

Custom Design of Knee Joint Prosthesis By Using Computerized Tomography (CT) Images and 3D Modelling

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Abstract

The articulating surface of standard femoral knee component is as generic shape while every individual patient has a unique shape of knee joint and this is causes some problems. The Conventional femoral knee component gives a satisfactory result in many cases that carry the patient back to active lifestyle and near normal patient and especially for younger patients. Most patients' gaits are altered after a total knee replacement (TKR) due to the change in surface geometry of femoral implant. The main objective of this work is to design custom design implant as smooth-implant interface of femoral component to increase appropriate bone ingrowths and to prevent bone remodeling found in conventional knee implants, also this design maintain the articulating surface of femoral with tibial component and patellar component as natural knee to maintain the patients gait without altered. This custom design of femoral knee implant will provide better results for patients who have more active lifestyle and strenuous activities such as younger patients. The custom design was done by creating 3D models from computerized tomography (CT) scan data through computer segmentation using Materialise MIMICS software. Geomagic studio software was used in this work for smoothing, preparation of the model and convert STL file format to STEP format. The 3D model as STEP format then exported from Geomagic Studio to CAD design software such as solidworks (Solidworks, USA) for design on the femoral components of the implant. From 3D model of the femur, a custom knee implant femoral component was designed. Finite Element Analysis was used to examine and evaluate the stress distribution over the interface between the implant and femur bone. The custom design as smooth surface describe a more even stress distribution in the contact region between femur bone and implant. This stress will reduce the uneven bone remodeling; also reduce the risk of premature loosening of implant.

Keywords

knee-component, TKR, 3D femoral component, Conventional knee implants.

1. Introduction

TKR involve three components; femoral, tibial, and patellar components. Femoral component has a convex shape which is a large plate bent to help the curvatures of the femoral condyles (located at distal femur). This plate is often fabricated from Cobalt-Chromium (CoCr) alloy or titanium.

The tibial component is a plate made of Ultra High Molecular Weight Polyethylene (UHMWPE). This plate is enclosed in a stemmed metallic back-up which is often made of Titanium. Patellar component is fabricated from Polyethylene [1, 2]. When conventional implant components are used, older patients have higher success rate than younger patients [3]. The common cause for premature failure of the femoral implant in younger patients is Aseptic Loosening. Many countries delay the surgical operation of knee joint replacement until the patient has reach 65 years; because younger patients have more active lifestyle which cause premature failure for knee prostheses [4]. Aseptic Loosening of the femoral implant is usually caused by the relation between bone and implant that prevent bone ingrowth or occur uneven bone remodeling due to uneven stress distribution on the design of bone implant interface [5]. This uneven stress distribution is caused due to the design of bone implant surface which is restricted by the current surgical techniques. By using current surgical techniques such as oscillating saw and cutting guides to reshape the distal femur bone in order to fit the implant component by straight five cut.

2. Methodology of custom design

One of the most important functional requirements of any femoral knee implant is its ability to replicate joint motion as closely as possible. Compromise on any motion or degree of freedom will be a suboptimal design. The following are other major functional requirements for design of the femoral knee prosthesis: 1) to provide easy insertion of femoral component on bone during surgery. 2) The size of the implant should be as close to the normal as possible to minimize any tissue damage and to avoid compromise on any change in motion. 3) The material used to manufacture such an implant should be biocompatible. 4) The bone-implant interface should be porous to promote bone in growth.

The implant design shall include optimization of thickness and development of methodology to get from a CT scan of the knee to final implantation in a patient. This shall be achieved by converting CT data into CAD model and then designing the implant using the original human femur specific data with the help of different 3D modeling software. Based on the above-mentioned functional requirements and aims of this work, the components of a femoral knee implant are designed for the same is proposed. The methodology of proposed custom design femoral component is designed as the following process:

2.1 Computed Tomography Scan

The first steps are obtain the geometric data of the knee joint as DICOM file format, The DICOM (Digital Imaging and Communications in Medicine) file image imported into MIMICS.

