34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

# Development and testing of patient-specific knee replacements

Dawie van den Heever, Cornie Scheffer, *Member, IEEE*, Pieter Erasmus, and Edwin Dillon

*Abstract*— **This study presents a design methodology for designing and manufacturing patient-specific unicompartmental knee replacements. The design methodology uses mathematical modeling and an artificial neural network to predict the original and healthy articulating surfaces of a patient's knee. The models are combined with medical images from the patient to create a knee prosthesis that is patient-specific. These patient-specific implants are then compared to conventional implants with respect to contact stresses and kinematics. The patient-specific implant experienced lower contact stresses at the tibiofemoral joint compared to a fixed-bearing design. Both the UKRs showed similar kinematic patterns to the normal knee using two different test rigs. The patient-specific UKR showed good results and with the other benefits it shows potential to dramatically improve clinical outcomes of knee replacement surgery.**

## I. Introduction

The knee, located between the body's two longest lever-arms, sustains high forces and is the biggest, most complicated and incongruent joint in the body (1). Due to the high forces, the knee is susceptible to injury and chronic diseases of which osteoarthritis (OA) is the most common (2) (3) (4). OA is a common disease prevalent among the elderly and causes softening or degradation of the cartilage and subcondral bone in the joint, which leads to a loss of function and pain. This problem can be alleviated through a surgical intervention commonly termed a "knee replacement". The aim of a knee replacement procedure is to relieve pain and restore normal function (3). Ideally, the knee replacement prosthesis should have an articulating geometry similar to that of the patient's healthy knee, and must allow for normal motion. Unfortunately, this is often problematic since knee prostheses are supplied in standard sizes from a variety of manufacturers and each one has a slightly different design. Furthermore, commercial prostheses are not always able to restore the complex geometry of an individual patient's original articulating surfaces.

Knee replacement surgeries have been performed on younger, more active patients in recent times and it is believed that they place a higher demand on the resurfaced joint (5) (6) (7). This could compromise the longevity of the replaced knee joint. Restoring the knee joint surface to as near as "normal" as possible, with minimum bone resection, could accommodate for this trend (8). This should lead to more natural biomechanics and further increase the longevity of the artificial knee. Contact stresses and areas are important considerations in knee replacements, and knowledge of these parameters is considered a reliable tool for predicting potential UHMWPE wear and thus longevity (9). The kinematic patterns of the normal knee describe the motion of the femur relative to the tibia with increasing flexion. Normal knee kinematics is believed to include some posterior translation of the femur, which is more pronounced on the lateral side, leading to relative internal tibial rotation. Numerous studies have shown that normal kinematics are lost after knee replacement procedures and the main reason for the change in kinematics is attributed to the change in articular geometry (10), (11).

In this study a design procedure for designing and manufacturing patient-specific unicompartmental knee replacements is presented. The design procedure uses mathematical modelling and an artificial neural network to estimate the original and healthy articulating surfaces of a patient's knee. The models are combined with medical images from the patient to create a knee prosthesis that is patient-specific. These patient-specific implants are then compared to conventional implants with respect to contact stresses and kinematics.

## II. Materials and Methods

### A. *Development of patient-specific prostheses*

Natural knee geometry was investigated by means of 18 embalmed cadaveric distal femurs (all males, mean age of 51.7 years) as well as MRI data of 41 volunteers with healthy knees (20 males, mean age of 33.3 years, and 22 females, mean age of 32.5 years). Sagittal en transverse planes were created in which the geometries were defined, using 3-Matic v5.01 (Materialise, Leuven, Belgium). A femur coordinate system as defined by Grood and Suntay was used (12). The transverse planes were positioned perpendicular to the femoral mechanical axis, intersecting the most posterior points of the condyles. The sagittal planes were positioned at the most prominent central part of each condyle, perpendicular to the surgical epicondylar axis (8). Intersection curves were then created where the condyles intersect the planes, and these were exported to Matlab where mathematical models were fitted to the data (Figure 1). Four different models were investigated and compared for their accuracy in reconstructing the complex sagittal and transverse profiles. These models included a single radius model, dual-radius model, polynomial model, and a B-spline model. The accuracy of each model was determined by calculating a maximum error as well as a root mean square error (rms) between the model and the original data points. Nonuniform rational B-splines (NURBS) proved to reconstruct the joint geometry best due to its flexibility.

