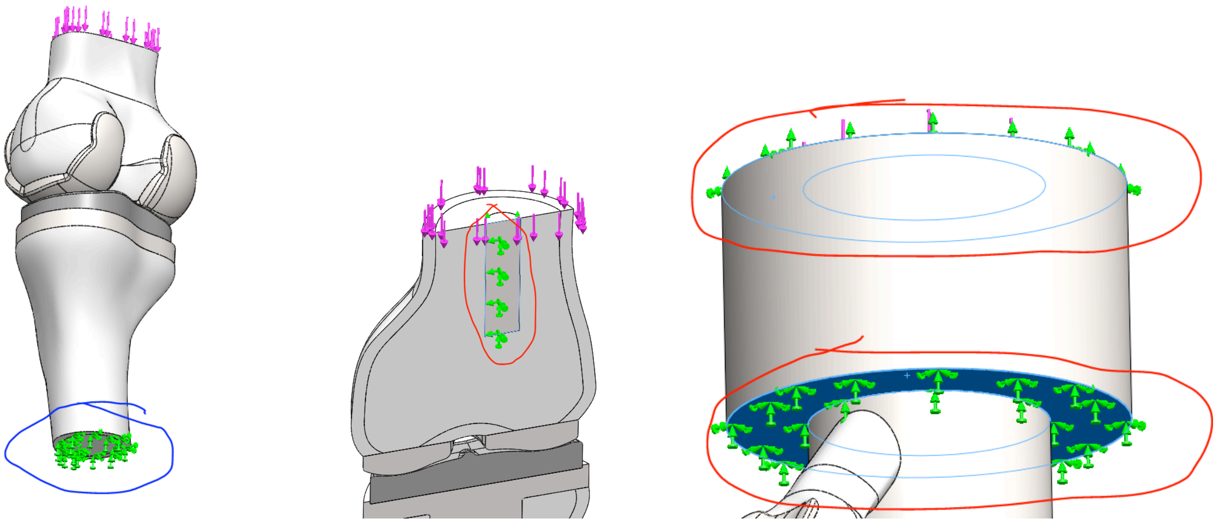


Figure [11]

5.4 Loading : For 0° flexion model was loaded on top surface of Femur bone, for 60° and 90° loaded top surface of inner cylinder. Load 70kg for each test.

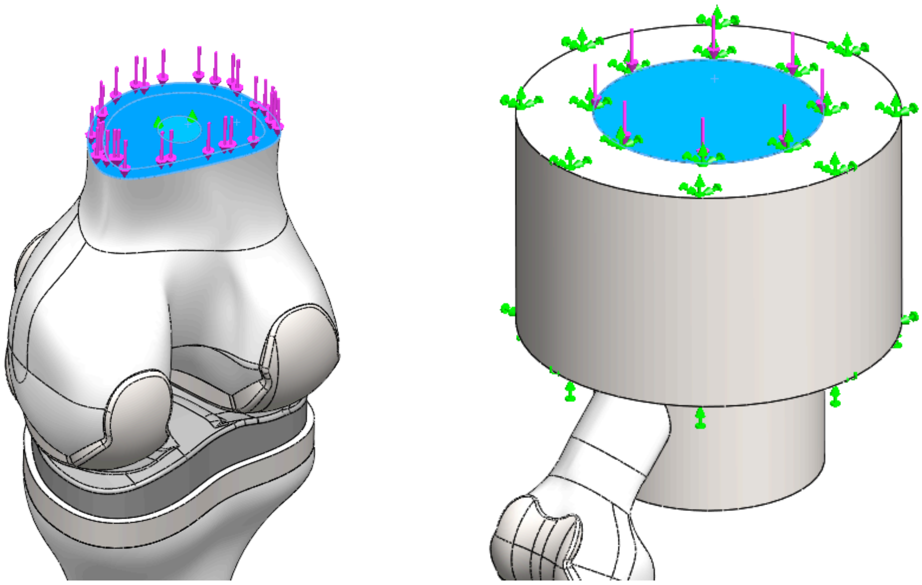


Figure [12]

5.5 Volume meshing :

Full knee model was meshed in Ansys see below figure [13]

