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[Continued on next page]

(54) Title: A METHOD OF DESIGNING A KNEE PROSTHESIS

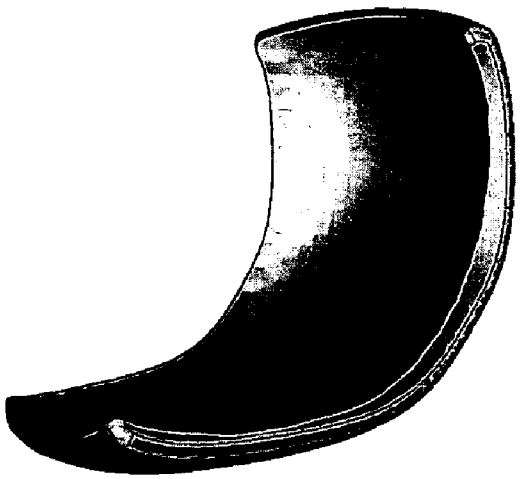

Figure 10

(57) Abstract: A method of designing a knee prosthesis is provided which includes imaging a knee, preferably in three dimensions, and comparing a number of features of the imaged knee to corresponding features of a plurality of reference knees. The features which are compared include the anterior length on the medial (APM) and lateral (APL) sides, the medio-lateral length (ML) and the distance between the most anterior points on the medial and lateral condyles (DAC). The features of the reference knees which most closely correspond to those of the imaged knee are selected and the prosthesis modelled to have an external geometry at least similar to the knee associated with the or each selected feature.

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A METHOD OF DESIGNING A KNEE PROSTHESIS

FIELD OF THE INVENTION

This invention relates to a method of designing and manufacturing a knee prosthesis.

BACKGROUND TO THE INVENTION

The knee is the largest, most complicated and incongruent joint in the human body. The articulating surfaces of the knees have complex, asymmetrical shapes and these influence the complex kinematics. Because of the high forces experienced during use, the knee is susceptible to injury and chronic diseases, of which osteoarthritis (OA) is most common. This can lead to the loss of function of the knee which can severely impact on the quality of life of the patient.

The most common treatments for OA include high tibial osteotomy (HTO), unicompartmental knee replacement (UKR) and total knee replacement (TKR). The aim of these procedures is to relieve pain and restore normal function to the joint. Large numbers of these operations are performed with over 350 000 TKRs being performed annually in the United States alone.

In order to function like a natural joint, a joint substitute or prosthesis needs to possess good mechanical strength and stiffness, have a customized geometric size and be made of biocompatible material. A further consideration is the difference between UKR and TKR. It is suggested that UKR restores normal knee kinematics better than TKR because of retaining the cruciate ligaments. It is however still very difficult to perfect natural knee kinematics. This is due to the fact that most UKR prostheses designs are

available in standard sizes only and the surface geometry in sagittal view is either of a specific single or multi-radius design which is predetermined by the manufacturer. Whilst this represents a practical solution to designing and manufacturing suitable prostheses, the resultant prostheses are not ideal as the joint articulation differs from its previous, natural articulation, resulting in strain on the ligaments and remaining bone. Also, bone surfaces have often to be cut away to receive the prostheses and it can be difficult to match to populations with bone structure smaller or larger than those for which they are designed. For example, most prostheses are designed for the typical population types of the United States of America and thus do not provide a good fit on smaller Asian populations. To date, however, no viable method of designing a custom prosthesis on an individual basis has been found which takes into account the individual's existing knee anatomy and provides a prosthesis demonstrating near normal articulation for that individual.

OBJECT OF THE INVENTION

It is an object of this invention to provide a method of designing a knee prosthesis which will at least partially alleviate some of the problems mentioned above.

SUMMARY OF THE INVENTION

In accordance with this invention there is provided a method of designing a knee prosthesis which includes

imaging a knee;

comparing a number of features of the imaged knee to corresponding features of a plurality of reference knees;

selecting the features which most closely correspond to those of the imaged knee; and

modelling the prosthesis to have an external geometry at least similar to the knee associated with the or each selected feature.