D. van den Heever and C. Scheffer are with the Department of Mechanical and Mechatronic Engineering, Stellenbosch University, Stellenbosch, 7600, South Africa (phone: +27-21-808-4856; fax: +27-86-615-5206; e-mail: dawie@sun.ac.za; cscheffer@sun.ac.za).

P. Erasmus is with Stellenbosch Medi-clinic, Stellenbosch, 7600, South Africa (e-mail: Pieter@orthoclinic.co.za).

E. Dillon is from the Department of Orthopaedic Surgery, Stellenbosch University, Stellenbosch, 7600, South Africa (e-mail: ed@drdillon.co.za).

978-1-4577-1787-1/12/$26.00 ©2012 IEEE 

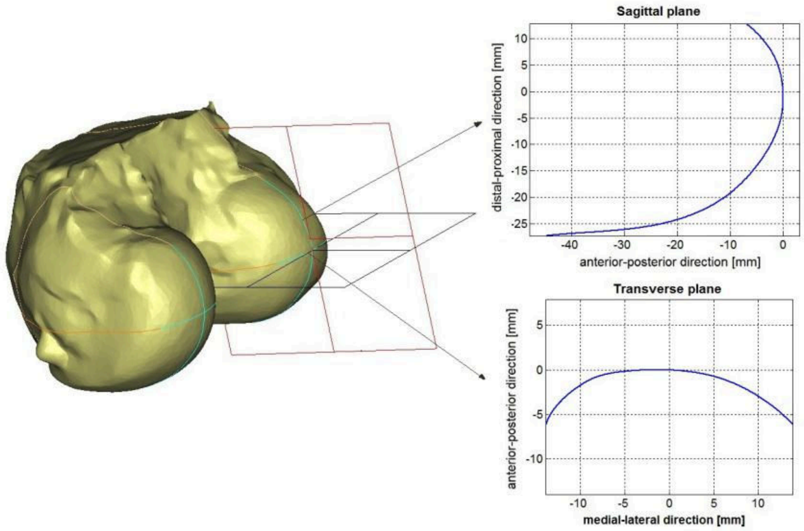


**Figure 1: Intersection planes through the lateral condyle of a distal femur with the corresponding sagittal and transverse intersection curves**

The determined B-spline parameters for each knee joint were stored in a database together with certain reference measurements. These are measurements not greatly affected by degenerative diseases such as OA and include medial-lateral length, posterior-anterior length of both condyles, the distance between the most anterior points on the condyles, and the distance between the most posterior points on the condyles. The database was then used in a self-organising map (SOM) algorithm to predict healthy knee geometries. The SOM is a type of neural network developed by Kohonen (13) and is a well-established tool used for data mining and analysis. The SOM learns to classify data without supervision and creates a two-dimensional representation of the input space, called a map. In this study the input space is the database containing the healthy knee geometries in the form of B-spline parameters and the reference measurements. Hidden relationships between the B-spline parameters and reference measurements are identified and used to predict the articulating geometries for an unhealthy knee joint with only the reference measurements known. The output is the B-spline parameters which can be used to reconstruct the articulating knee joint geometry of each condyle. This can be used to design unicompartmental knee replacement (UKR) prostheses. The superior surfaces (bone-implant surface) of the prostheses are customised to correspond to the condyle surfaces of the particular patient, ensuring an ideal fit with minimum bone loss. The only bone loss is due to the fixation peg.

The tibial component is designed based on MRI data of the patient to ensure complete cortical rim coverage. The mobile ultra-high molecular weight polyethylene (UHMWPE) bearing is designed to be congruent with the femoral component at 0º flexion. Due to the design of the femoral component, conformity in the medial-lateral direction with the bearing will be maintained throughout flexion to provide maximum contact area.

*B. Comparison of contact stresses*

The ability to predict the stress distributions within the UHMWPE components are provided by finite element (FE) analysis (14). Finite element models of patient-specific UKRs were developed for seven different cases. Two conventional UKR systems were reverse engineered using a 3D laser scanner (NextEngine, Santa Monica, USA). Finite element models of three different sizes of a fixed-bearing implant and two different sizes of a mobile-bearing implant were created. Analysis was performed on the implants with their accompanying bearings as well as a completely flat UHMWPE bearing to examine the effect of conformity. All components were modeled as deformable bodies using ten-noded tetrahedral elements and edge lengths of less than 1mm. The femoral components were modeled as linear elastic and isotropic with the material properties of cobalt-chromium ($E$ = 195 GPa, $v$ = 0.3). the UHMWPE bearings were modeled as non-linear with stress/strain curve as used by (15) and a Young's modulus of 1048 MPa.