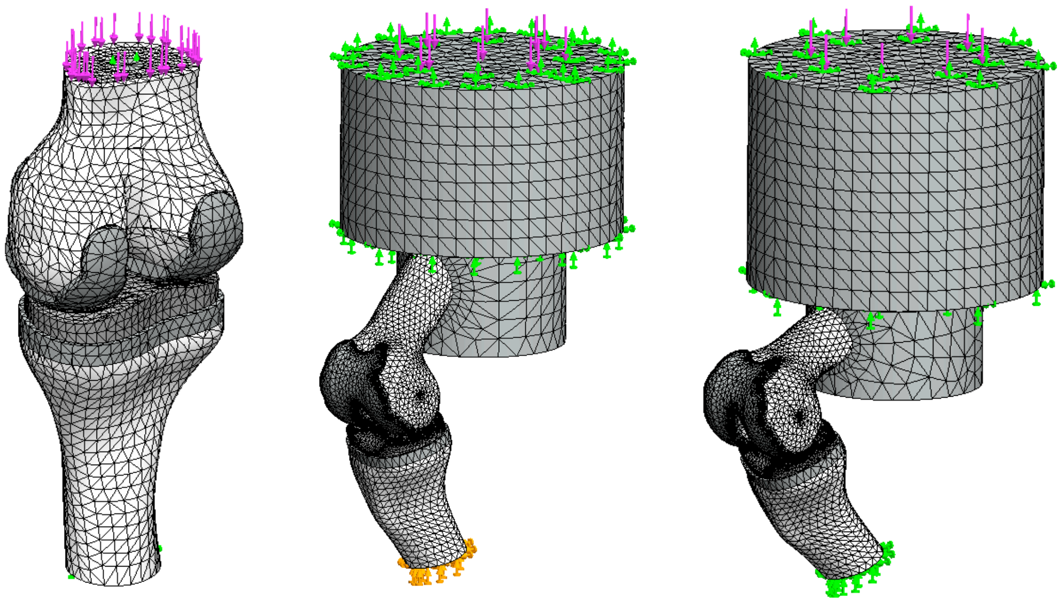


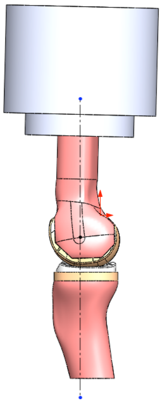
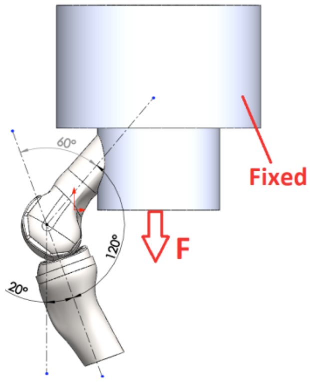
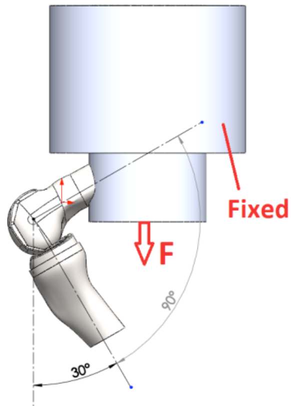
Figure [13]

6.0 Results Design 1:

Finite Element Analysis was run for all the cases with same load of 70Kg.

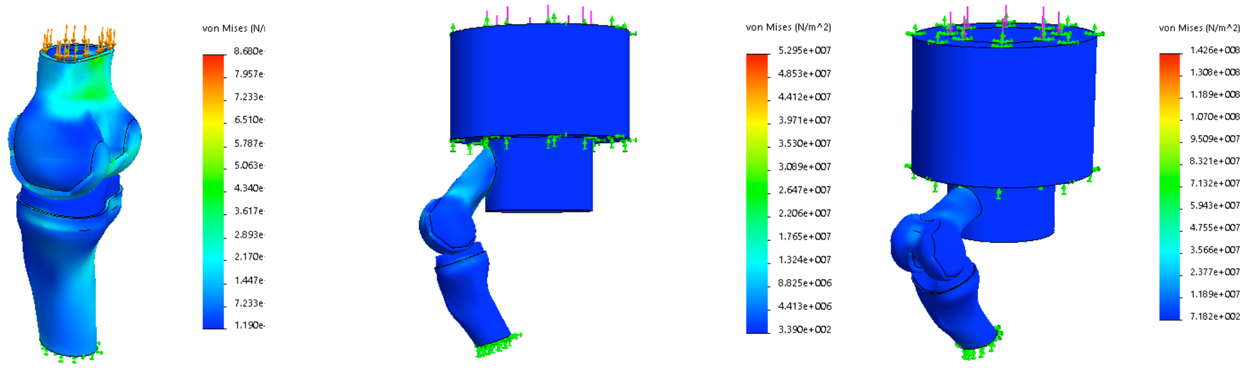
Surface area calculated is a sum of both contact places. It was observed from the simulation results that the surface area decreases with increasing of angle flexion as shown in table 1. These results show similar behavior as reported by [6]

Table 1. Calculation data and results

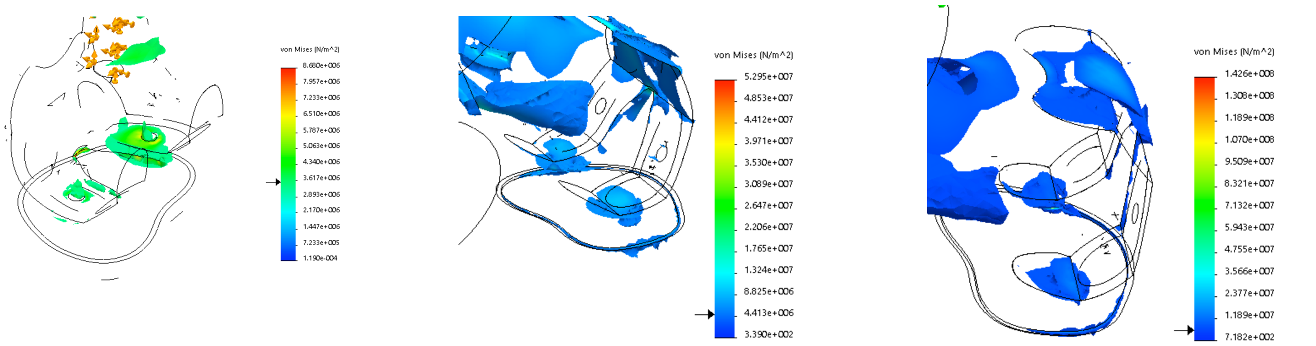
Angle	0°	60°	90°
Load, kg	70		
Surface area, mm^2	221	195	172
Stress, MPa	3,6	4,7	5,7
Position			

