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Development of a Patient-Specific Femoral Component for Unicompartmental Knee Replacement

D.J. Van Den Heever, C. Scheffer, *Member, IEEE,* P.J. Erasmus, and E.M. Dillon

Abstract— **This study describes the development of a novel, patient-specific unicompartmental knee prosthesis. The geometries of the lateral and medial condyles are approximated by polynomials, instead of single radius circles that are commonly used. Furthermore, a database containing the geometries of healthy knees is used to generate appropriate knee geometries according to certain measurements of the unhealthy knee. This new method enables a customized design of a unicompartmental knee replacement that will closely resemble the articulating surfaces of the normal, healthy knee joint.**

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 human body [1]. Because of the high forces experienced, the knee is susceptible to injury and chronic diseases of which osteoarthritis (OA) is most common [2-3]. This can lead to the loss of function of the knee which can severely impact on the quality of life of an individual.

The most common treatments for OA include high tibial osteotomy (HTO), unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA) [4]. The aim of the procedures is to relieve pain and restore normal function to the joint [5]. In order to function like a natural joint, a joint substitute needs to have certain characteristics according to He *et al.* [6]. These characteristics include:

- Mechanical: The prosthesis should possess the necessary mechanical strength and stiffness.
- Anatomical: The prosthesis should have a customized geometric size.
- Biological: The prosthesis material should be biocompatible.

The aim of any new knee replacement is to satisfy these characteristics. Another aspect to consider is the differences between UKA and TKA. In appropriate cases UKA has an advantage over TKA which can include better range of motion, preservation of bone, shorter recovery time, maintenance of normal cruciate ligament function and more normal kinematics [6-8]. TKA has shown better success rates over a long period of time, however in recent years UKA has shown an improvement in success rate and compares to that of TKA. UKA success rate improved from between 37% and 92% in the 70s and 80s to between 87% and 98% with 6 to 14 year follow-ups as reported for the period 1993 to 2003 [10]. There are certain accepted requirements for UKA though, the most obvious being that the arthritis be isolated to one compartment only. Other requirements include [9-10]:

- An intact Anterior Cruciate Ligament (ACL).
- Less than 10˚ of fixed flexion deformity.
- Less than 10˚ of varus deformity.
- Flexion more than 90˚.
- The diagnosis should be degenerative arthritis
- Patient should not be obese.

It is suggested that UKA restores normal knee kinematics better than TKA because of the procedure retains the cruciate ligaments, but it is however still quite different from perfect natural knee kinematics. This can be attributed to the complex, assimetrical geometry of the condyles and articulating tibial surfaces of the normal knee.

The geometry of the posterior condyles of the knee was first reported in 1836 to be circular and roughly of the same size, by Weber and Weber [14]. This hypothesis has been used in numerous kinematics-related studies [15-18] and is still very popular today. Freeman *et al.* [14] proposes that the posterior radius of both the medial and lateral condyle is in the order of 22 mm. This part is the articulating surface for flexion/extension from about 20˚ to 120˚. Freeman *et al.* further suggests that both condyles have a second radius which is located anteriorly and has a larger radius. In the medial condyle this radius is approximately 32 mm and spans an arc of 50˚. In the case of the lateral condyle, the radius is so large that it becomes almost flat, it is also a lot shorter. Both condyles also have an extreme posterior portion with a smaller radius, but in both cases this portion only comes in contact with the posterior horn of the meniscus. Most commercial prosthesis designs are based on such observations, and hence in commercially available prostheses the surface geometry in the sagittal view is either of a specific single or multi-radius design, which is predetermined by the manufacturer. This geometry does not necessarily present the true radius of a specific knee. The same applies to the mediolateral radius of both the medial and lateral condyles, when viewed axially. However, the geometry of a natural

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D. J. van den Heever and C. Scheffer are with the Department of Mechanical and Mechatronic Engineering, Stellenbosch University, South Africa (phone: +27 21 808 3613; fax: +27 21 808 4958; e-mail: dawie@sun.ac.za; cscheffer@sun.ac.za).