Vertical loads similar to that used by (16), (17) were modified for UKR by offsetting the load towards the medial condyle with a 60-40 ratio (15). This resulted in static loads being applied to the femoral component of 1320 N at 15º flexion, 1920 N at 45º and 1680 N at 60º. The femoral components were constrained to only move in a vertical direction while the inferior surface of the bearings remained fixed.

*C. Tibiofemoral kinematics*

We tested three cadaver knee joints in two different rigs, a loaded ankle (similar to the Oxford knee rig design) and an unloaded ankle rig (with the femur fixed and the tibia hanging freely), comparing normal tibiofemoral kinematics to kinematics after implantation with a patient-specific UKR. Patient-specific UKRs were designed using CT data of the cadavers and were manufactured on the EOSINT M270 metal laser sintering system in Ti64. Two knees received medial replacements while one knee received a lateral replacement.

Each knee was sectioned just below the femoral head, with the ankle and foot kept intact. The skin was removed around the knee and ankle joints. Threaded intermedullary rods were cemented into the femoral shafts for fixation to the testing rigs. Electromagnetic receiver sensors (Fastrak, Polhemus, Vermont, USA) were rigidly fixed to the femoral and tibial shafts. An electromagnetic transmitter sensor was rigidly fixed to the stationary testing rig frame. An additional stylus was used to digitise bony landmarks to create embedded coordinate systems in both the femur and tibia. Each specimen was preconditioned by manually flexing the knee at least 10 times between full extension and full flexion. First, knee kinematics was recorded with an intact joint capsule on both the test rigs. Next, the patient-specific knee replacement was implanted and tested on both test rigs and the kinematics was recorded. The femoral component was implanted by removing the cadaver femoral cartilage beneath the implantation region and making the fixation hole with help of the custom instrumentation. The tibia was prepared as per standard surgical technique using the fixed-bearing instrumentation. The system uses a tibial cut perpendicular to the tibial shaft axis. The fixation hole was prepared using the custom instrumentation. The patient-specific components were removed and the cadaver knee implanted with the fixed-bearing components as per standard surgical technique with the accompanying instrumentation. The knees were again tested on both test rigs and the kinematics recorded. The two knee rigs are described below.

## III. Results

### A. Model fitting

The B-spline model fitted the original data best with a mean maximum error of 0.15 mm (standard deviation 0.1 mm) and 0.6 mm (standard deviation 0.1 mm) in the sagittal plane for the medial and lateral condyles, respectively. The rms errors for the medial al lateral condyles were 0.07 mm (standard deviation 0.03 mm) and 0.10 mm (standard deviation 0.04 mm) respectively. The accuracy of the B-splines in the transverse plane also showed good results with mean maximum errors of 0.05 mm (standard deviation 0.03 mm) and 0.04 mm (standard deviation 0.02 mm) for the medial and lateral condyles, respectively. The means rms errors were 0.02 mm (standard deviation 0.01 mm) for both the medial and lateral condyles. The single-radius model showed the largest errors in both the sagittal and transverse planes.

### B. Contact Stresses

The maximum contact stresses for the patient-specific implant and the fixed-bearing implant usually occurred at 45º flexion. The maximum contact stress for a patient-specific case was 16.6 MPa at 45º flexion and the fixed-bearing design showed a maximum stress of 18.9 MPa at 45º flexion for the largest size component. The mobile-bearing design had a maximum contact stress of 13 MPa at 60º flexion. A maximum contact stress of 21.1 MPa was experienced by a patient-specific design for the analysis with a flat bearing component. The stress at 15º flexion decreased from 16.6 MPa to 12.7 MPa as the component size decreased for the fixed-bearing design. This was not the case at 45º or 60º flexion where the stress stayed relatively constant. Similar results were shown for the mobile-bearing design.

