

Finite Element Investigation of Hybrid and Conventional Knee Implants

Habiba Bougherara

*Department of Mechanical and
Industrial Engineering
Ryerson University
Toronto, M5B 2K1, Canada*

habiba.bougherara@ryerson.ca

Ziauddin Mahboob

*Department of Aerospace Engineering
Ryerson University
Toronto, M5B 2K1, Canada*

zmahboob@ryerson.ca

Milan Miric

*Department of Mechanical and
Industrial Engineering
Ryerson University
Toronto, M5B 2K1, Canada*

mmiric@ryerson.ca

Mohamad Youssef

*Department of Mechanical and
Industrial Engineering
Ryerson University
Toronto, M5B 2K1, Canada*

m3yousse@ryerson.ca

Abstract

Total Knee arthroplasty (TKA) procedures relieve arthritic pain and restore joint function by replacing the contact surfaces of the knee joint. These procedures are often performed following arthritic degeneration of the joint causing the patient pain. Cobalt-chrome, stainless steel (316L grade) and titanium alloys are widely used in the majority of distal femoral implants in TKA procedures. The use of such stiff materials causes stress shielding (i.e. a lack of mechanical stresses being experienced by the bone surrounding the implant) leading to gradual bone loss and implant failure. The aim of this paper is to develop a new hybrid knee implant which combines a polymer-composite (CF/PA-12) with an existing commercial implant system (P.F.C.® Sigma™) made from stainless steel. This hybrid implant is expected to alleviate stress shielding and bone loss by transferring much more load to the femur compared to conventional metallic implants. Results of the FEA simulations showed that the CF/PA-12 lined femoral component generated almost 63% less in peak stress compared to the regular stainless steel component, indicating more load transfer to the bone and consequently alleviating bone resorption.

Keywords: Total knee arthroplasty, hybrid composite material, finite element analysis, stress shielding, 316L grade stainless steel implant, bone resorption.

1. INTRODUCTION

Implant designs for TKA procedures replace the arthritic surfaces of the knee joint, resurfacing the femoral trochlear groove and both lateral and medial condyles. Polyethylene spacers are attached replacing the tibial articular surface through a plate of porous-finish metal, acting as the contact point for the femoral condyles. In procedures where total condylar prostheses are used the patella is also resurfaced, however this does not affect the performance of the femoral implant [1, 2].

Cobalt-chrome, stainless steel, and titanium alloys are used in the majority of distal femoral implants in TKA procedures [3-5]. In addition trabecular metal, a tantalum based biomaterial (80% porosity) with a crystalline microstructure similar to that of trabecular bone (cancellous bone) is used for contact surfaces requiring direct bone apposition [6]. With regards to the tibial plates specifically, porous metal (trabecular metal) allows for bone ingrowth and implant stability [6]. In addition this porosity encourages soft tissue growth and supports vascularisation of adjacent tissue.

Polyethylene spacers attached to the tibial plate are allowed to rotate on the tibial plate reducing abnormal wear and fatigue compared to fixed articular surface implants. Regardless of these advancements, wear of polyethylene is the limiting factor in long term performance of the implant and the cause of the majority of the 37,544 revision surgeries performed in 2005 [3]. The development of polyethylene has progressed since the 1970s to the ultra high molecular weight polyethylene (UHMWPE) currently used [7].

The use of high strength, high stiffness titanium and stainless steel alloys in distal femoral implants causes stress absorption in the implant shielding the femur from physiologic stress and loading. As such, abnormal stress/loading patterns develop along the shaft of the femur leading to bone degeneration. In addition, the titanium and stainless steel alloys used offer poor osseointegration and biocompatibility [8].

In this study, the femoral component of the implant is the focus in improving the design. The existing designs for polyethylene spacers, tibial plates and patella implants are not modified. Thus, the intent of this study was to develop a femoral component that would promote natural stress distribution within the femur and exhibit osseointegrative properties.