Stress Distriution Results Design I

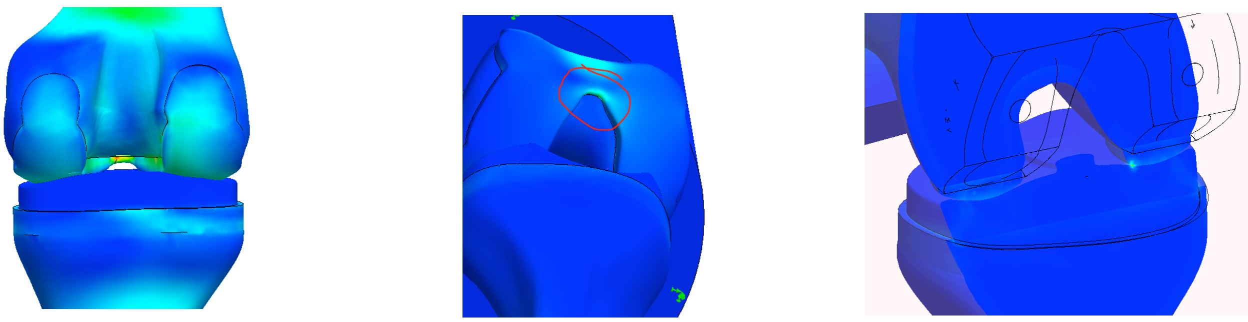
Test 1. Knee joint Flexion 0°   Test 2. Knee joint 60°   Test 3. Knee joint 90°



Contact area load



Critical load places



Cross section view

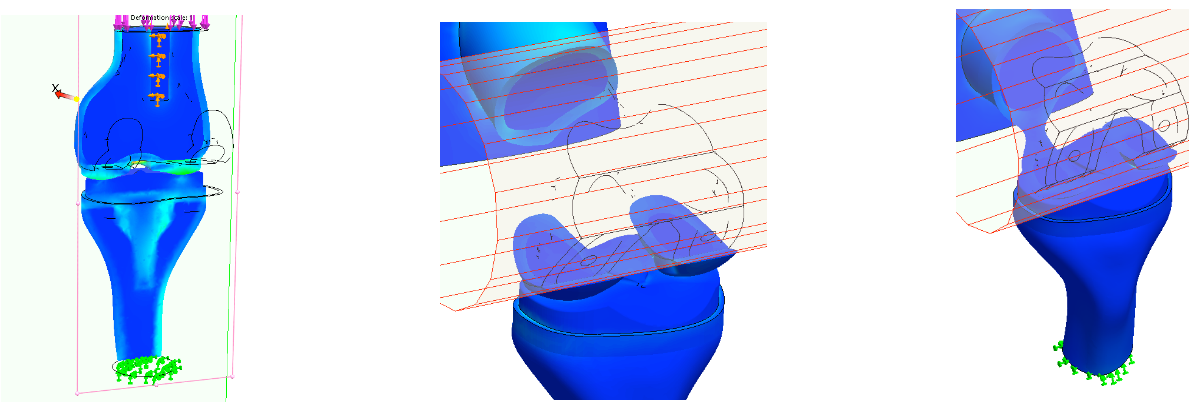


Figure [14]

6.1 Stress test results:

- Main load act on Cortical bones because of large difference in strength with Cancellous bone
- Load distributes non-symmetrically because of shape of bones. load acts on that side which has less space for displacement

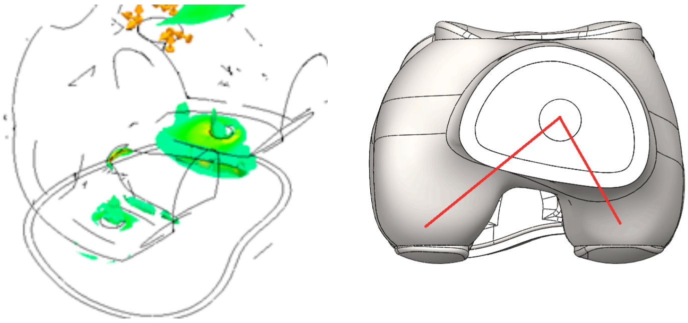


Figure [15]

6.2 Design Optimisation-

Finite element analysis highlighted following :

- For larger angles it is important to have the same compressive strength of implant and Femur cortical bone to avoid loosesning of contact between contact surfaces which are opposite to the contact points with middle part. It will help to decrease stress on thin part on the upper implant