### C. Tibiofemoral kinematics

Cadavers 1 and 3 received medial replacements while cadaver 2 received a lateral replacement. For the unloaded ankle rig, normal kinematics of cadaver 1 and 2 showed tibial rotation of more than 20º over a flexion range of 70º. The patient-specific UKR showed similar patterns to the normal knee kinematics, while the conventional UKR showed slightly more rotation for cadaver 1 while still following a similar pattern. Cadaver 3 showed normal tibial rotation of 10º over 70º flexion. Both UKRs showed higher rotations over the same range. For all three normal knees femoral rollback ranged between 4 mm and 5 mm, while the UKRs showed slightly more femoral rollback for cadaver 1. For cadaver 2 the patient-specific translation was very similar to that of the normal knee. For cadaver 3 the conventional UKR followed a similar pattern to that of the normal knee, with slightly more posterior translation. The patient-specific UKR also followed a similar pattern, with even more posterior translation.

Only cadavers 2 and 3 were tested on the loaded ankle apparatus while only cadaver 3 was implanted with the conventional UKR. Compared to the unloaded ankle rig, the normal knees showed more internal tibial rotation, with cadaver 3 showing up to four times more rotation. After 70º flexion both knees showed internal tibial rotation of 40º. For cadaver 2 the patient-specific UKR showed a similar pattern to that of the normal knee, with slightly less rotation. For cadaver 3 both the UKRs showed a similar pattern to the normal knee up to 60º flexion. After this, the normal knee's rotation stopped. Normal kinematics of cadavers 1 and 2 showed femoral rollback of almost 8 mm after a slight anterior translation at the beginning. For cadaver 2 the patient-specific UKR showed a similar pattern, with slightly more posterior translation. For cadaver 3, both the UKRs showed considerably less posterior translation, however, the patient-specific UKR showed a similar pattern to that of the normal knee, with a slight anterior translation at first before a steeper posterior translation.

## IV. Discussion

The main aim of knee replacement procedures is to relieve pain and restore normal function to the joint (3). An ideal knee replacement prosthesis would have an articulating geometry similar to that of the patient's healthy knee. This would imply restoring the degenerated articulating regions to the original geometry and level. The aim of this research was to find a method to restore an individual's articulating surfaces to normal and thus restore normal function to the knee joint.

In this study, the B-spline models proved most accurate in describing the geometry of the femoral condyles. This can be attributed to the ability of B-splines to provide the flexibility to design a large variety of shapes. B-splines are invariant under affine as well as perspective transformations. The SOM, in conjunction with B-splines, showed the most potential as a method that can be used to predict knee joint profiles. These predicted knee joint profiles are used to design patient-specific unicompartmental knee replacements. To avoid uneven stress distribution caused by the shape of conventional prostheses, a patient-specific bone-implant interface is used. In theory, the component should fit perfectly on the patient's femur without the need to remove bone. A custom tibial baseplate is also suggested, providing complete cortical rim coverage for optimal load transfer. The polyethylene insert in this study was designed to be congruent with the femoral component at $0^{\circ}$ flexion. Because of the design of the femoral component, this will ensure that the mobile polyethylene insert conforms in the medial-lateral direction with the femoral component throughout flexion. This provides maximum contact area. Bartel et al. (18) found that, when the articulating surfaces were more conforming in the medial-lateral direction, contact stresses in the tibial components were reduced.

A very effective method of examining the contact stresses produced in knee replacements is finite element analysis. In this study, the contact stresses in a patient-specific UKR were examined and compared to conventional implants using FE analysis. The custom implant showed lower maximum contact stress compared to the conventional fixed-bearing implant.

Numerous studies have reported that normal knee kinematics are not achieved after total knee replacement, (10), (11). This study compared normal knee kinematics to knee kinematics after implantation with a patient-specific UKR and a conventional UKR. The patient-specific UKR showed similar kinematic patterns to the normal knee. It was especially encouraging to see the normal kinematics being reproduced for the lateral implant. The geometry and kinematics of the lateral compartment are different to that of the medial compartment, and lower survival rates and other complications have been reported when using conventional UKRs for the treatment of lateral osteoarthritis (19), (20).