Previous studies of orthopaedic implants by one of the current authors [9] used a carbon fibre based polymer matrix composite to resurface hip joints. The implant designed used a composite to line the contact surfaces of a stainless steel implant reducing stress shielding and promoting physiologic loading. Carbon fibre based composites have been shown to provide significantly better osseointegration than titanium. The CF/PA-12 (Carbon fibre reinforced polyamide 12) composite developed by one of the current authors in previous studies demonstrated excellent fatigue life under loading exceeding by several orders of magnitude that of the knee under natural gait [9]. In designing a biomimetic distal femoral implant for TKA a similar approach was adopted using a carbon fibre based composite to line the bone apposition surfaces of the implant.

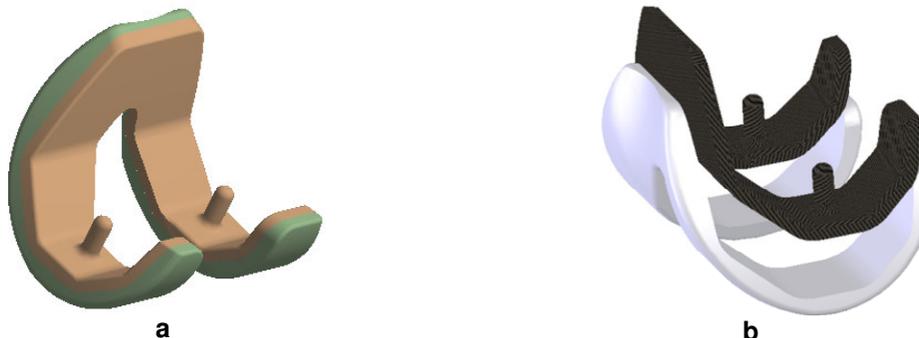


FIGURE 1: CAD depiction of hybrid CF/PA-12 lining on femoral component; a) Assembled view, b) Exploded view

Analysis of the performance of the implant was conducted using finite element analysis and compared to a 316L grade stainless steel implant of the same geometry. The validity of the results of this design concept was assessed based on the magnitude of stress in the tibial component's UHMWPE layer.

2. GENERATING THE MODEL

CAD model of femur and tibia

Computed tomography (CT) scans of a composite fourth generation femur and tibia supplied by Sawbones Worldwide (Items #3406 and #3402 respectively, Pacific Research Laboratories, Vashon, WA, USA) were performed at intervals of 0.5 mm along the length of the bones [10, 11]. FIGURE 2 and FIGURE 3 display the original femur and tibia models, respectively. The dimensions are given in TABLE 1. Using MIMICS® Medical Imaging Software (The Materialise Group, Leuven, Belgium) the cross sectional geometries of both the femur and tibia were exported into SolidWorks 2007 (Dassault Systèmes SolidWorks Corp, Concord, MA, USA) as independent files. With the aid of 'SPLINES' in SolidWorks 2007, the 'LOFT' function was used to generate the CAD geometry of both bones. Care was taken to maintain both cancellous and cortical bone geometries within both the femur and tibia.

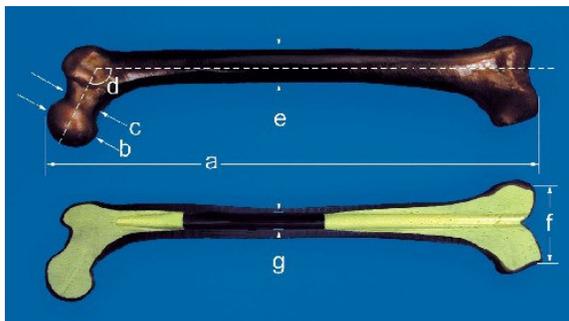


FIGURE 2: Fourth generation left femur [10]

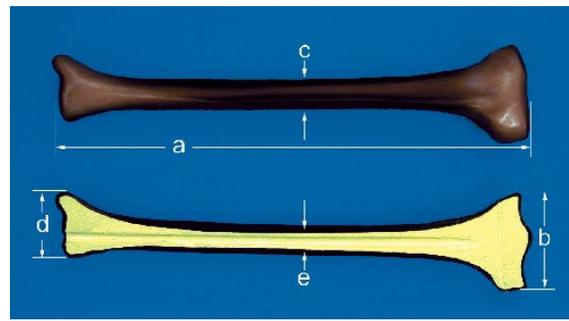


FIGURE 3: Fourth generation left tibia [11]