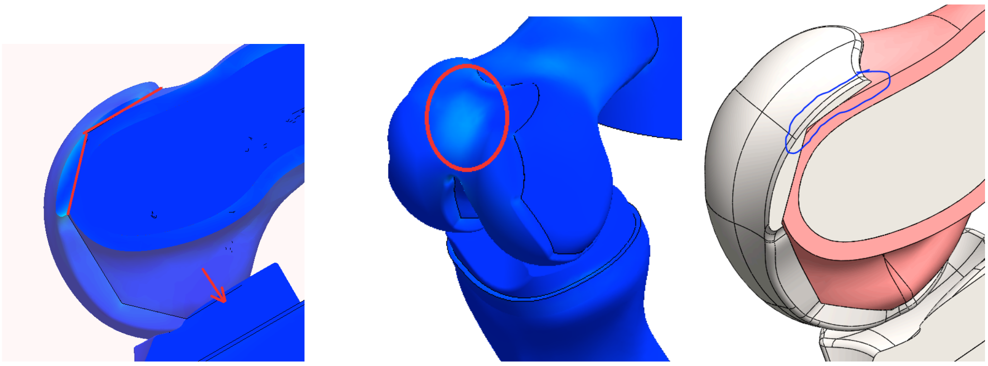


Figure [16]

- In the current model there are some weak places as indicated in figure [17]. It is sharp surfaces in contact with bone, for next design we plan to make these changes and run the simulation again. It would be useful to add some wall thickness around all upper implant at the points highlighted in the figure [17]

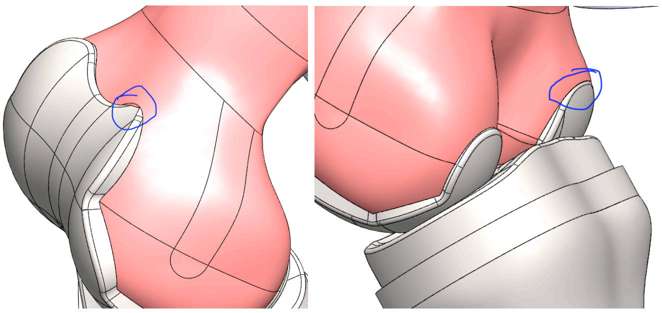


Figure [17]

- Load distributed in two direction on femur implant is a reazon why connection place for two sides of the implant is a weak point. In current design in this place are coincidense of edges from two set up surfaces and from cutout which divide implant. Such coincident needed to be avoided

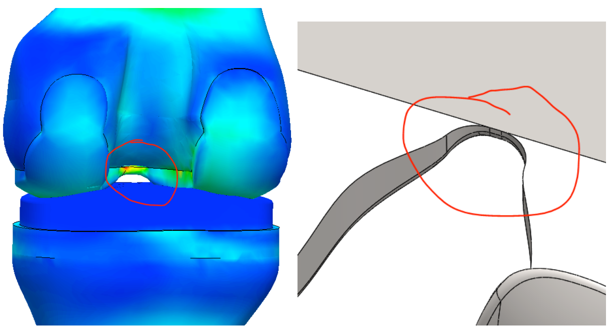


Figure [18]

- Current design fit for shape of cutted Femur bone and that is a reason why it has curved outer edge. Inner sides of these curves are weak places for load distribution. It is better to increase radius in this place or proceed with smooth surface for overlapping of implant on the bone. Figure[19]

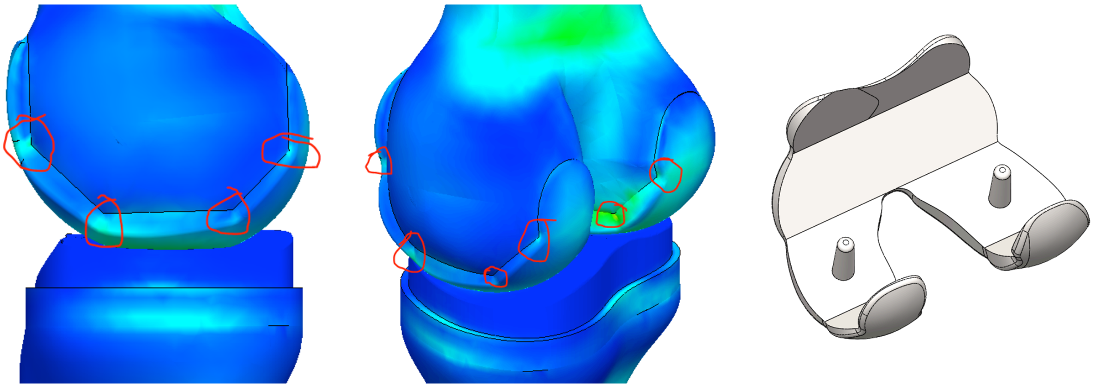


Figure [19]

- Ensure contact between femur implant and polyethielene insert only with larger radius surface to avoid concentration of load in one point. This problem appears after flexion angle 60° in one place. Necessary to avoid it during all range of motion