In conclusion, this research emphasised the importance of restoring a patient's original articulating surfaces when their knee joints are affected by injury or disease. A method for designing a patient-specific UKR was presented and tested with regard to contact stresses and kinematics. It was shown that patient-specific implants can have characteristics comparable to, and in certain cases better, than conventional prostheses. The unique design methodology presented here introduces a significant advancement in knee replacement technology, with the potential to dramatically improve clinical outcomes of knee replacement surgery

## REFERENCES


1. Biščević M, Hebibović M, Smrke D. Variations of femoral condyle shape. Collegium Antropologicum. 2005; 2: p. 409-414.
2. Sherwood J, Riley S, Palazzolo R, Brown S, Monkhouse D, M C, et al. A three-dimensional osteochondral composite scaffold for articular cartilage repair. Biomaterials. 2002; 23: p. 4739-4751.
3. Krevolin J. Specimen-specific, three dimensional knee joint mechanics: Normal and reconstructe. Doctor of Philosophy Thesis, University of Texas. 2003.
4. Saxler G, Temmen D, Bontemps G. Medium-term results of the AMC-unicompartmental knee arthroplasy. The Knee. 2004; 11: p. 349-355.
5. Morgan M, Brooks S, Nelson R. Total knee arthroplasty in young active patients using a highly congruent fully mobile prosthesis. The Journal of Arthroplasty. 2006; 22: p. 525-530.
6. Hernigou P, Nogier A, Manicom O, Poignard A, De Abreu L, Filippini P. Alternative femoral bearing surface options for knee replacement in younger patients. The Knee. 2004; 11: p. 169-172.
7. Murphy T, Brubaker S, Mihalko W, Saleh K, Mulhal K. Review of Unicompartmental Knee Arthroplasty in younger patients. Seminars in Arthroplasty. 2007; 18: p. 162-167.
8. van den Heever D, Scheffer C, Erasmus P, Dillon E. Mathematical reconstruction of human femoral condyles. Journal of Biomechanical Engineering. 2011 June; 133: p. 064504.
9. Sathasivam S, Walker P, Campbell P, Rayner K. The effect of contact area on wear in relation to fixed bearing and mobiler bearing knee replacements. Journal of biomedical materials Research. 2001; 58: p. 282-290.
10. Bull A, Kessler O, Alam M, Amis A. Changes in knee kinematics reflect the articular geometry after arthroplasty. Clinical Orthopaedics and Related Research. 2008; 466: p. 2491-2499.
11. Coughlin K, SJ I, Churchill D, Beynnon B. Tibial axis and patellar position relative to the femoral epicondylar axis during squatting. The Journal of Arthroplasty. 2003; 18: p. 1048-1055.
12. Grood E, Suntay W. A joint coordinate system for the clinical description of three-dimensional motions: application to the knee. Journal of Biomechanical Engineering. 1983; 105: p. 136-144.
13. Kohonen T. The self-organizing map. Neurocomputing. 1998; 21: p. 1-6.
14. Simpson D, Gray H, D'Lima D, Murray D, Gill H. The effect of bearing congruency, thickness and alignment on the stresses in unicompartmental knee replacements. Clinical Biomechanics. 2008; 23: p. 1148-1157.
15. Halloran J, Petrella A, Rullkoetter P. Explicit finite element modeling of total knee replacement mechanics. Journal of Biomechanics. 2005; 38: p. 323-331.
16. Villa T, Migliavacca F, Gastaldi D, Colombo M, Pietrabissa R. Contact stresses and fatigue life in a knee prosthesis: comparison between in vitro measurements and computational simulations. Journal of Biomechanics. 2004; 18: p. 45-53.
17. Shi J. Finite element analysis of total knee replacement considereing gait cycle load and malalignment University of Wolverhampton; 2007.
18. Bartel D, Bicknell V, Wright T. The effect of conformity, thickness, and material on stresses in ultra-high molecular weight components for total joint replacement. Journal of Bone and Joint Surgery. 1986; 68A: p. 1041.
19. Gunther T, Murray D, Miller R, Wallace D, Carr A, O'Connor J, et al. Lateral unicompartmental arthroplasty with the Oxford meniscal knee. The Knee. 1996; 3: p. 33-39.
20. Ashraf T, Newman J, Evans R. Lateral unicompartmental knee replacement: Survivorship and clinical experience over 21 years. Journal of Bone and Joint Surgery. 2002; 84B: p. 1126-1130.