2.2 Segmentation Procedure and 3D model using MIMICS

Once the images are imported into MIMICS 10.01, 3D model of knee joint was created by using some commands such as Thresholding, Edit Masks, Region Growing and Calculate 3D.

2.2.1 Thresholding Value

Once the images are imported, the next stage is to select the correct threshold value for the region growing function. The threshold function will separate the hard tissue (bone) from the soft tissue (ligaments, muscle and cartilage); also separate each bone from the bone structure (figure 1).

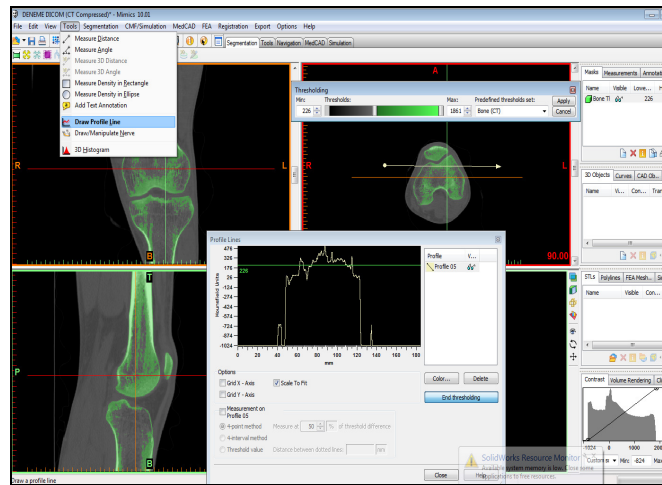


Figure 1 Profile line drawn on axial view.

2.2.2 Region growing

To complete the separation of the bone (hard tissue), "Region Growing" function was used. During region growing, the color of the mask is selected in an image and all the images connected to that mask get selected and copied in a new mask. Multiple regions growing with different masks and colors were applied because the distal femur bone and proximal tibial bone are not connected to each other. (figure 2).

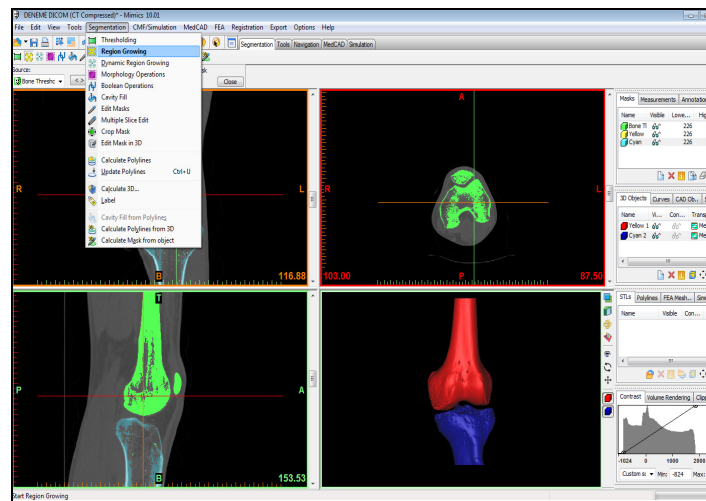


Figure 2 Region growing operation and 3D CAD model

2.2.3 Three dimensional reconstructions

Following region growing, the model is now ready for 3D reconstruction. Each mask was converted into a 3D CAD model using the "calculate 3D" function (figure 2).

2.3 Preprocessing CAD Model for Design

The 3D model as STL format exported from MIMICS is now ready for further processing. Geomagic Studio 2012 was used in this research for smoothing and preparation of the model and convert STL files format into STEP files format.