Dimensions	Femur [mm]	Tibia [mm]
a	485	405
b	52	84
c	37	28
d	120	58
e	32	10
f	93	n/a
g	16	n/a

TABLE 1: Dimensions of the fourth generation femur and tibia models [10, 11]

CAD model of implant for TKA

The CAD model of the press-fit condylar P.F.C.® Sigma™ Knee System (DePuy Orthopaedics Inc, Johnson & Johnson, Warsaw, IN, USA) used was generated in SolidWorks 2007 based on the specific dimensions of the 71 M/L x 65 A/P sized femoral implant. Likewise, the geometries of the UHMWPE layer and tibial plate were based on the same DePuy implant system.

The modified implant concept developed by the authors, which is the innovation in this study, consists of a layer of CF/PA-12 that is around half the thickness of the original femoral implant.

This hybrid model has a final assembled geometry that is exactly the same as the original metal implant.

3. FINITE ELEMENT ANALYSIS

Assembly model for FEA

Assembly of the implant and its placement into the bone was conducted in the 'ASSEMBLY' window of SolidWorks 2007. The configuration established was focused on direct axial loading of the implant and thus only concerned the femoral and tibial bone mass within 20 cm of the tibial articular surface. This was done to ensure that uncompromised physiologic loading was simulated in the areas of focus. Thus the assembly only contained the implant, the distal end of the femur, and the proximal end of the tibia. The assembled geometry was exported into 'DesignModeler' of ANSYS® Workbench 10.0 (Canonsburg, PA, USA) software suite. The exported assembly is shown in **FIGURE 4**.

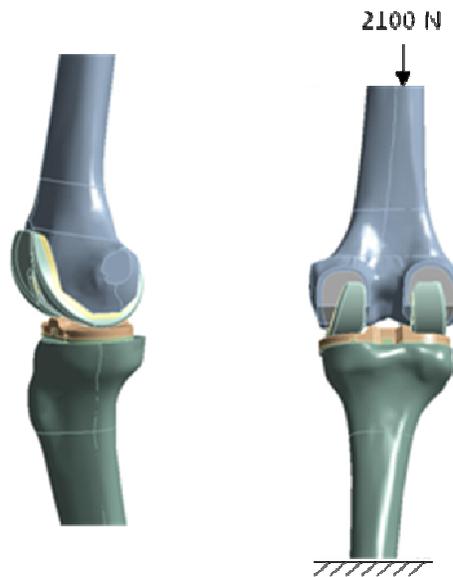


FIGURE 4: Geometry of the implant-bone system and boundary conditions

Mesh generation in ANSYS

From the 'DesignModeler' window in ANSYS® Workbench 10.0 the model was exported into the Simulation window where the mesh was generated based on 10 node quadratic tetrahedral elements sized at 5 mm. The generated mesh contained a total of 59037 nodes as a result of 38821 total elements. The meshed assembly of the bone-implant is shown in **FIGURE 5**.



FIGURE 5: Meshed assembly of implant system configuration

Material properties

Properties for the 4th generation composite femur and tibia were taken from the manufacturer [12], given in TABLE 2, and verified with previous studies [13-18]. The macro-structure and material properties of CF/PA-12 were based on earlier studies [9, 19, 20].

	Simulated cortical bone	Simulated cancellous bone	
		Solid	Cellular
Density [g/cc]	1.64	0.27	0.32
Compressive strength [MPa]	157	6.0	5.4
Compressive modulus [GPa]	16.7	0.155	0.137
Tensile strength [MPa]	106	n/a	n/a
Tensile modulus [GPa]	16.0	n/a	n/a

TABLE 2: Material properties of simulated cortical bone and cancellous bone [12, 16]

