Personalization of Ankle Implant using 3D Scan data : Simulation driven design optimization and testing.

Abstract

Ankle arthroplasty initially had limited success however the newer generations of total ankle replacement have shown good medium term results. Among the various reasons for this change include a better overall understanding of ankle biomechanics; lessons learnt from hip and knee arthroplasty and improved ankle implant designs that offer better mobility.

In this work we describe methodology of designing a patient specific implant for total ankle replacement and virtual testing new implants using finite element simulation.

1.0. Introduction

Primary osteoarthritis is less common in the ankle, compared with the knee and hip joints, but arthritis secondary to traumaoccurs frequently[1,2]. Non-operative management includes analgesics and antiinflammatory medication, activities modification, physiotherapy, orthotics (bracing) and intra-articular injections[1]. Surgical management of end-stage arthritis of the ankle joint has traditionally been by arthrodesis, which is considered the 'gold standard [1-3].

Minimally invasive, possibly arthroscopically assisted, ankle fusion has recently gained popularity[1–4]. Ankle replacement is an alternative to arthrodesis. The advantage of replacing the ankle using a prosthesis is preservation of movement and function. This may also result in improvements in gait including reduction of limp, and protection of other joints[5–9]. The major complications associated with failure of ankle arthroplasty are infections and loosening of the components. Absolute contraindications for ankle arthroplasty include acute and chronic foot infections, an insensate foot, Charcot's arthropathy, avascular necrosis of the talus, inadequate leg foot musculature, paralysis and severe tibiotalar malposition and lower limb deformities[1,3]. Relative contraindications include younger age, heavy physical work, high body mass index, diabetes and smoking. In the presence of ipsilateral knee osteoarthritis requiring surgery, a knee replacement should be considered before an ankle arthroplasty, to restore the limb's mechanical axis[1,2].

The ideal candidate for total ankle arthroplasty (TAA) is a reasonably mobile middle-to-old-aged patient, with normal or low body mass index, good bone stock and minimal deformities, with multiple joint arthritis (e.g. rheumatoid arthritis), without neurovascular impairment of the lower leg. Ankle arthrodesis, on the other hand, can be, more safely, performed in cases with deformity, paralysis, neuropathy and talus avascular necrosis in patients of any age and body type[1,9]. The presence of infection, poor soft tissue envelope, co-existing medical problems and smoking carry, however, a higher risk for non-union.

The stimulus for TAA derives from partial dissatisfaction with ankle arthrodesis[11 – 14] and the success of total hip and knee arthroplasties[1,15] Ankle arthrodesis has often been associated with high complication and reoperation rates, with overloading of the adjacent joints[16] frequently already arthritic[1,17] leading to further degeneration in the long term[1,12]. Furthermore, loss of ankle joint motion leads to abnormal gait patterns and causes restriction on patients' activities[1,18].

A successful ankle replacement, on the other hand, provides a near-normal gait pattern in terms of kinematics of the knee, ankle and tarsal joints[1,5]. A gait analysis study[6] comparing ankle replacement and arthrodesis showed that the ankle replacement group had greater movement at the ankle, symmetrical timing of gait and restored ground reaction force pattern, although gait was slower. An isolated ankle fusion in the younger patient may thus progress into a pantalar fusion with its increased limitations and morbidity, whereas maintenance of high level of activities is a constant demand of modern lifestyle, even after disabling trauma and idiopathic joint degeneration[1,2]. The frequent failure of ankle implants may be related to surgeons' and designers' inability to restore adequately the critical stabilizing role of the ligaments, to poor reproduction of the normal mechanics of the ankle joint and to the lack of involvement of the underlying subtalar joint in the coupled pattern of motion of the entire ankle complex[1,13,16].

Although the ankle is a challenging joint to be replaced, there is clearly space for the development of improved implants using techniques like patient specific design and 3D printing.

2.0 Why Patient Specific Ankle Implant:

Perfectly matched shape of the custom implant to the patient's anatomy makes them the best response to the functional and aesthetic patient's needs. Patient specific implants offer many benefits in comparison to standard implants including

a) Better shape matching and fit.
b) Shorter surgery and recovery time.
c) Implants for complex shape and geometry.

3.0 Methodology: Patient Specific Ankle 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 ankle that required the total ankle replacement (TAR). The ImageSim software was then used to segment the data using image processing algorithms to form a mask and capturing the required area/volume of interest. Segmentation was performed to detect the bones and hard tissue ranges and then generating a three-dimensional model from the image data as shown in figure [1]. This three-dimensional model was then used as a reference to create the implant. In the next sections we describe all the steps done for complete model

Segmentation –

Computed tomography(CT) data of a patient suffering from tibia fracture was received from surgeon. CT scan of both the ankle was used to design the implant. The CT dataset was processed through the ImageSim software (From VOLMO LTD) that used each slice of the scan to create a three-dimensional model. Basic image processing techniques were used to obtained the best quality and most accurate model. The total number of slices were 200. 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 dynamic region grow filters. The masks were merged using the Boolean OR operations. Figure [1] and Fig.[2] shows the CT scan data views in ImageSim, in axial, coronal and sagittal views and mask being created using various image processing technique available in the tool.