Further features of the invention provide for the imaging to be three-dimensional; for prosthesis to include an external, articulating surface; for the features to include the anterior length on the medial (APM) and lateral (APL) sides, the medio-lateral length (ML) and the distance between the most anterior points on the medial and lateral condyles (DAC); for the articulating surface of each reference knee to be represented as a mathematical function; and for the articulating surface of the prosthesis to be modelled using the mathematical function associated with each selected feature.

Still further features of the invention provide for the use of a pattern recognition algorithm, such as the self organising map (SOM), to compare the features of the imaged knee to the corresponding features of the reference knees and to interpolate an external geometry for the prosthesis from those associated with the selected features.

The invention also provides a knee prosthesis manufactured in accordance with a design substantially as defined above.

The invention further provides a method for providing a prosthesis for a knee which includes obtaining information relating to the knee in a healthy condition, storing the information, and at a later time fabricating the prosthesis based on the stored information.

Further features of the invention provide for the information to include an image of the knee; and for the information to be updated periodically.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:-

Figure 1	is a computer tomography (CT) image of a knee;
Figures 2 to 5	are a sagittal and axial view respectively of a medial condyle;
Figures 6 and 7	are plots comparing a designed surface to an actual surface;
Figure 8	is a computer-aided design (CAD) model of a prosthesis;
Figure 9	shows two perspective views of the model in Figure 8 fitted to a knee condyle reconstructed from a CT image; and,
Figure 10	is a perspective view of model prosthesis having a custom bone-prosthesis interface.

DETAILED DESCRIPTION WITH REFERENCE TO THE DRAWINGS

A method of designing a knee prosthesis, in this embodiment a unicompartmental knee replacement (UKR) prosthesis, includes computer tomography (CT) imaging of the knee. This provides a detailed three dimensional image of the knee and shows diseased or damaged areas together with healthy areas, as shown in Figure 1. A number of features of the knee are then measured from the image and compared to corresponding features of a plurality of healthy reference knees which are stored in a

database. These features are also obtained from CT images of healthy knees of people drawn from as wide a population sample as possible. It is envisaged that the database will be continually expanded and that it may be categorised according to gender, population group and the like.

From the comparison, the reference features which most closely correspond to those of the image are selected and the geometry of the knees associated with these features used to model the prosthesis on. In making the comparison a number of reference measurements are used. These are measurements relating to features of the knee which are generally not affected by diseases, such as osteoarthritis. Typically, the articulating surface of one or both of the femoral condyles becomes damaged. The meniscus and tibial plateau are often also damaged but it is a prosthesis for the condyles that is the focus of this description. The features used may however include any suitable features which are determined not to have been extensively damaged. The most common features include the anterior length on the medial (APM) and lateral (APL) sides, the medio-lateral length (ML) and the distance between the most anterior points on the medial and lateral condyles (DAC).

The most efficient method of making the comparison is by way of a computer implemented system. In this embodiment the system uses self organising maps (SOM) as the search mechanism, but several other pattern recognition algorithms can achieve the same outcome. The reference measurements can either be taken and input directly in to the system or reference points can be plotted on the electronic image using suitable segmentation software, such as Mimics (Materialise, Leuven, Belgium), and the system then used to calculate measurements and compare these to corresponding points on the reference knees.

Once the most closely corresponding features have been selected, the corresponding articulating surfaces of the associated condyle or condyles are

used as the basis for designing the prosthesis. This is achieved by including in the database a definition of the articulating surfaces of each condyle as mathematical functions, for instance polynomials or splines, and then using the mathematical functions to define the outer, articulating surface of the prosthesis. In this embodiment polynomials are used.

For simplicity, the coefficients of the polynomials are stored in the database as the descriptors of the geometries of the relevant portions of the healthy knees. In this embodiment, the coefficients were determined using Matlab version 7.0.1 (The Math Works Inc), but any mathematical manipulation software can be used for this purpose. Using three dimensional computer models of the healthy knees (generated by Mimics or other suitable segmentation software), numerous points were plotted along the articulating surfaces of the condyles in both sagittal view, as shown in Figure 6, and the axial view as shown in Figure 7. The coordinates of the points are then imported into Matlab. The geometry in sagittal view is divided into two parts with the most posterior point as the common reference point. The coordinates are normalized with the reference point (most posterior point) at coordinate 0,0. For the geometries in axial view, the most lateral point of the articulating surface of the condyle is used as reference point 0,0.