Carbon fibre (CF) weight fraction [%]	68
Polyamide 12 (PA-12) weight fraction [%]	32
CF volume fraction	0.55
PA-12 volume fraction	0.45
Density of CF [g/cc]	1.78
Density of PA-12 [g/cc]	1.03
Theoretical density of CF/PA-12 composite [g/cc]	1.443
Modulus of elasticity [GPa]	$E_x = 3.0; E_y = 10.7; E_z = 10.7$
Shear modulus [GPa]	$G_{yz} = 2.0; G_{zx} = 2.5; G_{xy} = 2.5$
Poisson ratio	$\nu_{yz} = \nu_{zx} = \nu_{xy} = 0.3$

TABLE 3: Material properties of the CF/PA-12 composite [9, 19, 20]

Simulation and solution

Axial loading and restraints were applied to the meshed assemblies as described in the section “Assembly model for FEA”. The assembly was restrained by restricting motion along all three axes at the distal-most cut end of the tibia. This assembly was loaded axially with 2100 N at the proximal-most end of the femur (FIGURE 5), representing approximately 3 times a nominal body weight of 70 kg. Many researchers have estimated that the maximum compressive load on the knee joint during natural gait fall within 2 to 4 times the body weight [3, 21-27], so 2100 N is reasonably typical test load. This compares well with the 2200 N used by Chu [24], two 1000 N compressive forces used by Miyoshi et al. [23], 2200 N axial force used by Godest et al. [25],

2300 N used by Halloran et al. [26], and 2000 N used by Villa et al. [27]. Bonded contact was used for all connected parts.

4. RESULTS

Validation of the FE model

Comparison between the hybrid and the conventional implants

Stress distribution contours of the 316L stainless steel and the hybrid implant are shown in FIGURE 6. Stress distribution in the composite CF/PA-12 layer alone is shown in FIGURE 7.

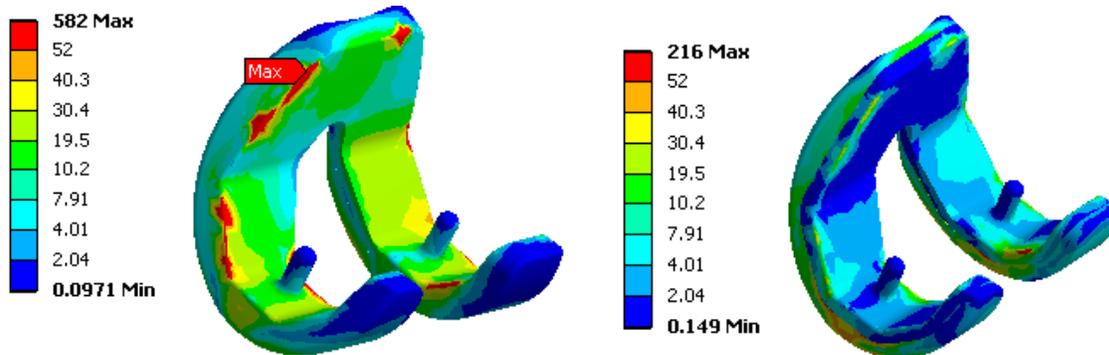


FIGURE 6: Stress distribution contours (MPa) in the 316L implant (left) and the hybrid implant (right)

The 316L implant generated minimum and maximum stresses of 0.0971 MPa and 582 MPa respectively. The hybrid implant generated a higher minimum stress of 0.149 MPa, and a much lower maximum stress of 216 MPa.

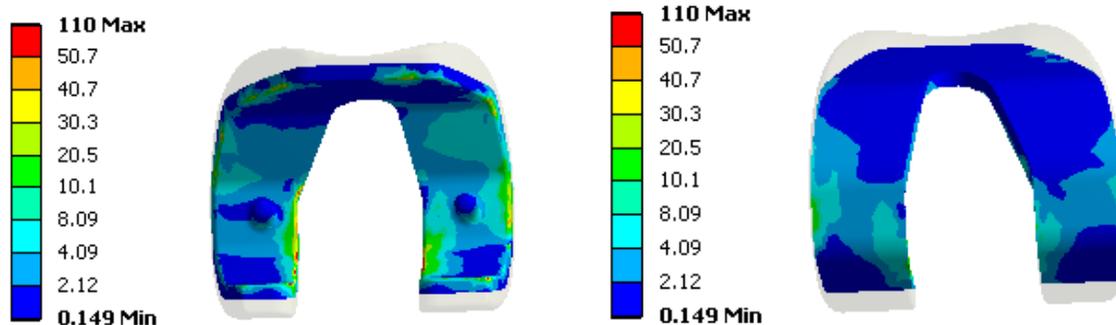


FIGURE 7: Stress distribution contours (MPa) in the CF/PA-12 layer; posterior view (left) and anterior view (right)