P.J Erasmus is an orthopedic surgeon in private practice in Stellenbosch, South Africa (email: pieter@orthoclinic.co.za)

E.C. Dillon is an orthopedic surgeon in private practice in Stellenbosch, South Africa (email: edwin@orthoclinic.co.za).

knee is more complex and consists of a continuous varying radius along the surface of each condyle.

Commercially available prostheses are also only available in a few standard sizes, which are designed in the Western world and are mainly intended for Caucasian people. These prostheses are frequently too large for the Asian population. Kwak *et al.* [16] reports a decrease in aspect ratio with increasing anteroposterior dimension of the proximal tibia as compared to the constant aspect ratio of conventional prostheses. This results in mediolateral undersizing in smaller-sized prostheses. The larger-sized prostheses were found to show mediolateral overhang.

There also exist many cases in which conventional knee prostheses do not suffice because of pathological conditions involving abnormal geometry [17]. Sathasivam *et al.* [17] proposed a custom-constrained condylar knee using CAD-CAM for such cases. He *et al.* [18] reports the design and fabrication of a custom hemi-knee joint based on CT data and rapid prototyping. Harrysson *et al.* [19] presents a custom prosthesis based on CT scan data of a patient. The bone-implant interface is customized which results in less bone to be removed and more even stress distribution. This reduces the risks of premature loosening.

It is clear that there is a need for custom-designed knee prostheses. This study describes a novel patient-specific unicompartmental knee prosthesis that is being developed at Stellenbosch University.

II. Methods

As previously mentioned, most conventional unicompartmental prostheses have a single or multi-radius design to represent the surface geometry of the condyle in the sagittal view. An addition, most of these designs also use the same prosthesis for both the medial and lateral side of the knee, even though the geometry and the kinematics are different.

On the medial side there is little anteroposterior movement, but on the lateral side the movement is more prominent because there exists femoral rollback of 15 – 20 mm [11, 14, 15]. This is due to the geometry of both the femur and tibia.

The mediolateral shape of most prostheses is circular, with a similar radius to that of the posterior radius. This results in the prostheses to behave as a sphere in certain instances, i.e. having little anteroposterior movement and it enables rotation about all three axes. This is similar to the medial condyle of a natural knee. In the natural knee however, the lateral condyle is not a single radius when viewed mediolaterally, and can not accurately be represented by a single circle.

In this study the complex geometries of the condyles in both sagittal view as well as axial view are represented by polynomials. Polynomials are mathematical equations of the form:

$$f = a_0 x^n + a_1 x^{n-1} + \cdots + a_{n-1} x + a_n$$

Polynomials were used because they can be easily determined and reproduced requiring only their coefficients. The coefficients can easily be stored in a database and used to reproduce the desired shape. Other more complex equations such as B-splines are also being investigated. B-splines have the ability to closely follow a set of complex data points; they however require more coefficients to describe them.

CT data of 36 healthy knee joints were obtained (mean age 39.3) with a slice thickness of 1 mm with a resolution of 512 x 512 and used to investigate the articulating surface. 18 Cadaveric specimens were also used to investigate the articulating surfaces (mean age 51.7 years). The advantage of the cadaveric specimens is that they include the cartilage. Computer models of the distal femur of cadaveric specimens were created using a 3D laser scanner (NextEngine, Santa Monica, USA). The CT and cadaver data were imported into Mimics version 12.01 (Materialise, Leuven, Belgium). Mimics is a software package used for editing and 3D reconstruction of CT data. Numerous points were placed along the articulating surfaces of the condyles in both the sagittal view (Fig. 2) and the axial view (Fig. 3). Other points were also used to determine certain reference measurements which are not severely affected by osteoarthritis and which are easy to identify. These include anteroposterior length on the medial (APM) and lateral (APL) side, medio-lateral (ML) length and the distance between the most anterior points on the medial and lateral condyles (DAC).