A polynomial function is then fitted through the points, by first fitting a spline through the points to obtain a smoother set of points for the polynomial function as it minimizes the input error caused when the points are not plotted correctly. The coefficients of a polynomial f(x) of degree n that fit the data f(x(i)) to y(i)) in a least squares sense are then determined. The result f is a vector of length n+1 containing the polynomial coefficients in descending powers.

The degree of the polynomials used was determined by examining the behaviour of different polynomials. A 4th order polynomial was selected to describe the condyles in axial view as well as the distal portion of the sagittal

view. A 3rd order polynomial was selected to describe the posterior portion of the condyle in sagittal view. This is possible as the posterior portion is shorter than the distal portion and thus requires less points for the polynomial fit.

By way of example, the polynomial coefficients for the distal part of the medial condyle may take the following form:

0.000027635156
0.003003981024
0.127257251768
2.474252809130
-3.444357771621

The articulating surfaces of the healthy femurs obtained through the CT imaging and cadaveric specimens are analysed in this way to build up the database and the coefficients of each part of each knee as well as the corresponding reference measurements are then used as input to the pattern recognition algorithm, for instance the SOM.

The SOM is known in the art and is a type of neural network that is trained using unsupervised learning. Its operation is apparent to those skilled in the art and need not be described in detail here. The SOM attempts to implement the orderly mapping of high-dimensional data onto a regular low-dimensional grid in order to identify hidden relationships between the high-dimensional data. Thus the SOM produces a 2-dimensional representation of the input space, called a map. In this invention the SOM is used to produce a map consisting of the coefficients of the polynomials and other reference measurements. These reference measurements are the only measurements taken on the unhealthy knee and are the input to the SOM.

The SOM is trained with the data in the database which consists of the polynomial coefficients and the reference measurements. The SOM then

attempts to find relationships between the parameters. After training, when the SOM is presented with the input of the reference measurement as described above, it first compares the measurements to find the closest reference measurements and then uses the relationships it has determined to estimate the original articulating surfaces of the unhealthy knee. These it presents as polynomial coefficients and are subsequently used to design the prosthesis as described in more detail below.

To illustrate the method, a cadaveric specimen was chosen as the unhealthy knee even though it is in fact a healthy knee. The reference measurements were determined using Mimics. The SOM algorithm was used to estimate what the original knee surfaces would look like given these reference measurements as the input. Figures 2 to 5 illustrate the results compared to the actual knee surfaces where Figure 2 is a plot of the lateral condyle in sagittal view, Figure 3 is a plot of the medial condyle in sagittal view, Figure 4 is a plot of the lateral condyle in axial view and Figure 5 is a plot of the lateral condyle in axial view. From these it will be noted that reasonably accurate surfaces compared to the original knee surfaces were produced.

The output of the SOM algorithm is a set of coordinates relating to each polynomial. These coordinates are stored as points in a spreadsheet and are used to design the articulating surfaces of the prosthesis. The number of points representing each polynomial can be chosen keeping in mind that more points will give more detail and less points will result in a smoother surface. The points are, in this embodiment, imported into Inventor Professional 2008 (Autodesk), a CAD package used to make solid model designs.

As indicated, the SOM output is a set of coordinates describing the articulating surfaces of the femoral condyle in the sagittal plane and the axial plane. It is however necessary to consider the patient's condyle curvatures in the anterior/posterior plane. This curvature plays an important role in the

knee kinematics as the contact areas/points of articulation between the femoral condyles and the tibial surface also follow a curved path. Being individual to each knee, this curvature is, however, generally not taken into account in conventional prostheses and can sometimes lead to the femoral component not fitting on the condyle.