2.4 Design of femoral component using solidwork software

Three dimensional CAD model of the distal femur was imported into solidwork 2012. The geometry surface of femoral component was saved intact to prevent any changing of the patient gait and to maintain the correct patellar groove so as to prevent resurfacing the surface and patellar dislocation. The design of femoral implant surface was done as smooth surface to prevent the loosening of implant. *Loft cut command* was used to design and generate the smooth surface of the femoral implant. The smooth bone-implant interface was created by using six planes which passed through the origin. On each of these six section planes a sketch was drawn, which replicated the external implant curves. This was achieved using the function "Intersection Curve". These curves shall act as a reference for generate inner surface. This curve replicates the external articulating surface of the implant. Single *3D guide* curve was created to connect all curves in a central plane between the condyles. Using fillets command to provide an implant with smooth surface. The result was a femoral component as smooth bone-implant interface with a natural articulating surface. In this study, two major design factors are considered for the design of a custom knee implant; specific implant thickness, and stability of implant after the surgery. An important step in the implant design is to decide on the thickness of the femoral implant. The thickness should be as uniform as possible to avoid any concentrated stress-failure. There are two main thickness selection factors to be considered, namely; implant must be thick enough to prevent mechanical failure, and the implant should promoting bone ingrowth at bone-implant interface. Mechanical failure of the implant would occur at the smallest cross section. As shown in figure 3, two condyles merge together at Section A-A. This section has two small areas and is at higher risk of failure. Since the force acting on the joint will not pass through this section, a moment will be created. Under this condition, the failure mode at this section shall be due to bending moment.

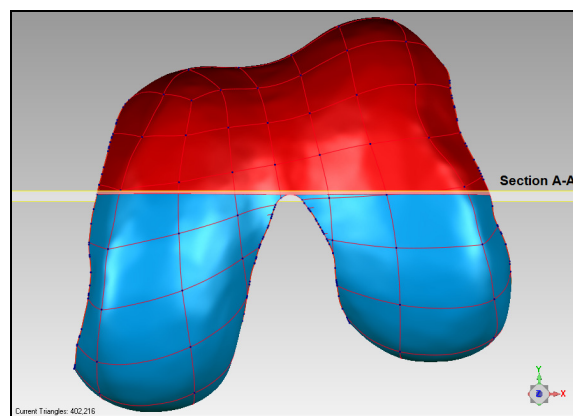


Figure 3 Implant failure site

This mechanism could be compared with a cantilever beam, with section A-A as fixed. The maximum force acting on this cantilever shall be the impact load while running. Considering the

normal load on implant as half the total load of human and load being equally distributed on both the condyles, the cantilever action of condyle can be explained as shown in Figure 4.

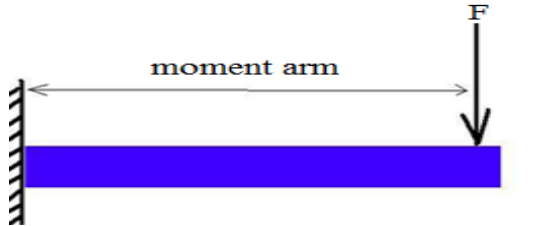
$$\sigma = \frac{\text{Bending Moment (M)} \times \text{deflection (y)}}{\text{Moment of Inertia (I)}}$$


Figure 4 Cantilever load on one condyle

The femoral implant thickness could be adjusted based on material such as cobalt-chromium or titanium, also based on the patient weigh.

Bending Moment(M)= (Patient weight/2) * moment arm

σ = maximum stress (for each material used)

deflection(y) = thickness/2

Moment of inertia(I) = $bh^3/12$

Substitute the values of maximum bending stress, Bending Moment, Deflection and Moment of Inertia into the main equation to get the minimum thickness of the implant.