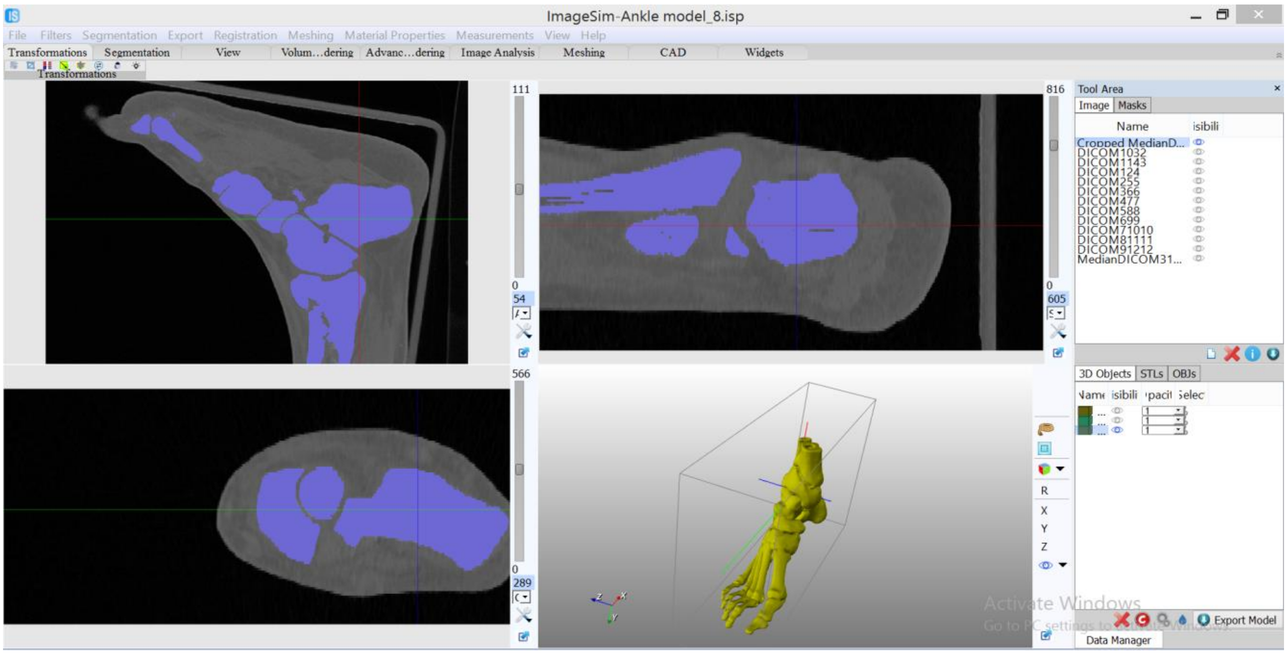
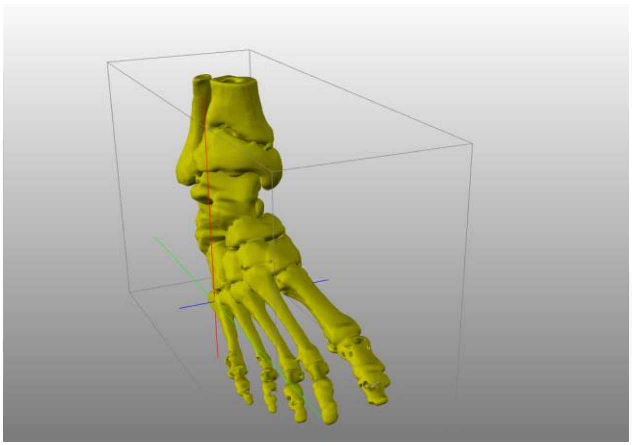


Figure [1] Patient Scan data segmented in ImageSim software



Figure[2] Tibia with Fracture

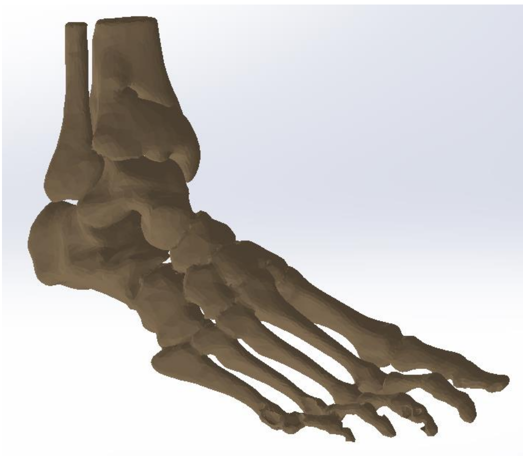
To design a ankle joint implant both the joints, one with tibia fracture and another one without tibia fractures were segmented and STL models were exported from ImageSim.

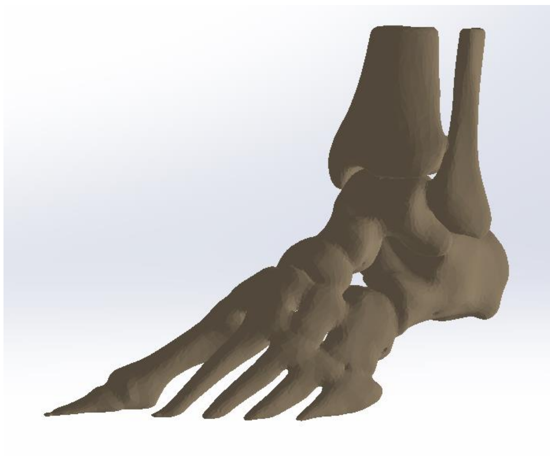
Mirror image of right tibia helped to recreate tibia bone that matched closely to patients fractured bone and thus create articulating joint surface closer to original joint. The optimal TAR implant should reproduce ankle function, maintain bone-implant interface integrity, and resist wear. The kinematics and loads on the TAR implant are very important to the success of TAR. To create a customized TAR implant, an iteration procedure is required to optimise stress, material wear, and ankle kinematics. While experimental validation in laboratory using wear simulator testing is invaluable for understanding polyethylene wear mechanisms and pre-clinically evaluating new implant designs and materials. However, the experimental testing is associated with substantial cost and time, as a large number of low frequency gait cycles are required. On the contrary finite element analysis can be used to test the implants in an environment that can closely resemble the actual human movement and can be done iteratively and can offer significant cost and time saving.

b) CAD model to Implant Design

In order to design and create an implant for ankle with fractured tibia, STL models of both the ankles were imported in Solidworks figure [1] and using mirroring feature new tibia was placed in place of broken tibia figure [2a]. This model was later used for bone resection and implant design. This process helped to create a new implants that closely matches the shape of the bone to ensure good fit.