Condyle curvature is included in the design of the prosthesis when the reference measurements are made in Mimics by plotting four points on each femoral condyle. The first point is placed in the middle of the most posterior part of the condyle. The second point is placed in the middle of the most proximal part of articulation and a third point is placed in the middle of the most distal point of articulation. The latter point can generally be found on the lateral condyle where a distinct bump is present. A fourth point is placed in the middle about halfway between points one and three. Points one and four will also define the length of the final component to ensure that the length is also specific to the patient.

These points are then used to create polynomials describing the curvature. A 2nd order polynomial (a parabola) is used to describe the curvature of the lateral condyle and a 3rd order polynomial is used to describe the curvature of the medial condyle. This is because the curvature tends to be pronounced on the medial side. The same methods are used to derive the polynomials as is the case with the sagittal and axial surfaces.

The final output from the Matlab algorithm is a spreadsheet containing two sets of coordinates for each condyle. The first set describes the axial view in two dimensions. The second set describes the sagittal view and coronal view using three dimensions. Table 1 gives an example of the output for the medial condyle.

Table 1: SOM output for medial condyle

Axial	Plane
X	Y
0	0.11175
2.4	2.468013
4.8	4.155465
7.2	5.313893
9.6	6.056008
12	6.467444
14.4	6.606762
16.8	6.505444
19.2	6.167899
21.6	5.571459
24	4.66638
26.4	3.375844
29.18652	1.332835

Sagittal-	Coronal	Plane
X	Y	Z
12.96861	1.248736	13.86954
13.11241	2.748736	12.18014
13.2562	4.248736	9.615039
13.4	5.748736	5.075054
14.04608	2.087222	12.16385
14.097	3.887222	9.617855
14.39354	5.524435	5.393495
14.37684	6.592046	0.823685
14.44443	5.380631	-6.10184
14.36862	1.815358	-12.5208
14.10721	-2.05278	-16.634
13.63982	-5.90206	-18.8287
12.8253	-10.1528	-20.2126
11.57859	-14.5648	-21.2482
10.10446	-18.3953	-21.9651
7.571316	-23.3553	-22.1249
5.128729	-27.0906	-20.7737

The number of coordinate points can be selected by the operator as can the direction of the curvature based on whether it is for a right knee or a left knee.

The output is imported into Inventor and the axial plane coordinates are imported when in 2D sketch mode while the sagittal- coronal plane coordinates are imported when in 3D sketch mode. Hereafter a spline is fitted through the points. This is first done for the axial view and the resulting spline represents the articulating surface of the femoral condyle in the axial plane. In order to make a solid part, a thickness is then added to the surface. This is accomplished by offsetting the articulating surface spline to the inside. A thickness of 5 mm is typically used.

Next a spline is fitted through the sagittal- coronal plane points. This is done in the 3D sketch mode. The axial plane sketch is positioned to be at the most posterior point of the sagittal- coronal spline, with its midpoint lying on the

spline. Using the sweep function in Inventor a solid model is created. The sweep function uses a closed profile, in this case the axial plane sketch, and sweeps it along a chosen path. In this case the path is the sagittal- coronal plane spline which lies in three dimensional space. After the sweep function is completed, the sharp edges are rounded using the fillet option. A small cylinder is placed in the inside of the part, on the most posterior point. This helps in aligning the part for the bone-prosthesis interface as described below. Figure 8 shows the solid part created in Inventor.

The bone-prosthesis interface is the surface of the prosthesis directly in contact with the patient's femoral condyle. Currently most designs require the femoral condyles to be reshaped to fit the implant with the bone being squared-off to fit complementary surfaces on the prosthesis. These shapes are restricted by the surgical techniques currently available and cause uneven stress distribution.

To avoid uneven stress distribution, and to minimize bone loss, a patient specific bone-prosthesis interface is used. The Inventor model is imported into 3matic version 4.3 (Materialise, Leuven, Belgium) together with the Mimics model of the patient's femur. The femoral component is then moved into the desired implant position using the N points registration function. This function allows a number of points on the one object which should lie flush with the corresponding number on the second object to be defined. In this embodiment, the first point is chosen as the most posterior point on the femur. This is a point which is easily identifiable. The corresponding point on the component is in the middle of the small cylinder placed there for this purpose. Points 2, 3 and 4 are then placed to help with the positioning.