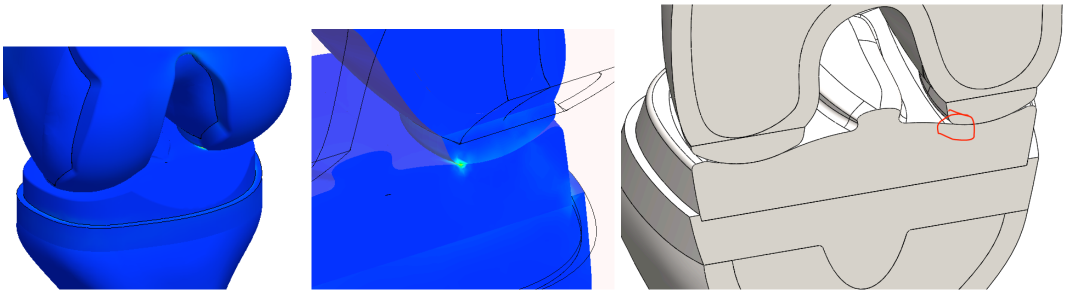
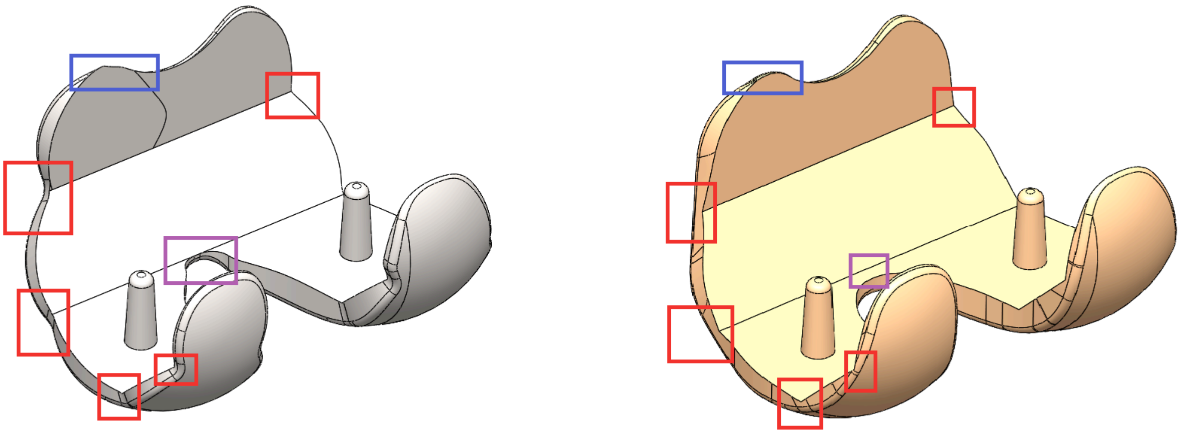


Figure [20]

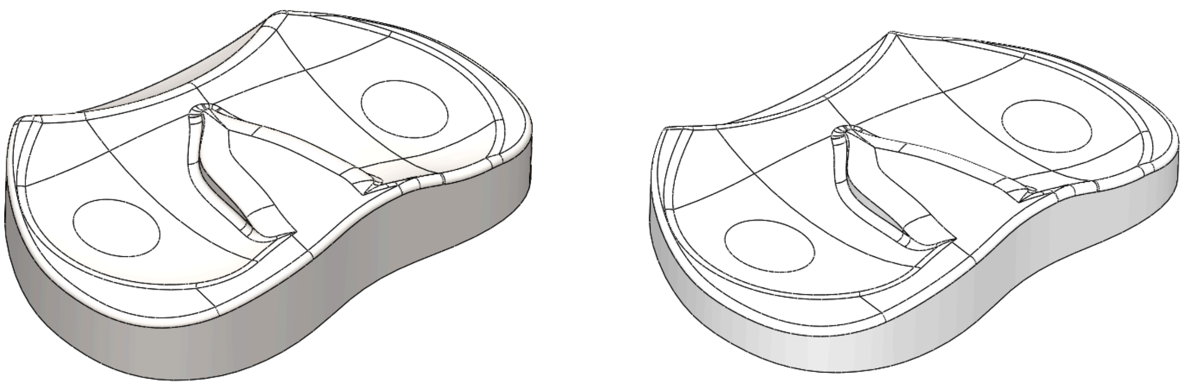
6.3 Results Design 2

For second design following changes were made to design I discussed in the previous sections:

- Increased radiuses on side surfaces (red areas)
- Removed sharp edges (blue area)
- Increased inner radius (purple area)