Full 3d ankle solid model was created in Solidworks figure [2] Bone resection on tibia and talsus was performed in Solidworks and from resected geometry correct shape and articulating surfaces were captured and used as guiding surfaces to created a new implant for tibia, talus and polymer insert figure [2-7].





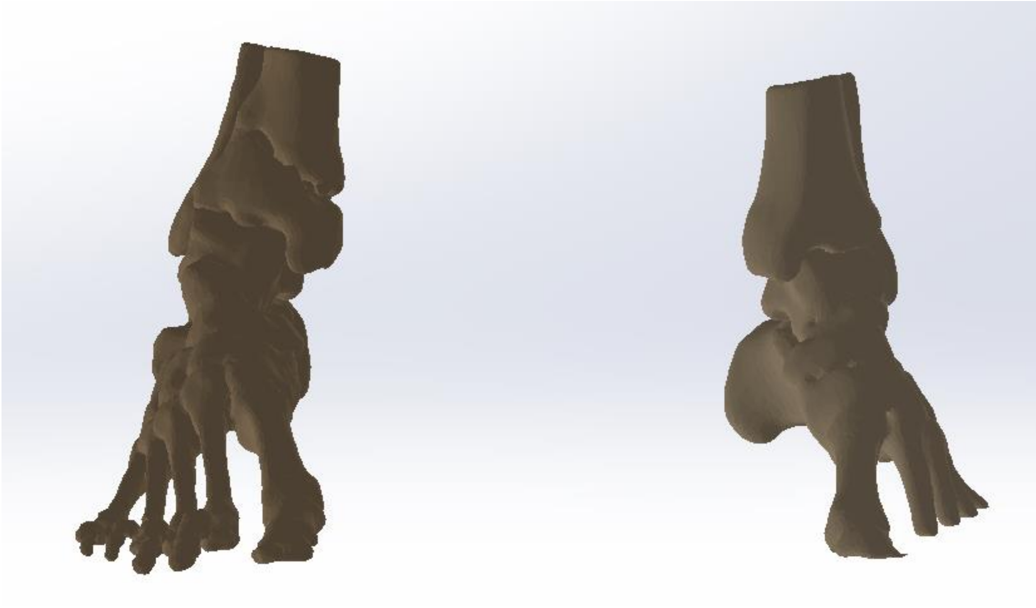
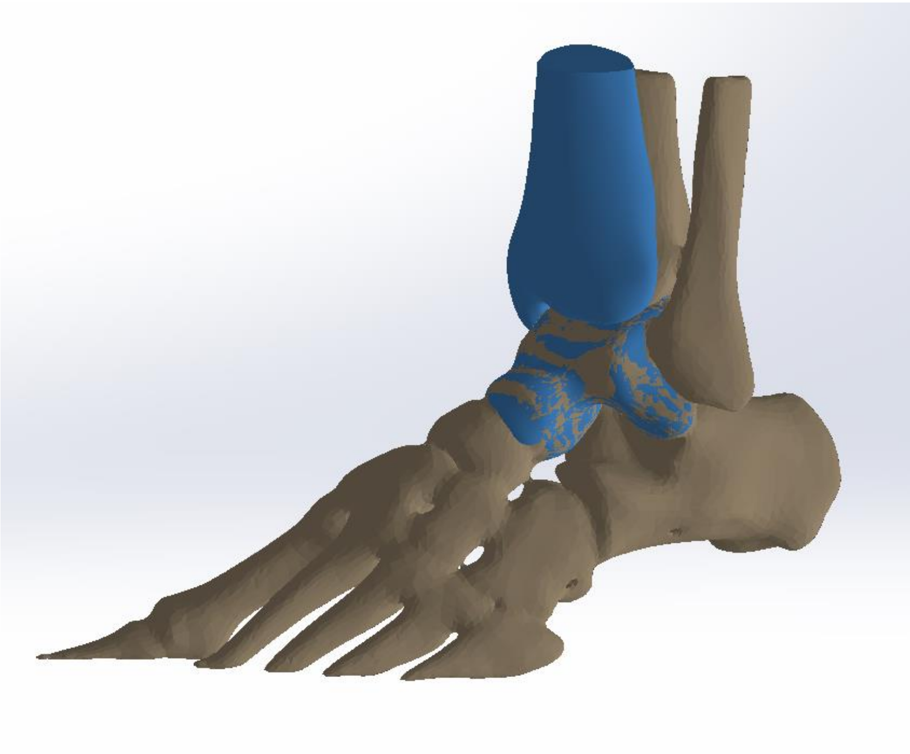


Figure [1] Right ankle (broken tibia) and Left ankle (normal tibia)



Figure[2a]

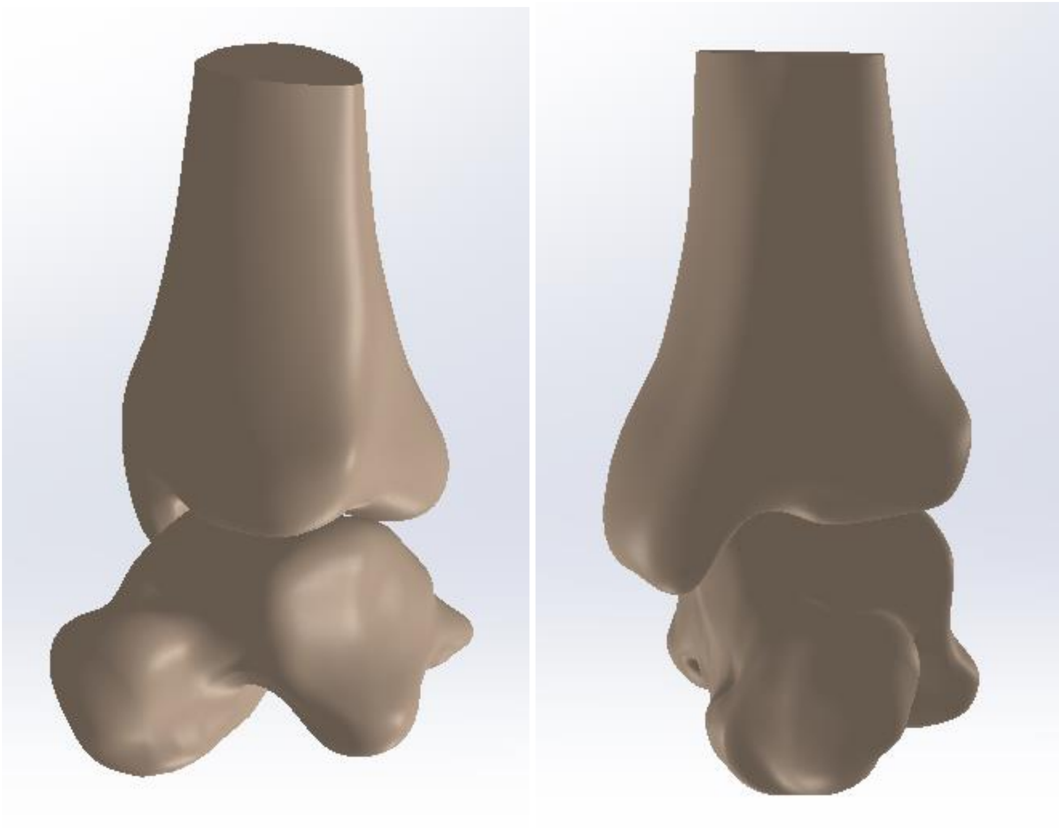


Figure [2] Design and alignment of Talus and Tibia bones

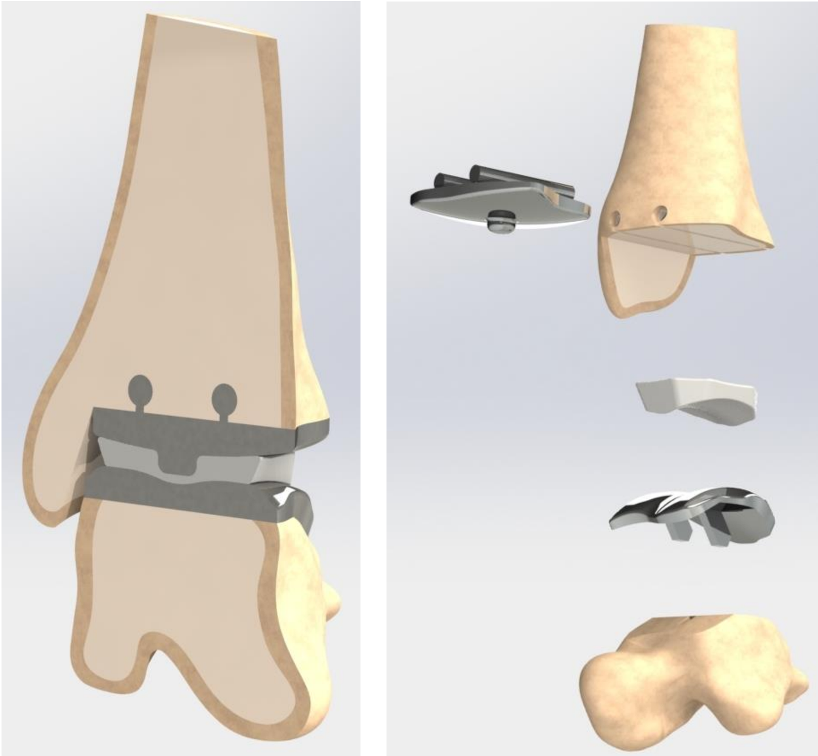


Figure [3] Design of implants

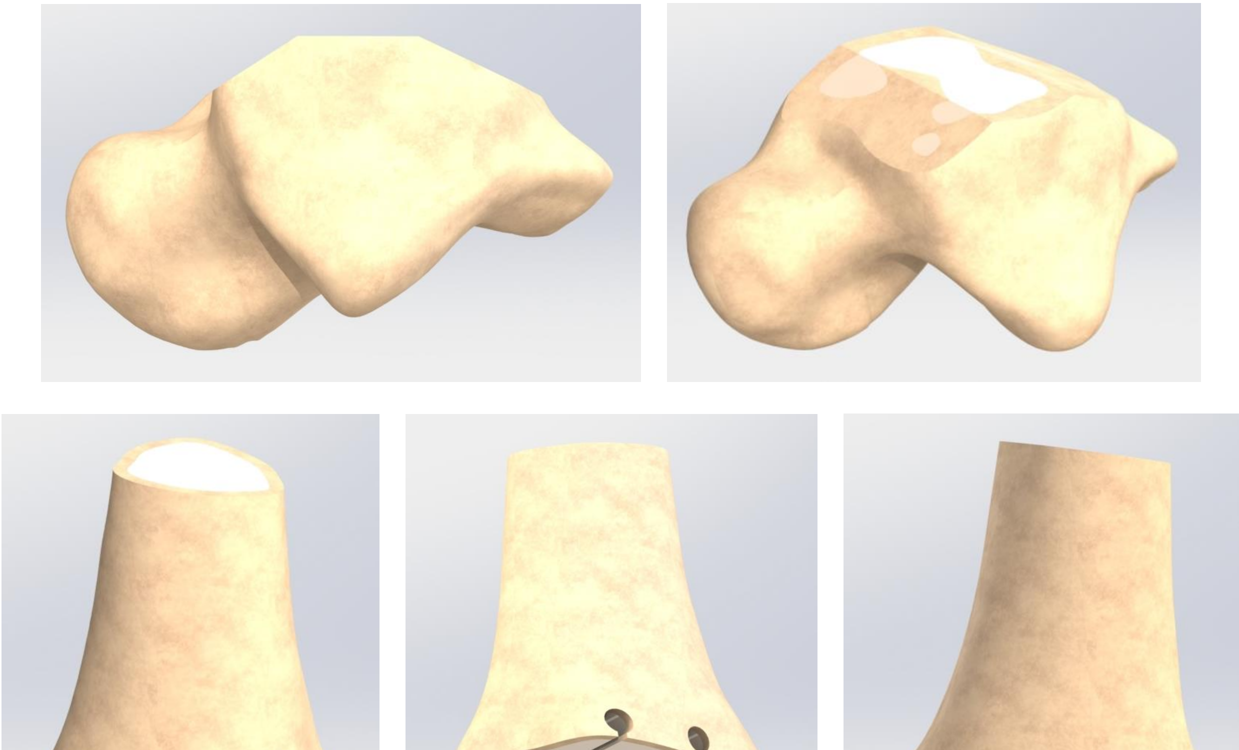


Figure [4] Talus and Tibia cuts

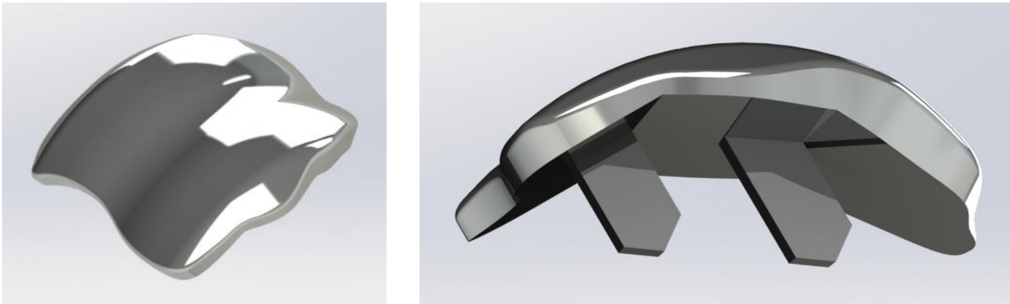


Figure [5] Talus implant

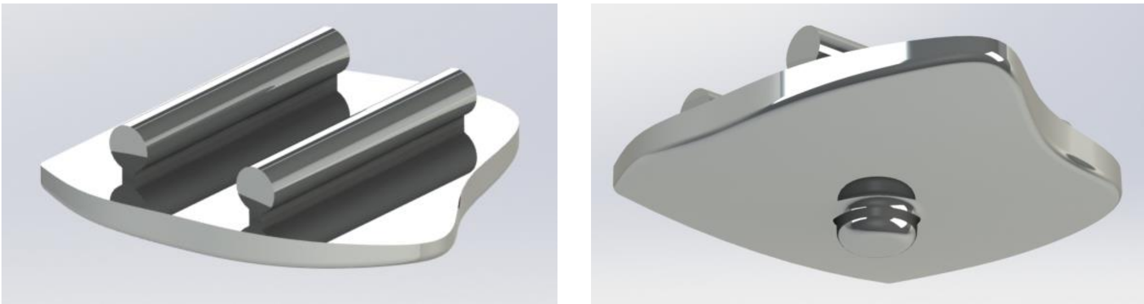