Once the points are placed, and the function applied the prosthesis snaps into position. Further manual translation and rotation movements can be applied to ensure the prosthesis is in the desired position. This will be the position in which the prosthesis will be implanted. The prosthesis is also

moved to ensure that the entire inside surface intersects with the outer surface of the femoral condyle. Figure 9 shows two views of the component in the desired position.

Once the component is in the desired position, the cut function is used to cut the surface of the femur into the component. Thus, the femur is the cutting object and the component is the object being cut. Performing this action produces a bone-prosthesis interface surface on the component complementary to the femoral condyle surface produced by the CT scan. In theory the component should fit perfectly on the patient's condyle once all the cartilage is removed, as shown in Figure 10. There is, however, usually some detail lost in the CT scan and reconstruction in Mimics.

The final thickness of the part will be the 5 mm of the original Inventor model minus the volume cut away to form the complementary interface surface. The thickness will thus vary throughout the component. If desired, an analysis can be performed in 3matic to check the thickness to ensure that it stays above a certain limit for strength considerations.

Many different methods exist for fixing the prosthesis to the condyle. Most are successful and there is no clearly superior method. The designs generally include one or more posts extending from the prosthesis and which locate in complementary sockets formed in the condyle. Variations to the shape of the post and provision of webs between the post and prosthesis are provided by each of the different designs.

A further consideration in this regard is whether to use cemented or cementless fixation. Cemented fixation relies on fast-curing bone cement and a solid mechanical bond to hold the prostheses in place. The cement is usually pressed into the distal femoral surfaces and on the inner surface of the prosthesis. Cementless fixation relies on bone growing into the special

surface topography to hold the prostheses in place. Cemented fixation shows a slight advantage in terms of avoiding component loosening.

The provision of a custom bone-prosthesis interface should permit a better fit and hence a smaller post or fin for fixing. It is considered that the optimal fixation method is a thin fin as it produces the largest contact area with the lowest volume. This ensures minimal bone removal and a greater contact area for the fixation. However, strength calculations need to be performed to prevent failure under load. While a post with a small diameter can also give a large contact area with low volume, a post in conjunction with a fin provides superior strength but may be the poorest design in terms of volume. Any suitable method can be used to fix the prosthesis in place.

Once the model is completed, a rapid prototyping process is used to manufacture the prosthesis. Preferred materials are a suitable stainless steel, cobalt chrome and titanium. However, any suitable material and process can be used including the use of CNC devices and the like. The apparatus used will preferably be capable of receiving instructions in a digital format directly from the system used to design the prosthesis.

The tibial component does not form part of the current invention. It is, however, envisaged that a polyethylene articulating surface with an all polyethylene insert or a metal-backed tibial (MBT) base plate will be used. The tibial base plate as well as the polyethylene insert will be customized to ensure for a better fit, and higher contact area in order to prevent loosening and wear. This can be done using the CT image data.

The prosthesis of the invention allows close reproduction of the original knee surface in a very effective manner. This permits near natural articulation of the knee which in turn reduces discomfort and stress loading resulting in bone failure.

It will be appreciated, however, that many other methods of designing a knee prosthesis, particularly regarding the type of imaging used, the manner in which the database is searched and the type and of information which is stored in the database. Also any suitable mathematical method of modelling the prosthesis can be used. For example, instead of using polynomials to define the articulating surfaces, one or more planes can be passed through the knee and the coordinates of intersection of the articulating surface with the planes recorded. A spline can then be fitted, possibly using a least squares method, through the coordinates for each plane. The average for the planes is then calculated and the curve which is obtained is then segmented, into say 1mm sections, and a centre and radius determined for each section. These are plotted and define the articulating surface. Of course many other suitable modelling methods exist.