The stress distribution in the CF/PA-12 portion of the femoral component indicates a minimum stress of 0.149 MPa, and a maximum stress of 110 MPa. These values, when compared to the stresses in the assembled hybrid implant, show that the maximum stress generated in the hybrid femoral component (216 MPa) is not in the CF/PA-12 layer.

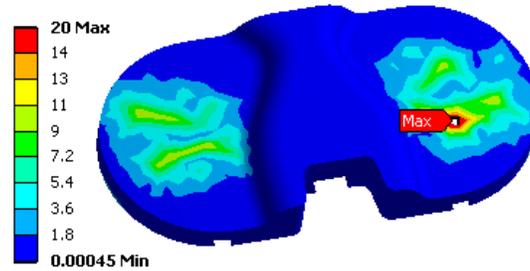


FIGURE 8: Stress distribution contours (MPa) in the UHMWPE tibial plate

The stresses generated in the UHMWPE layer peaked at 20 MPa, with most of the layer largely unaffected by the loading.

5. DISCUSSION

The stress distribution within the UHMWPE layer of the tibial component was used to validate the performance of the modelled implant assembly. Studies by Miyoshi et al. [23] have demonstrated peak stresses of 23.3 MPa in the UHMWPE tibial component, under a combined loading of 2000 N on the tibial plate. The axial load of 2100 N used in this study at the proximal end of the implant assembly produced maximum stresses in the UHMWPE layer of up to 20 MPa, as shown in FIGURE 8. This agrees well with the results of Miyoshi et al.

The FEA indicated considerably lower peak stresses in the CF/PA-12 lined femoral component when compared with the 316L stainless steel model. As shown in FIGURE 6, a peak stress of 582 MPa was generated in the 316L implant, compared to a much lower peak stress of 216 MPa generated in the hybrid implant. This decrease in the stress is due to the flexibility of the composite layer (i.e., at a maximum elastic modulus of 10.7 GPa, CF/PA-12 is 19 times more flexible than stainless steel at 193 GPa [28]).

This 63% (nearly two-thirds) reduction in peak stress tends to indicate that stress shielding, which is a transfer of load from the bone to the implant, can be expected to be much less in the hybrid implant. This reduction of overall peak stresses within the implant confirms that more load is being transferred to the bone when attached to a hybrid CF/PA-12 lined implant. This is an extremely significant improvement in exposing the femoral bone to natural physiologic loading.

6. CONCLUSION & FUTURE WORK

The results, as discussed in the previous section, indicate that a hybrid implant will reduce stress shielding and subsequent bone resorption. In turn, this will accommodate better osseointegration and lead to longer implant life. This study is specifically geared towards a finite element analysis, and the stress transfer in the model is validated by comparing the stresses generated in the tibial UHMWPE layer to published results of implant systems under similar loading conditions [23].

Further validation of the CAD and FEA model used in this study can be performed to support the inferences derived. Some of the current authors are conducting an experimental stress analysis study on the actual commercial implant to ensure that the FEA results of the metal implant match the experimental results. The experimental study is expected to use composite femur and tibia specimens (supplied by Sawbones Worldwide [10-12]) attached to the implant system. Once it has been verified that the numerical metal implant model generates stresses comparable to the experimental one, it can be safely concluded that any subsequent modifications to the model (i.e. applying a composite layer) will produce reliable results. As shown by a previous study [9], CF/PA-12 has displayed promising results in improving the stress shielding effects in hip arthroplasty, and this study seeks to show that the same composite will prove to be similarly advantageous in knee arthroplasty.

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