Figure [6] Tibia implant

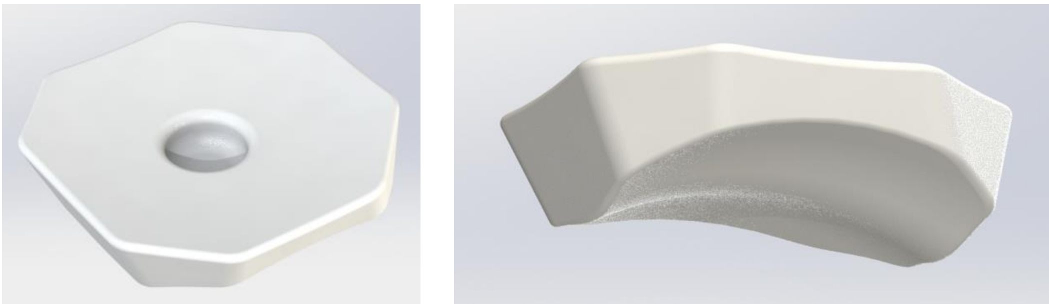


Figure [7] Polyethylene middle part

4.0 CAD to finite element model generation.

Finite element analysis was done in Ansys. In this study we simulated three positions of tibia bone (-10°, 0° ,10°) and used additional parts to simulate load direction as shown in figure [8] .