The invention also provides a method of providing a prosthesis for a knee which includes imaging a patient's knee in a healthy condition and storing the image. Imaging by way of, for example, a CT scan allows a detailed 3-dimesional image of the knee to be obtained, which provides sufficient information to permit fabrication of a prosthesis directly from the image. Should the patient later require a prosthesis, one can be fabricated using the stored information. The resultant prosthesis will accurately duplicate the original knee.

Patients at high risk of suffering knee damage, such as professional sports players and those with a history of osteoarthritis can thus store images of their knees in a healthy condition to be used in the event of injury or damage. However, any person could "insure" themselves against knee injury or damage in this way.

The stored information may be updated periodically to take into account any changes to the knees. This in itself may act as an early diagnostic tool to indicate diseases or disorders. The information store will preferably be

accessible from remote locations to enable information to be received and sent irrespective of the location of the patient imaging facility or fabrication facility. Thus the information store will preferably be accessible through a public communications network, such as the Internet, and may require a fee to be paid for the use thereof.

The information stored need not be the CT image but could include information derived from the image, such as mathematical functions defining its articulating surfaces as described above. Fabrication of the prosthesis can take place by way rapid prototyping or any other suitable process.

CLAIMS

1. A method of designing a knee prosthesis which includes
imaging a knee;
comparing a number of features of the imaged knee to corresponding features of a plurality of reference knees;
selecting the features which most closely correspond to those of the imaged knee; and
modelling the prosthesis to have an external geometry at least similar to the knee associated with the or each selected feature.

2. A method of designing a knee prosthesis as claimed in claim 1 in which the imaging is three-dimensional.

3. A method of designing a knee prosthesis as claimed in claim 1 or claim 2 in which the prosthesis includes an external, articulating surface.

4. A method of designing a knee prosthesis as claimed in any one of the preceding claims in which the features compared include the anterior length on the medial (APM) and lateral (APL) sides, the medio-lateral length (ML) and the distance between the most anterior points on the medial and lateral condyles (DAC).

5. A method of designing a knee prosthesis as claimed in any one of the preceding claims in which the articulating surface of each reference knee is represented as a mathematical function.

6. A method of designing a knee prosthesis as claimed in claim 5 in which the articulating surface of the prosthesis is modelled using the mathematical function associated with each selected feature.

7. A method of designing a knee prosthesis as claimed in any one of the preceding claims in which a pattern recognition algorithm is used to compare the features of the imaged knee to the corresponding features of the reference knees and to interpolate an external geometry for the prosthesis from those associated with the selected features.

8. A method of designing a knee prosthesis as claimed in claim 7 in which the pattern recognition algorithm is a self organising map (SOM).

9. A knee prosthesis manufactured in accordance with a design as claimed in any one of the preceding claims.

10. A method for providing a prosthesis for a knee which includes obtaining information relating to the knee in a healthy condition, storing the information, and at a later time fabricating the prosthesis based on the stored information.