2.5 Finite element analysis (FEA)

To test the custom design smooth surface of femoral component implant will offer more even stress distribution in all contact region between the implant and bone, finite element analysis (FEA) were used. Two femoral components were designed with the same articulating surface. One conventional femoral component as five flat surface, and the other custom design femoral component as smooth bone implant surface. ANSYS Workbench 13.0 (ANSYS Inc., Southpointe, USA) was used in this study. The femur bone has two parts for material assignment. The cortical bone found in the outer shell of the femur bone, the cancellous bone in the inner part. The implant in the vicinity of cancellous bone has the maximum bone ingrowth probability. The Young's modulus of 19GPa and 1871MPa were obtained and assigned into the cortical and trabecular bone respectively. Poisson's ratio of 0.3 and 0.12 were also adopted from the previous study [6], and then assigned into cortical and trabecular bones respectively. The material property of the implant has assigned as 110GPa for Young's modulus and poisson's ratio is 0.3 approximating some grades of Titanium alloy Ti6Al4V [7]. For these analyses, two different positions through a gait cycle were simulated. The center position and middle position (figure 5).

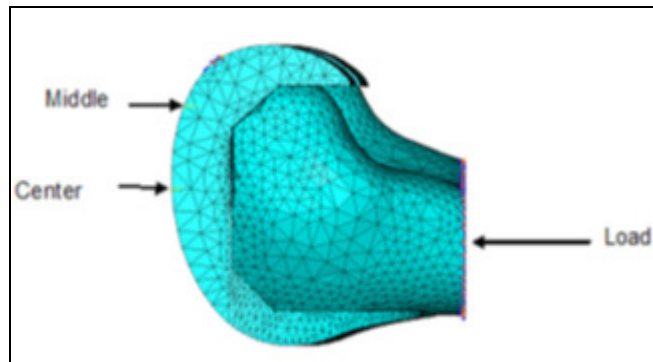


Figure 5 Load and reaction force.

The reaction force in the center position case which represent a starting position of a gait cycle. The end of the normal walking gait cycle represent as the middle position. The vertical loading is coming down the proximal end femur bone following the axis and to have a system in equilibrium, there are **reaction force** has to be the same as the load. The vertical loaded was 2100N at the proximal-most end of the femur, representing approximately 3 times a nominal body weight of 70 kg. The angle of the load during the middle was adjusted to better simulate the correct conditions. Boundary conditions needed to be specified were following: 1) *force* (including magnitude, direction, and location), 2) *fixed support*, 3) *reaction force*, and 3) *contact* which specifies the boundary condition between the implant and distal femur bone boundaries. The reaction force were defined as narrow surfaces represent the femoral component interact with the tibial component, this narrow surface an approximately width of 2–3 mm. These reaction forces can be seen as point forces or distributed over a fairly small area. The interaction contact between the femoral implant and the distal end femur bone was defined as augmented Lagrange contact which chooses from the bonded contact command.

3. Results and Discussions

The purpose of an FEA study is to examine the stress distribution on in implant. All stresses plotted in this thesis were von Mises. The results of this study show that the stresses were highly concentrated along the sharp edges for the conventional implant design as shown in the upper figure (figure 6), while the custom implant design showed a more uniform stress distribution as shown in the lower (figure 6). The custom design implant generated much lower maximum stress. For the conventional implant design-upper picture, the average stresses at the sharp edges were 16MPa during the center position case; and for the custom implant smooth surface design (lower picture), the average stresses were 6.687MPa in the contact region (figure 6). The red color represents the maximum stress and the green color represents the average stress.