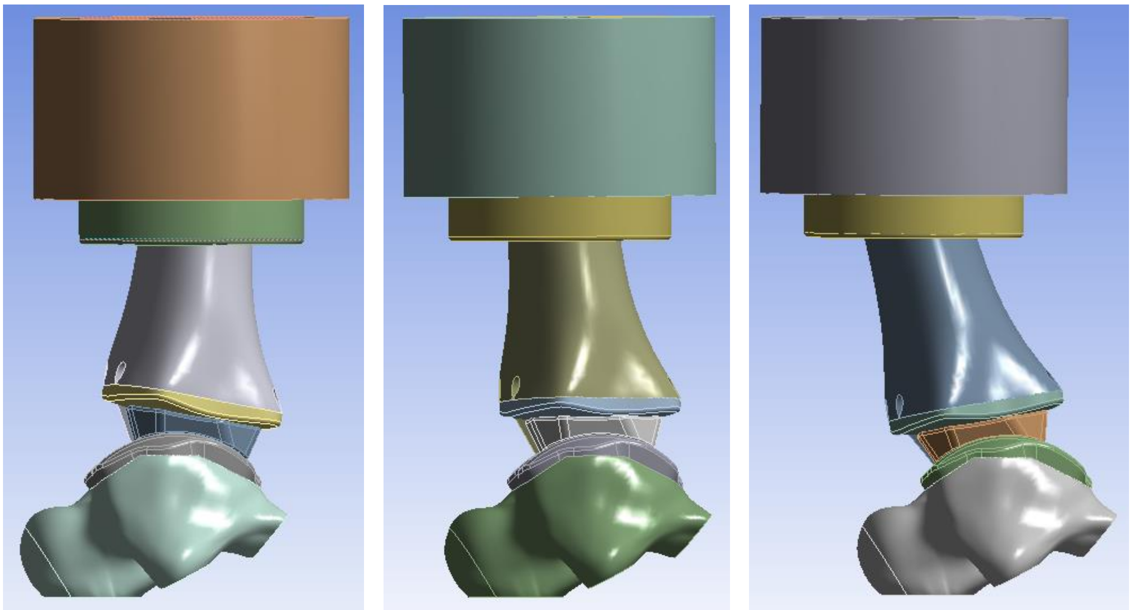


Figure [8] Assembled model at different tibia bone position.

4.1 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

4.2 Contacts :

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

1- Contacts between Polyethylene middle implant with Talus and Tibia implants set as "No Separation". It allows bodies to move, slide, push each other but doesn't allow to separate bodies.

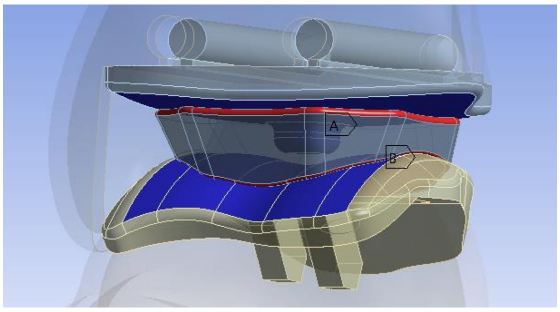


Figure [8] Implant contact Area

4.3 Constraints:

Fixation on Talus bone was applied as shown in the Figure[9].

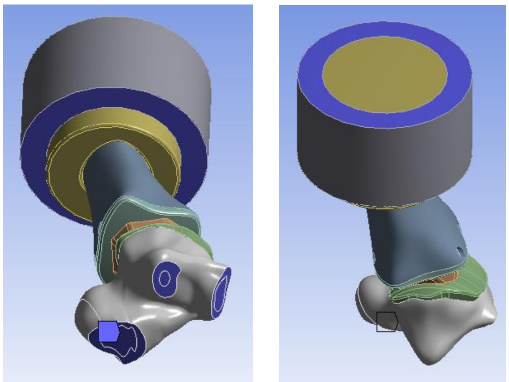


Figure [9] Assembled Model

4.4 Loading : Load was applied on top surface of inner cylinder and it is 70kg for each test.

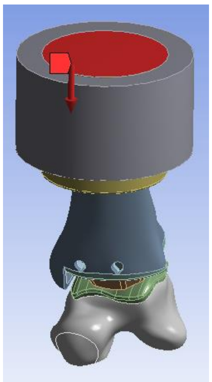


Figure [10]: Assembled model with loading .

4.5 Volume meshing :

Full Ankle model was meshed in Ansys . Global size of mesh is 13mm with tolerance 0.7mm. Standard mesh automatically change size of elements based on surface sizes and contact parameters as seen in figure [11], mesh is smaller in contact areas between implants.