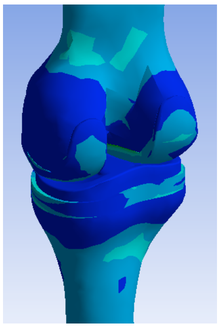
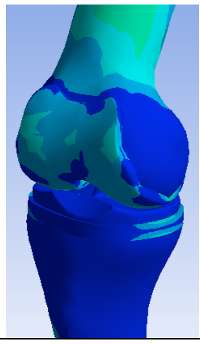
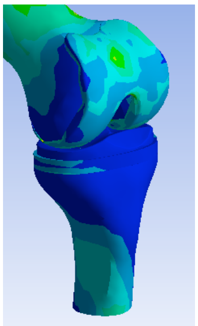
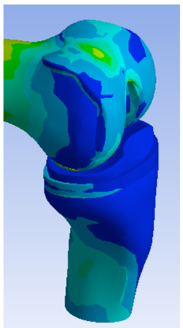
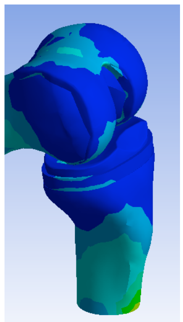
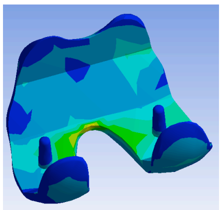
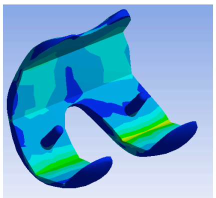
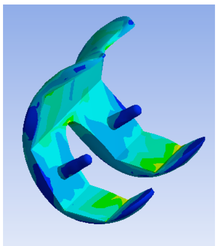
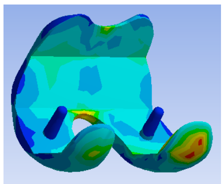
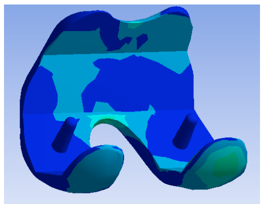
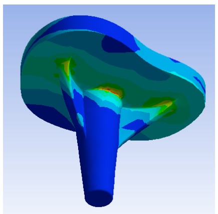
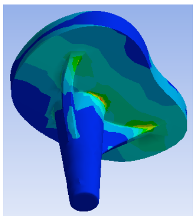
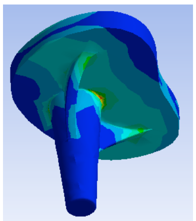
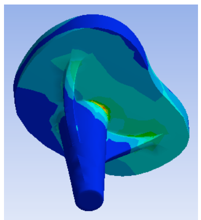
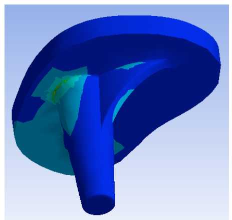
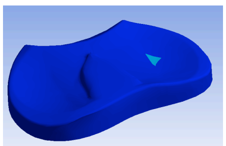
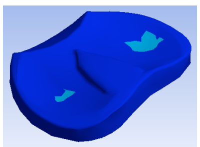
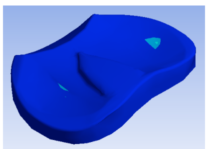
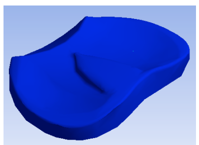
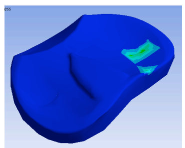
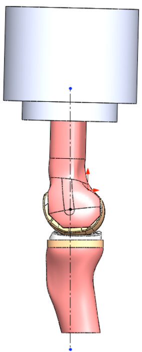
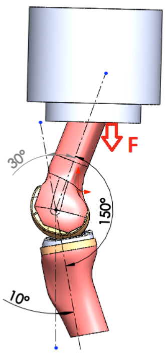
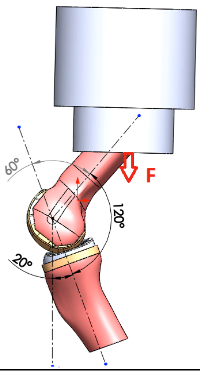
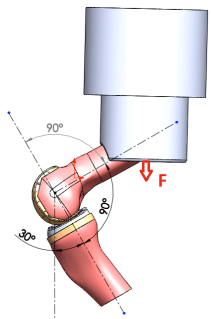
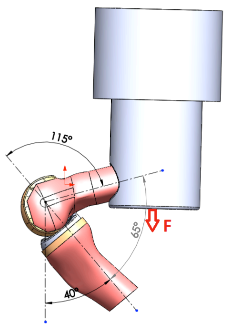
- Decreased height of middle implant on 3mm



- Test was done for 5 different angles instead of 3 as done in the design phase 1

- Table II below shows data for stress calculations at various angles

Table 2. Calculation data and results

Angle	0°	30°	60°	90°	115°
Load, kg	70				
Surface area, mm^2	221	207	195	173	152
Max stress contact area, MPa	5 	6.6 	7.9 	15 	11.4 
Max stress Femur implant, MPa	7.8 	8 	10 	15 	11.4 
Max stress Tibia implant, MPa	10 	12.3 	13 	15.3 	21.8 
Max stress Middle implant, MPa	1.9 	2.8 	3.3 	1.7 	13 
Position					

6.4 Results II

Finite element simulations were done on the new design described above. Results showed clear improvements in performance. However there is scope to improve the design further focusing on following :

- femur implant shape for angle larger than 90°. Basiacally it needs bigger thickness and height to avoid load concentration
- Improvement of middle polyethylene insert to avoid interference with femur bone for angle bigger that 110°. Also thickness of the insertcan be decreased because of small load on it.
- Improvement of tibia implant to avoid load concentration. Connection of implant with tibia bone is not optimal and needs redesign.

Less smoothed bone models and use material properties based in Hounsfiled Units.

In general movement of knee joint is quite complex and not symetrical (uniform contact areas under both condyles)as is assumed in this work. More realistic kinematics and contacts could be included to further improve the design.