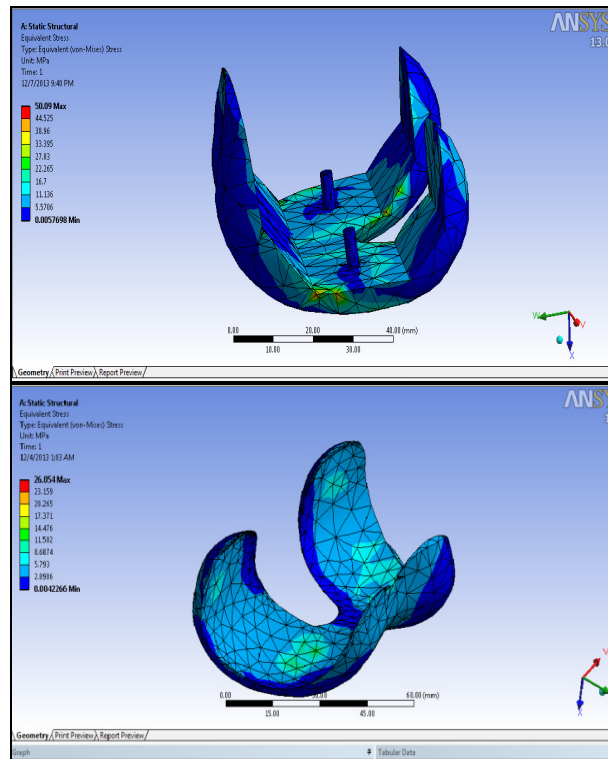


Figure 6 stress distribution in the conventional implant and custom implant.

For the middle position case, the average stresses at the sharp edges 16 MPa when using conventional implant design (upper figure 7), and the average stress for custom implant smooth surface design in the contact region was 7 MPa (lower figure 7).

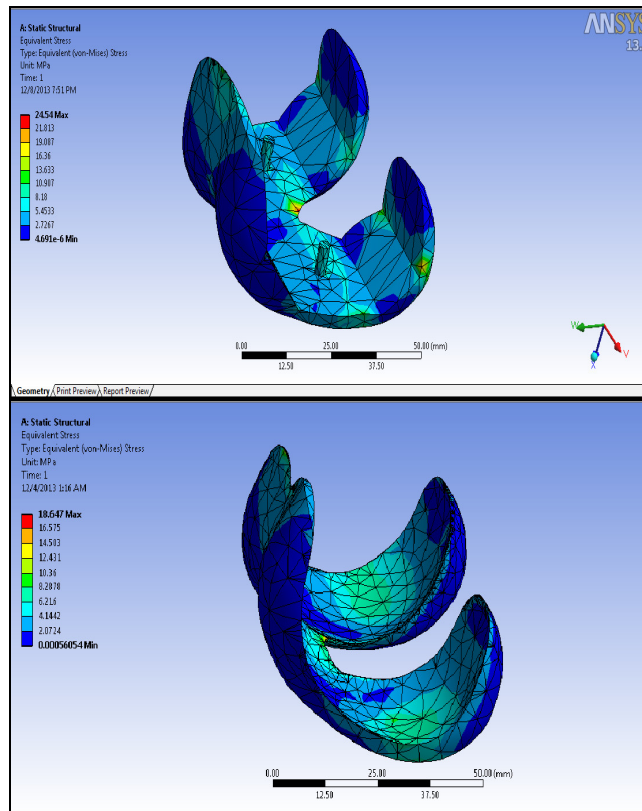


Figure 7 stress distribution in the conventional implant and custom implant.

Boolean operations function in ANSYS workbench software was used to simulate the distal femur bone cuts to fit and fix the implant with the femur bone. This surface of distal femur bone as smooth surface is done during the surgical procedure by using the *robotic surgical* technology. Also from the results above, it can be seen that a custom design femoral component as smooth surface offer a more even stress distribution in all contact region between the implant and bone than the conventional femoral components implant which have uneven stress distribution.

4. Conclusion

The custom design femoral component as smooth surface has the following advantages compared with a standard femoral knee implant. i) The surface articulation of femoral component as the surface of natural knee, there is no need for resurfacing of the patella, and the patient gait not change. ii) Depending of the result of stress distribution in contact regions, uneven bone remodeling will be reduced that reduce the risk of premature loosening. iii) The proposed custom design of femoral implant can be applied to patient who has dangerous activity and a more active lifestyle such as younger patient, also this custom design component will stay for a long time without revision knee replacement. iv) the bone cutting when using custom design proposed is less than when using the conventional knee.

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