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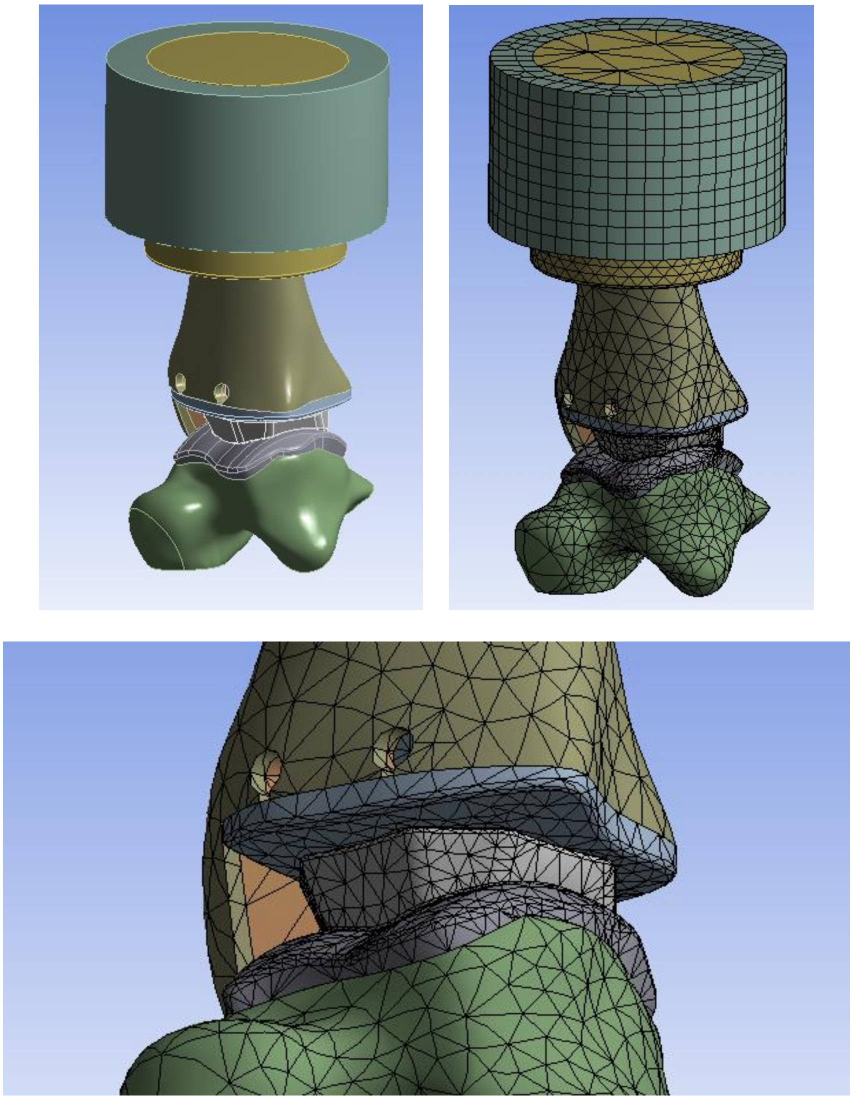
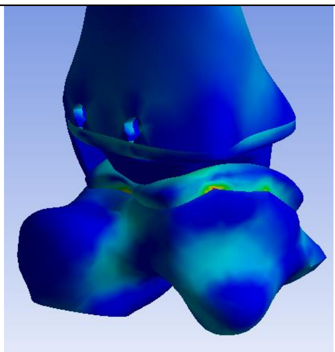
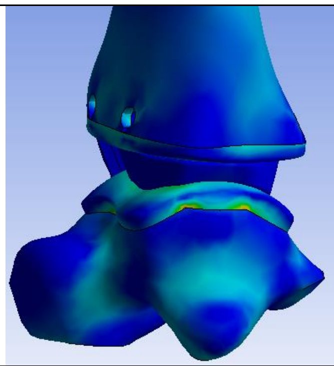
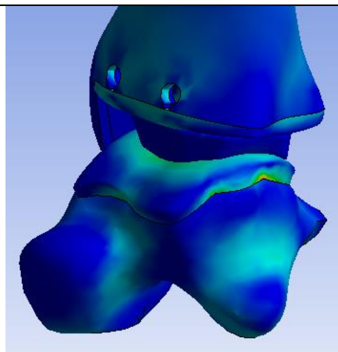
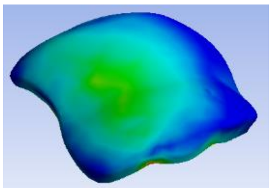
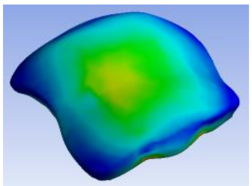
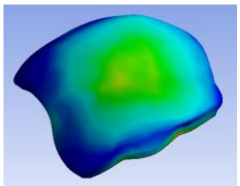
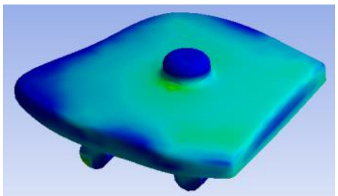
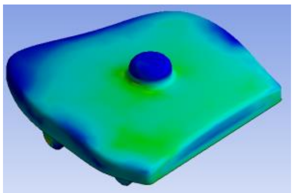
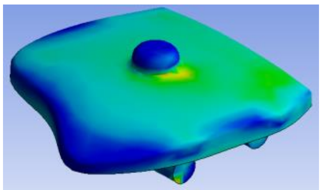
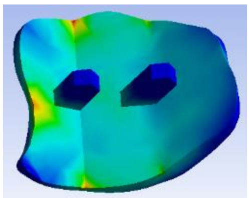
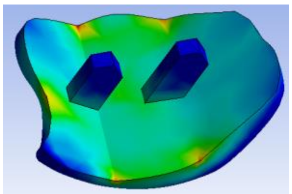
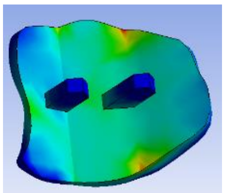
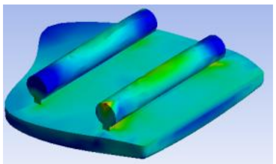
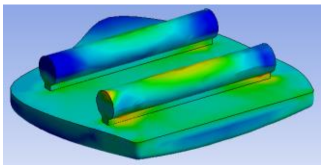
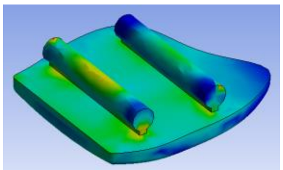
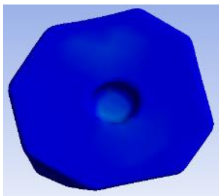
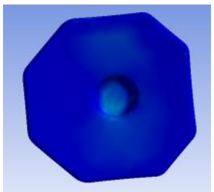
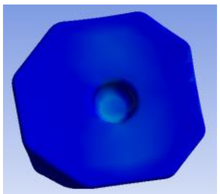


Figure [11] Meshed Model .