Current polyethylene middle insert is a solid body without meniscus flexibility. Improving design of this part can highly increase perfomance of knee joint. For now middle implant doesn't ensure good contact with femur implant during rotation and next step for this part is find a way to add rotation.

Summary & Discussion

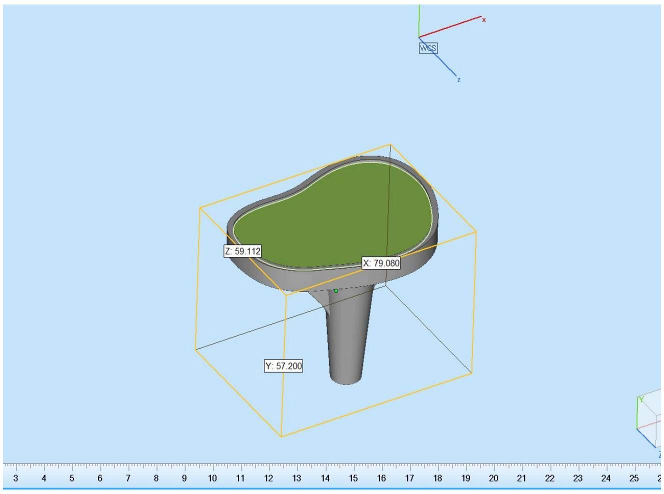
The model was partially validated for predicting locations of maximum contact parameters (contact pressure, contact area) . Our result show similar pattern as reported in the literature. This suggests that the model geometry and kinematic boundary conditions utilized in this FE model are appropriate, however limitations in the material properties used, as well as loading boundary conditions represent areas for improvement.

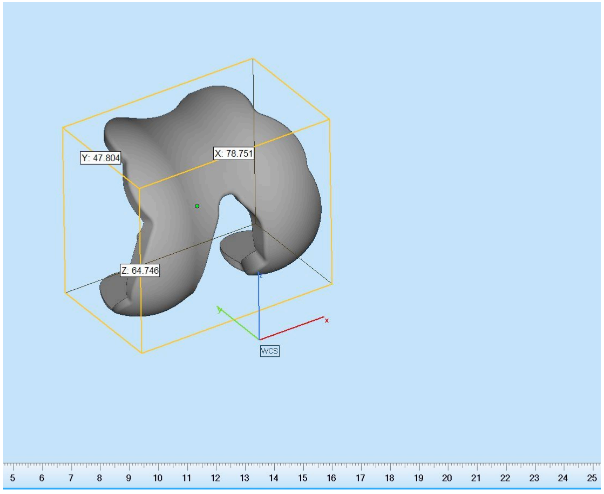
In this paper a procedure of creating a customized TKR implant has been discussed. Full details of design, test and 3D print have been reported. The focus of this approach is using patient-specific scan data and gait dataset for knee implant designs for total knee replacement.

Customized TKR implant has the potential to greatly improve knee kinematics and patient knee functions compared to off-the-shelf TKR implant. However, further studies need to be carried out to clearly demonstrate the benefits and value .