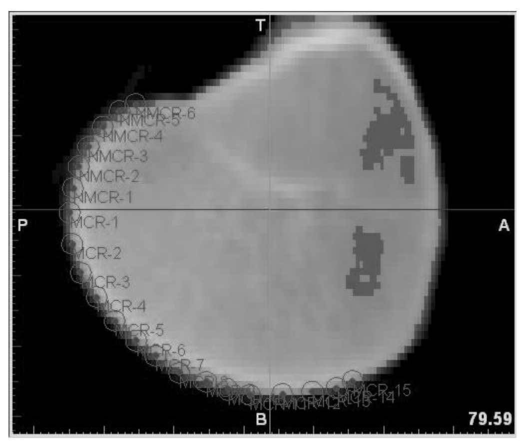

Fig. 2. Points on medial condyle in sagittal view

The coordinates of the points describing the surface geometry were imported into Matlab version 7.0.1 (MathWorks, Natick, Massachusetts, U.S.A.). The geometry in the sagittal view was divided into two parts, with the most posterior point taken as a common reference point. The coordinates were normalized with the reference point (most posterior point) at coordinate (0,0). For the axial views, the most lateral point of the articulating surface of the condyle was used as reference point (0,0).

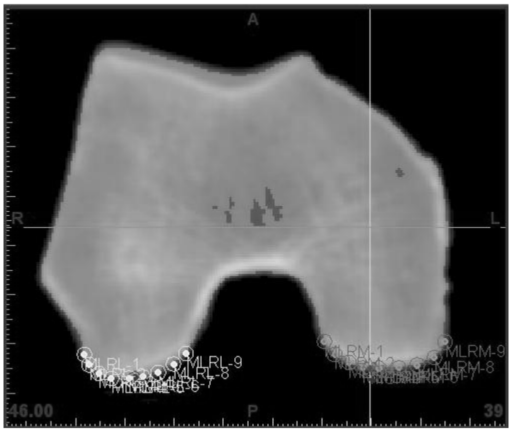

Fig. 3. Points on condyles in axial view

The *polyfit* function in Matlab was used to fit a 4th order polynomial through the points of the distal part of the sagittal view as well as for the axial view. A 2nd order polynomial was used for the proximal portion of the sagittal view. The reference point was used as the starting point in each. The polyfit function returns the coefficients of the polynomials as the output. These polynomials can be used to represent the articulating surfaces of a knee joint replacement.

Another aspect considered in this study is the condyle curvature, viewed in the anterior/posterior plane. The curvatures of the individual condyles, as viewed in the anterior/posterior plane, are also ignored in most conventional replacement designs and in most designs there is no difference between the design for the medial and lateral condyles. In practice the curvature on the medial side is much more pronounced than on the lateral side. This curvature is important in movement as the femoro-tibial contact area follows the curvature.

To produce the surface geometry for a specific knee prosthesis, the four reference measurements are taken on a CT of the affected knee using Mimics. These measurements are then the input for a Self-Organising Map (SOM). SOM is a type of neural network that is trained using unsupervised learning to produce a 2-dimensional representation of the input space, called a map. The map in this case consists of the coefficients and measurements in the database as well as the four reference measurements of the affected knee. In the learning phase, the SOM makes certain connections between all the data and can approximate the coefficients for the affected knee using its reference measurements and the data of coefficients and measurements in the database. The SOM thus produces the geometry for the affected knee in both the sagittal view and the axial view as the coefficients of polynomials. These can then be used to design a knee prosthesis.

III. RESULTS

In order to compare the results of the SOM generated geometry versus a circular geometry, CT data of a healthy knee was used. Numerous points was placed along the surfaces of the healthy knee and imported into Matlab. These points were displayed on a plot. The four reference measurements required for the SOM was taken on the healthy knee using Mimics. These measurements were then used as input for the SOM. The polynomials were created using SOM and were displayed together with the actual points on the natural knee and a fitted circle (Fig. 4 and 5).

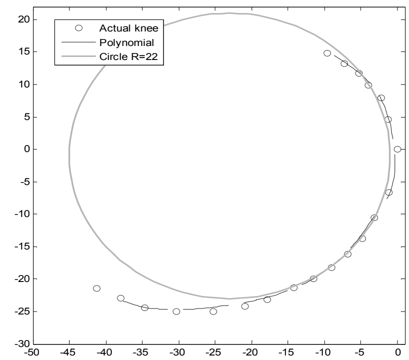

Fig. 4. Comparison of lateral condyle surface geometry in sagittal view

In the sagittal view (Fig. 4) it can be seen that the circle approximates the actual knee well for a large portion, but it fails to do near the extremes. At the extreme posterior portion the circle becomes too large, and at the more anterior portion, the circle becomes too small. It can also be seen that at the most posterior point, the natural knee lies outside of the circle.

The polynomial approximates the actual knee a lot better throughout the entire articulating surface. The polynomial has the ability to become flatter at the anterior portion and more rounded at the posterior portion.

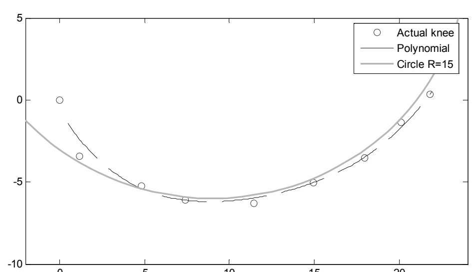

Fig. 5. Comparison of lateral condyle surface geometry in axial view

When considering the axial view (Fig. 5), it can again be seen that the circle approximates the actual knee well for the middle part, but becomes much worse near the ends. This is most evident at the lateral condyle where the condyle radius becomes smaller at the one end. Again the polynomial follows this trend much better.

Fig. 6 shows prosthesis designs that were virtually implanted (using Mimics) on the cadaveric specimen. The anterior/posterior curvature of the condyles can clearly be seen in this figure. Most conventional prostheses designs do not consider this curvature and hence in many cases a proper fit will not be achieved without compromise

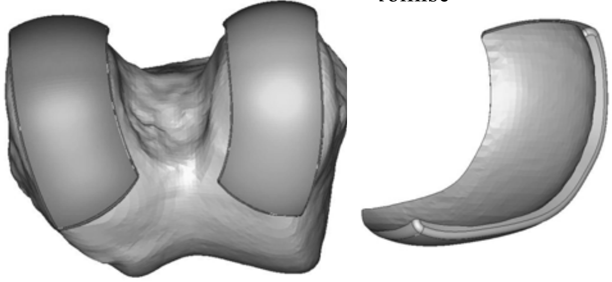

Fig. 6. Anterior/posterior curvature of the knee.

Figure 6 also shows the custom bone-implant interface of the femoral component. Commercially available implants require the distal femur to be reshaped to fit the implant. The shapes are restricted by the surgical techniques currently available and cause an uneven stress distribution [19]. To avoid this uneven stress distribution, and to minimize bone loss during surgery, the aim of a custom prosthesis is to develop a patient-specific bone-implant interface.

Using 3Matic (Materialise, Leuven, Belgium), the CT data of a patient is used to create the bone-implant interface of the prosthesis to be similar to the condyle geometry of the patient. This ensures a near perfect fit between the implant and the femur once all cartilage is removed. Such an interface will also result in more uniform stress distribution compared to conventional implants.

IV. Discussion

The value to use UKA as a treatment for osteoarthritis has increased in the last couple of years. This can be attributed to the good survivorship reports [20-21] and also the demonstration that progression of arthritis to unaffected compartments is not inevitable [22]. In appropriate cases UKA can have an advantage over TKA, which can include better range of motion, preservation of bone, shorter recovery time, maintenance of normal cruciate ligament function and more normal kinematics [6-8]. There are still improvements to be made in UKA though to produce even more normal knee kinematics.

Normal knee kinematics is greatly dependent on joint geometry and therefore it is greatly dependent on implant design [23]. It is thought that by approximating the normal knee geometry more closely, it can result in more natural kinematics. Using the techniques discussed in this paper, it is possible to design patient-specific knee implants. The geometry of the implant will consist of several mathematical equations which are shown to better approximate the normal knee than a circle or even a pair of circles. The coefficients describing the equations determined for healthy knee geometries are stored in a database. These are then used to produce a set of equations used to design the prostheses for an unhealthy knee.

Using rapid prototyping techniques to fabricate patient-specific prostheses gives rise to another potential advantage, because the inner surface of the femoral component (the surface that will form part of the bone-implant surface) can also be customized to perfectly fit the patient. This will result in the preservation of bone stock as well as a better fit.

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