5.0 Results Design 1:

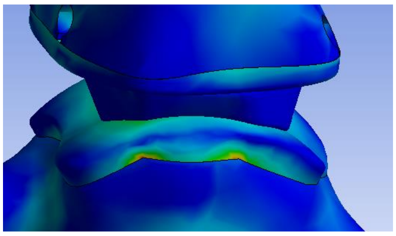
Table 1. Calculation data and results

Load, kg	70		
Surface area Talus – Middle implant, mm^2 (1)	560		
Surface area Middle implant - Tibia, mm^2 (2)	740		
Angle	-10°	0°	10°
Stress distribution			
Max stress contact area 1, MPa	15.6 	14.9 	14 
Max stress contact area 2, MPa	15.4 	12 	17.5 
Max stress Talus implant, MPa	26.6 	21.6 	21 
Max stress Tibia implant, MPa	27 	20.4 	22 
Max stress Middle implant, MPa	3.6 	3.7 	3.6 

5.1 Results and discussion

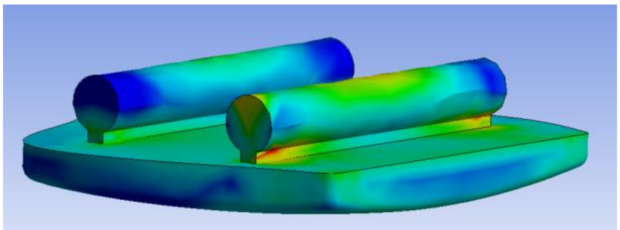
In order to understand the biomechanical and functional behavior of the newly designed implant a full ankle joint model was created and assembled as shown in figure [8] . Static finite analysis was done using Ansys software. Initial results showed following

- Small stress area in polyethylene middle part.
- As shown in figure [12] side corners of Talus implant have stress concentration and thus implant needs to be optimized to decrease this stress.



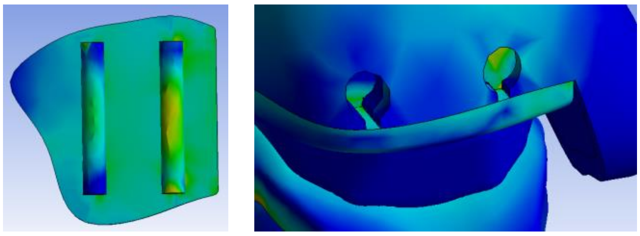
Figure[12]

- Front side of Talus implant has bigger stress than back side. Thus thickness of the implant should be optimized for equal stress distribution
- As seen in figure [13] tibia implant mount cylinders have narrow connection with body of implant and it caused stress concentration on the connections.



Figure[13]

- Figure [13] clearly shows tibia implant mount cylinders have different stress on it. It could be because they have different distance to the cortical bone. Thus cylinder length/location can be optimized to reduce the stress concntration areas.



Figure[14]

Summary : Newly designed implants show reasonable behavior however for actual TAR application further design modification and simulation are needed to improve the biomechanical and functional behavior .

References :

[1] Gougoulias NE, Khanna A, and Maffulli N. History and evolution in total ankle arthroplasty. British Medical Bulletin 2009; 89: 111–151.

[2] Rhys TH, Daniels TR (2003) Ankle arthritis. Current concepts review. J Bone Joint Surg Am, 85A, 923 –936.

[3] Jackson MP, Singh D (2003) Total ankle replacement. Curr Orthop, 17, 292–298.

[4] Gougoulias NE, Aggathangelidis F, Parsons SW (2007) Arthroscopic ankle arthrodesis. Foot Ankle Int, 28, 695–706.

[5] Piriou P, Culpan P, Mullins M (2008) Ankle replacement versus arthrodesis: a comparative gait analysis study. Foot Ankle Int, 29, 3–9.

[6] Doets HC, van Middelkoop M, Houdijk H, Nelissen RG, Veeger HE (2007) Gait analysis after successful mobile bearing total ankle replacement. Foot Ankle Int, 28, 313–322.

[7] Valderrabano V, Hintermann B, Nigg B, Stefanyshyn D (2003) Kinematic changes after fusion and total replacement of the ankle—part1: range of motion. Foot Ankle Int, 24, 881–887.

[8] Valderrabano V, Hintermann B, Nigg B, Stefanyshyn D, Stergiou P (2003) Kinematic changes after fusion and total replacement of the ankle—part 2: movement transfer. Foot Ankle Int, 24, 889–896.

[9] Valderrabano V, Hintermann B, Nigg B, Stefanyshyn D, Stergiou P (2003) Kinematic changes after fusion and total replacement of the ankle—part 3: talar movement. Foot Ankle Int, 24, 897–900.

[10] Abidi NA, Gruen GS, Conti S (2000) Ankle arthrodesis. Indications and techniques. J Am Acad Orthop Surg, 8, 200–209.

[11] Haddad SL, Coetzee JC, Estok R, Fajrbach K, Banel D, Nalysnyk L (2007) Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systemic review of the literature. J Bone Joint Surg, 89A, 1899–1905.

[12] Coester LM, Saltzmann CL, Leupold J, Pontarelli W (2001) Long-term results following ankle arthrodesis for posttraumatic arthritis. J Bone Joint Surg, 83A, 219 –228.

[13] Guyer AJ, Richardson EG (2008) Current concepts review: total ankle arthroplasty. Foot Ankle Int, 29, 256 –264.

[14] Chou LB, Coughlin MT, Hansen S Jr et al. (2008) Osteoarthritis of the ankle: the role of arthroplasty. J Am Acad Orthop Surg, 16, 249–259.

[15] Learmonth I, Young C, Rorebeck C (2007) The operation of the century: total hip replacement. Lancet, 370, 1508–1519.

[16] Wu WL, Su FC, Cheng YM, Huang PJ, Chou YL, Chou CK (2000) Gait analysis after ankle arthrodesis. Gait Posture, 11, 54–61.

[17] Sheridan BD, Robinson DE, Hubble MJW, Winson IG (2006) Ankle arthrodesis and its relationship to ipsilateral arthritis of the hind- and midfoot. J Bone Joint Surg, 88B, 206–207.

[18] Nelissen RGHH, Doets HC, Meskers C (1998) The value of ankle prostheses—a gait analysis approach. In Kofoed H (ed.) Current Status of Ankle Arthroplasty. Berlin: Springer, 72 –77.

[19] Giannini S, Leardini T, O’Connor JJ (2000) Total ankle replacement: review of the designs and of the current status. Foot Ankle Surg, 6, 77–88.