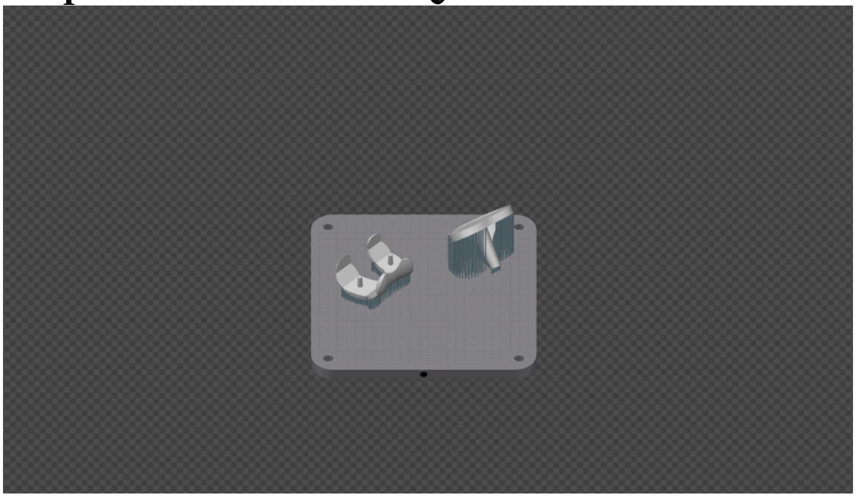
3D Printing

Study of files in 3D printing Software

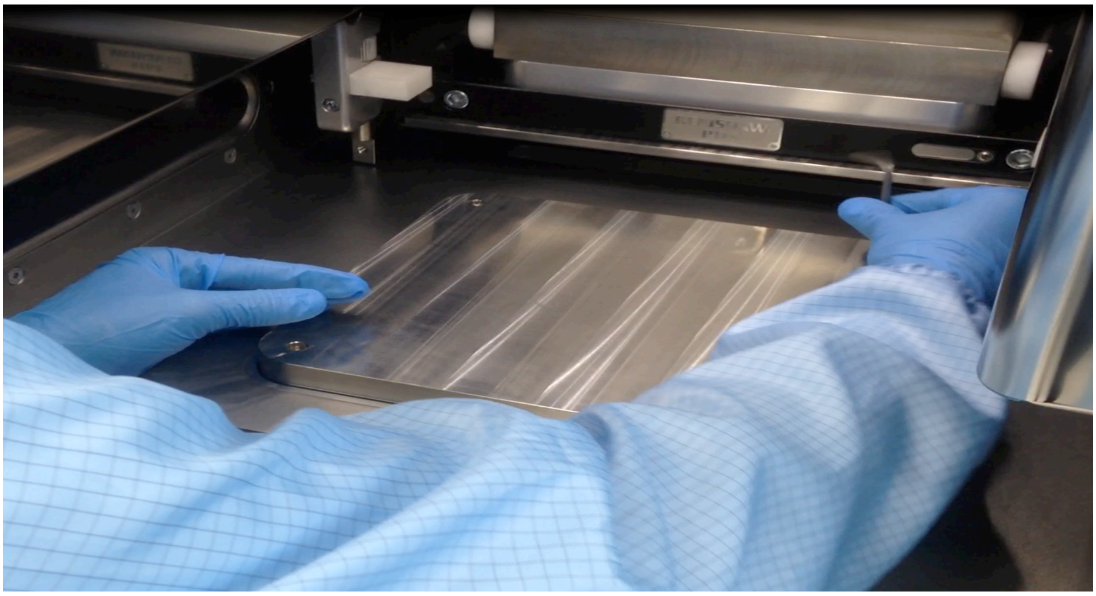




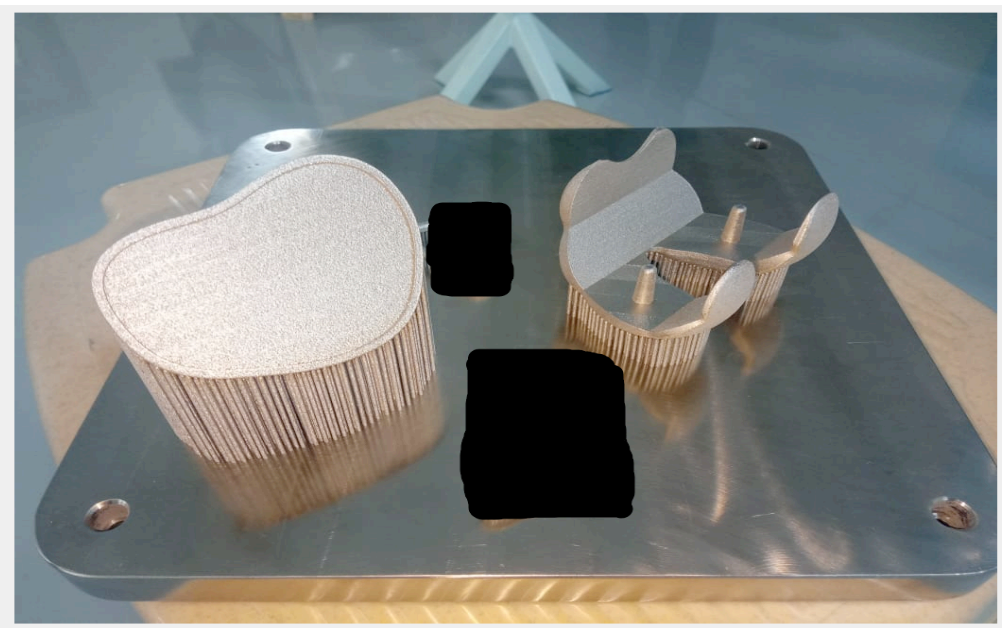
Preparation of build in Quant AM software



Build Preparation



Build removed from Chamber



Post processing of the parts in process

Final part after post processing

References:

1. Medical Policy - .01.144 Patient-Specific Cutting Guides for Joint Arthroplasty:
https://www.premera.com/medicalpolicies/7.01.144.pdf

2. Carr and Goswami : Knee implants – Review of models and biomechanics: Materials and Design 30(2):398-413 · February 2009

3. https://www.conformis.com/uploads/2017/09/Why-iTotal-Brochure.pdf

4. Ian M. Zeller, Adrija Sharma, et al : Customized versus Patient-Sized Cruciate-Retaining Total Knee Arthroplasty: An In Vivo Kinematics Study Using Mobile Fluoroscopy : The Journal of Arthroplasty 32 (2017) 1344-1350 : https://toa.com/storage/wysiwyg/CR%20Itotal%20Kinematic%20publication.pdf

5. Jing Zhanga , Zhenxian Chena,* , Ling Wanga , Dichen Lia , Zhongmin Jina,b: A Patient-specific Wear Prediction Framework for an Artificial Knee Joint with Coupled Musculoskeletal Multibody-dynamics and Finite Element Analysis. https://core.ac.uk/download/pdf/74233746.pdf

6. Toru Fukubayashi & Hlsashi Kurosawa: The Contact Area and Pressure Distribution Pattern of the Knee: A Study of Normal and Osteoarthrotic Knee Joints: Acta Orthopaedica Scandinavica
. 51,871-879,1980:
https://www.tandfonline.com/doi/abs/10.3109/17453678008990887