11. A method as claimed in claim 10 wherein information includes an image of the knee.

12. A method as claimed in claim 11 or claim 12 wherein the information is updated periodically.

Figure 1

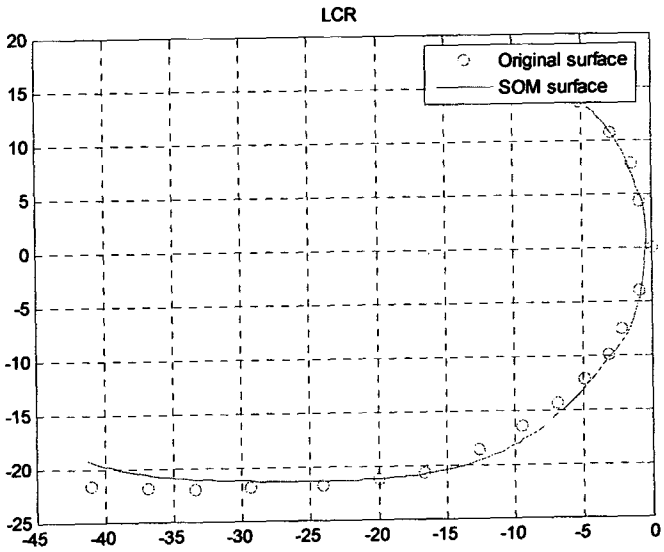

Figure 2

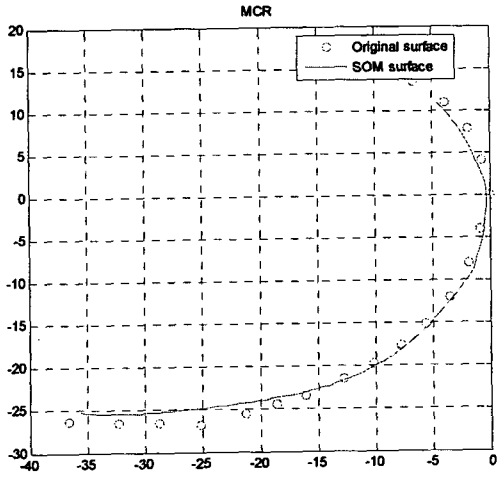

Figure 3

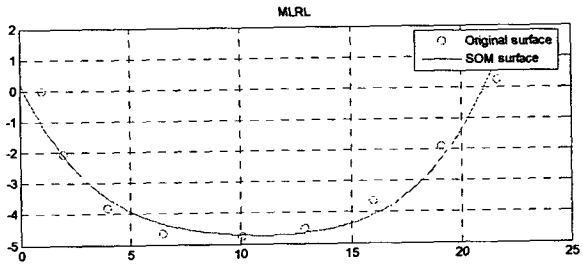

Figure 4

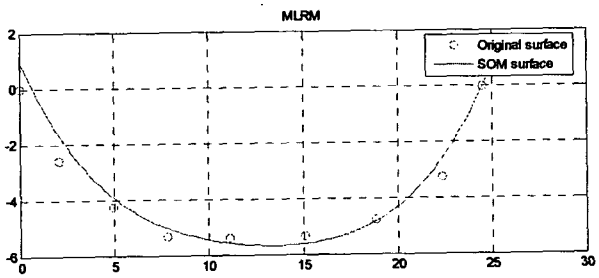

Figure 5

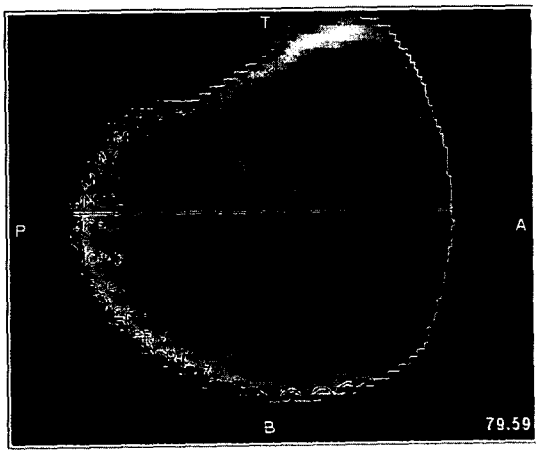

Figure 6

Figure 7

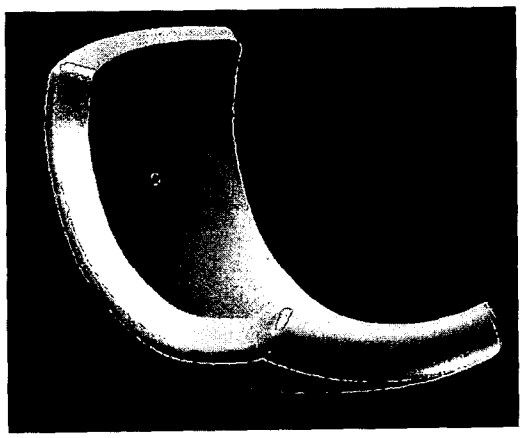

Figure 8

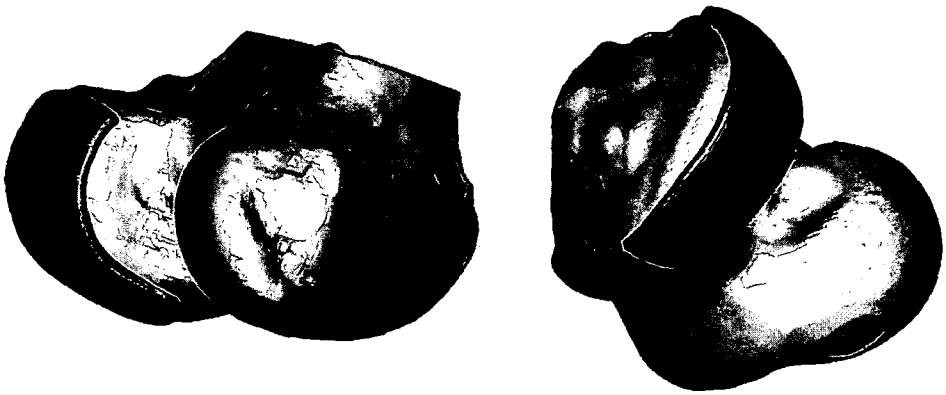

Figure 9

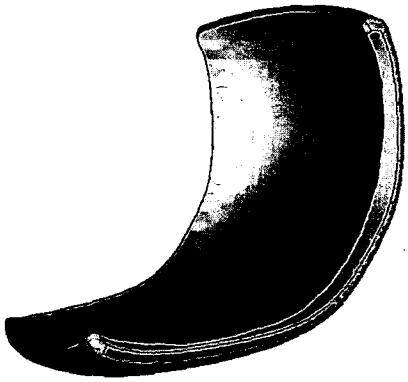

Figure 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2010/001218

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61F 2/38 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPI, EPODOC: IPC and EC A61F2/30/low & Keywords: arthroplasty, imaging, scan, map, computer, database, library, population, reference, articulate, surface, knee, natural, healthy, personal, individual; and like terms.
GOOGLE PATENTS & Keywords: arthroplasty, prosthesis, articulate, surface, library, imaging, record; and like terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 5735277 A (SCHUSTER) 7 April 1998	
X	Column 2, lines 8-17, 29-32 and 56-62; column 3, lines 5-20; claim 6	1-3, 9
Y		4-8
Y		10-12
	EP 1074229 B1 (SCHUSTER) 5 October 2005	
X	Claims 1, 3 and 5	1-3, 9
	US 4936862 A (WALKER et al.) 26 June 1990	
Y	Column 2, lines 40-46; column 3, lines 2-4; column 5, lines 58-61; column 6, lines 18-32	4-8
	US 2006/0229918 A1 (FOTSCH et al.) 12 October 2006	
Y	Abstract; paragraphs [0016], [0017], [0022] and [0023]	10-12

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 November 2010	16 NOV 2010
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **WAN KIT CHAN** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2974

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2010/001218

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6786930 B2 (BISCUP) 7 September 2004 Whole document	
A	US 2007/0276501 A1 (BETZ et al.) 29 November 2007 Whole document	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2010/001218

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

As reasoned on the extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box 1
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-9 are directed to a method of designing a knee prosthesis which includes imaging a knee, comparing the imaged knee to a plurality of reference knees then modelling the prosthesis based on the features of the closest knee. It is considered that *comparing the features of the imaged knee to a plurality of reference knees then modelling the prosthesis based on the features of the closest knee* comprises a first distinguishing feature.

- Claims 10-12 are directed to a method of providing a prosthesis which includes storing the information of a healthy knee and at a later time fabricating the prosthesis based on the stored information. It is considered that *fabricating a prosthesis based on the stored information of a healthy knee* comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/IB2010/001218

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5735277	DE	4434539	EP	0704193		
EP	1074229	NONE					
US	4936862	US	4822365				
US	20060229918	US	20040181428	US	20040181430	US	20050165627
		US	20060143052	WO	2006102206	WO	2007024555
US	6786930	US	20040117015	US	20040167637		
US	20070276501	EP	2029059	WO	2007139949		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX