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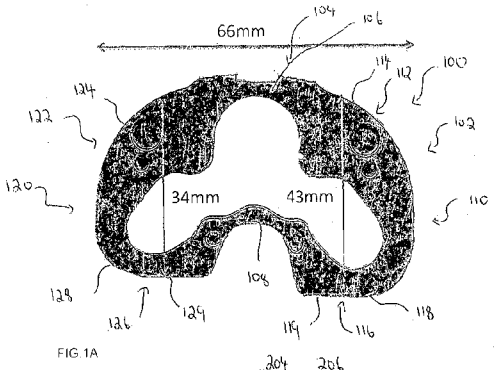

FIG. 1A

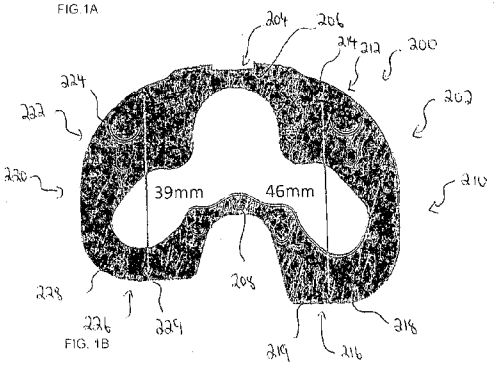

FIG. 1B

(57) Abstract: A tibial tray comprises an asymmetrical body comprising a medial section and a lateral section; the medial section comprising a medial overlay and a posteromedial shoulder; the lateral section comprising a lateral overlay and a posterolateral shoulder; both the medial section and lateral section comprising a shape and size to increase tibial coverage and reduce posterolateral overhang. Also provided is a method of producing or designing the tibial tray to have suitable dimensions to fit a wide distribution of the human population.

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TITLE

SURGICAL IMPLANT, METHOD OF SURGERY AND METHOD OF DESIGNING A SURGICAL IMPLANT

FIELD

THIS INVENTION described herein relates generally to a surgical implant, method of surgery using such an implant and a method of designing a surgical implant. In particular, the invention is directed to an asymmetric tibial tray with equal or improved tibial plateau coverage and reduced posterolateral overhang, although the scope of the invention is not necessarily limited thereto.

BACKGROUND

Total knee arthroplasty (TKA) or total knee replacement (TKR) is a surgical technique in which a surgical implant is inserted to replace the knee. The surgical implant includes a tibial tray or plate. Various tibial trays are available; however the available trays all have disadvantages.

Most current tibial trays have a symmetric shape. Asymmetric trays have been designed in an attempt to improve the coverage of the native tibial bone. However, the fit of even these asymmetric trays is not ideal. An improved asymmetric tibial tray is required.

SUMMARY

The present invention is broadly directed to an asymmetric tibial tray. The present inventors have realised that an asymmetric tibial tray provides equal or greater tibial plateau coverage and decreased posterolateral oversizing and/or overhang which may reduce or avoid the problems associated with other tibial trays such as, subsidence, bone bleeding, soft tissue impingement, loss of knee extension and pain.

In one aspect, there is provided a tibial tray comprising:

an asymmetrical body comprising a medial section and a lateral section;

the medial section comprising a medial overlay and a posteromedial shoulder;

the lateral section comprising a lateral overlay and a posterolateral shoulder;

both the medial section and lateral section comprising a shape and size to increase tibial coverage and reduce posterolateral overhang.

In a second aspect the invention provides a method for making a tibial tray including:

forming an asymmetrical body comprising a medial section and a lateral section;

the medial section comprising a medial overlay and a posteromedial shoulder;

the lateral section comprising a lateral overlay and a posterolateral shoulder;

both the medial section and lateral section comprising a shape and size to increase tibial coverage and reduce posterolateral overhang, to thereby make the tibial tray.

In a third aspect the invention provides a method for knee arthroplasty or reconstruction including inserting a tibial tray according to the first aspect or a tibial tray made according to the second aspect into a knee joint in need of arthroplasty or reconstruction, to thereby perform the knee arthroplasty or knee reconstruction.

In a fourth aspect the invention provides a kit comprising the tibial tray according to the first aspect or made according to the second aspect.

The kit of the fourth aspect may also comprise instructions for use.

According to any above aspects the posteromedial and/or posterolateral shoulder profiles may comprise a gently curved or substantially straight section.

According to any above aspects the medial and/or lateral overlays may comprise a gently curved or straight section.

According to any of the above aspects the gently curved or substantially straight section of the shoulder profiles and/or the overlays may comprise a radius of curvature of, or greater than, approximately or about 4.0-12.0 cm. In some embodiments, this may be approximately or about 5.175, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5 or 10.0 cm.

According to any of the above aspects the radius of curvature may be selected to increase tibial coverage and/or reduce posterolateral overhang.

According to any above aspects the tibial tray may comprise a mediolateral length of between approximately or about 60 and 90mm.

In preferred aspects the mediolateral length may be approximately or about 66, 71 or 80mm.

According to any above aspect the medial section may comprise a medial section anteroposterior width of between approximately or about 40 and 65 mm.

In preferred aspects the medial section anteroposterior width may be approximately or about 43, 44, 46, 50, 51 or 55mm.

According to any above aspect the lateral section may comprise a lateral section anteroposterior width of between approximately or about 30 and 55 mm.

In preferred aspects the mediolateral section may comprise a lateral section anteroposterior width of approximately or about 34, 39, 40, 42, 44 or 48mm.

According to any above aspect the medial aspect ratio may be between approximately or about 0.6 and 0.75. Suitably, this is a ratio of the anteroposterior distance of the medial tibial plateau (typically parallel to the anteroposterior axis of the tibia from the medial-middle 1/3 of patellar tendon to posterior cruciate ligament insertion) to the mediolateral tibial width.

In preferred aspects the medial aspect ratio may be approximately or about 0.62, 0.625, 0.651, 0.688, 0.697 or 0.718.

According to any above aspect the lateral aspect ratio may be between approximately or about 0.5 and 0.65. Suitably, this is a ratio of the anteroposterior distance of the lateral tibial plateau (typically parallel to the anteroposterior axis of the tibia from the medial-middle 1/3 of patellar tendon to posterior cruciate ligament insertion) to the mediolateral tibial width.

In preferred aspects the lateral aspect ratio may be approximately or about 0.515, 0.525, 0.563, 0.591, 0.6 or 0.62.

A preferred tibial tray according to any above aspect may have a mediolateral length of 66mm, a medial section anteroposterior width of 43mm, a lateral section anteroposterior width of 34mm, a medial aspect ratio of 0.652 and a lateral aspect ratio of 0.515.

Another preferred tibial tray according to any above aspect may have a mediolateral length of 66mm, a medial section anteroposterior width of 46mm, a lateral section anteroposterior width of 39mm, a medial aspect ratio of 0.697 and a lateral aspect ratio of 0.591.

Another preferred tibial tray according to any above aspect may have a

mediolateral length of 71 mm, a medial section anteroposterior width of 44mm, a lateral section anteroposterior width of 40mm, a medial aspect ratio of 0.62 and a lateral aspect ratio of 0.563.

Another preferred tibial tray according to any above aspect may have a mediolateral length of 71mm, a medial section anteroposterior width of 51mm, a lateral section anteroposterior width of 44mm, a medial aspect ratio of 0.718 and a lateral aspect ratio of 0.62.

Another preferred tibial tray according to any above aspect may have a mediolateral length of 80mm, a medial section anteroposterior width of 50mm, a lateral section anteroposterior width of 42mm, a medial aspect ratio of 0.625 and a lateral aspect ratio of 0.525.

Another preferred tibial tray according to any above aspect may have a mediolateral length of 80mm, a medial section anteroposterior width of 55mm, a lateral section anteroposterior width of 48mm, a medial aspect ratio of 0.688 and a lateral aspect ratio of 0.6.

In a fifth aspect the invention provides a method for designing a surgical implant or prosthesis, the method including:

interrogating a data set comprising sizing information for the population into which the surgical implant is to be implanted to obtain one or more dimensions for the surgical implant;

based on the obtained one or more dimensions designing the surgical implant.

The method of the fifth aspect may further include the step of interrogating imaging data set to obtain the sizing information.

In a sixth aspect the invention provides a surgical implant or prosthesis designed by the method of the sixth aspect.

The surgical implant may be a tibial tray.

In a seventh aspect the invention provides a method for designing a size range to cover or partially cover a normally distributed population, the method including:

interrogating a data set comprising sizing information on a normally distributed population to obtain one or more dimensions;

determining an upper value and lower value from the obtained one or more

dimensions;

dividing the range between the upper value and the lower value into a number of sizes to thereby design the size range.

According to the seventh aspect the sizing profile may be for a surgical implant or prosthesis.

In an eighth aspect the invention provides a surgical implant comprising a size designed according to the eighth aspect.

As used herein, except where the context requires otherwise, the term "comprise" and variations of the term, such as "comprising", "comprises" and "comprised", are not intended to exclude further additives, components, integers or steps.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the present invention may be readily understood and put into practical effect, reference will now be made to the accompanying illustrations, wherein like reference numerals are used to refer to like elements.

FIG. 1A: shows an outline drawing of a tibial tray of size 3 according to one aspect of the invention.

FIG. 1B: shows an outline drawing of a tibial tray of size 4 according to one aspect of the invention.

FIG. 2 shows comparative percent coverage of the asymmetric tibial tray according to the invention.

DETAILED DESCRIPTION

The inventors have recognised that poor fitting tibial trays may have dire consequences. An undersized tibial tray may cause subsidence, bone bleeding and femoral component size matching problems. An oversized tibial tray may cause soft tissue impingement, loss of knee extension and pain.

The inventors have further recognised that an asymmetrical tibial tray provides equal or greater tibial plateau coverage and decreased posterolateral oversizing.

Surprisingly, as exemplified herein, the inventors have provided an asymmetric tray which has an increased tibial coverage compared to other tibial trays

and which has a reduced posterolateral overhang well below that achieved with other tibial trays. The improved tibial tray provided by the inventors is of significant advantage by virtue reducing the incidence of overhang of the tibial tray which thereby eliminates or at least reduces the impingement on and possible trauma to surrounding soft tissue structures. While the principles described herein are based on tibial trays for humans, this invention may also be extended to other mammals such as livestock, performance animals (*e.g.* racehorses) and domestic pets (*e.g.* dogs, cats), although without limitation thereto.

As used herein, the terms "approximately" and "about" refer to tolerances or variances associated with numerical values recited herein. The extent of such tolerances and variances are well understood by persons skilled in the art. Typically, such tolerances and variances do not compromise the structure and/or function of the tibial tray.

As used herein "absolute undersize" means a tibial tray is greater than 3mm undersize.

As used herein "relative undersize" means a tibial tray is between 1 and 3mm undersize.

As used herein "optimal fit" means a tibial tray is less than 1mm over or undersize.

As used herein "relative oversize" means a tibial tray is between 1 and 3 mm oversize.

As used herein "absolute oversize" means a tibial tray is greater than 3mm oversize.

The tibial tray according to the invention comprises asymmetric lateral and medial sections.

FIG. 1A shows one embodiment of a tibial tray 100 according to the invention. Tibial tray 100 comprises a body 102 which comprises a medial section 110 and a lateral section 120 which are located on either side of mid-section 104. Mid-section 104 comprises an anterior mid-section 106 and a posterior mid-section 108.

Medial section 110 comprises a medial overlay 112 and a posteromedial

shoulder 116.

Similarly lateral section 120 comprises a lateral overlay 122 and a posterolateral shoulder 126.

Medial overlay 112 and lateral overlay 122 comprise a medial overlay profile 114 and lateral overlay profile 124, respectively, selected to conform to tibial anatomy. As shown in FIGS. 1A and 1B profiles 114 and 124 are substantially curvilinear. Profiles 114 and 124 comprise a gently curved or substantially straight section 115, 125. The combination of the curved and straight sections result in a better fit once implated into a joint.

Posteromedial shoulder 116 and posterolateral shoulder 126 comprise a posteromedial shoulder profile 118 and a posterolateral should profile 128, respectively, selected to conform to tibial anatomy. Shoulder profiles 114 and 124 also comprise a gently curved or substantially straight section 119, 129. As above, inclusion of the straight sections 119, 129 result in a better fit once implated into a joint.

As shown in FIG. 1A the radius of curvature of gently curved or substantially straight sections 115, 125, 119, 129 is relatively large and approaching a straight line. In other embodiments gently curved or substantially straight sections 115, 125, 119, 129 may comprises a radius of curvature greater than approximately or about 5.175, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5 or 10.0 cm.

The radius of curvature may be selected to increase tibial coverage and/or reduce posterolateral overhang

Medial section 110 and lateral section 120 are asymmetrical. As indicated on FIG. 1A tibial tray 100 has a mediolateral length (ML) of 66mm, a medial section 110 anteroposterior width (AP1) of 43mm and a lateral section 120 anteroposterior width (AP2) of 34 mm. The asymmetrical sizing of tibial tray 100 can be quantified by calculating the medial aspect ratio by dividing AP1/ML and by calculating the lateral aspect ratio by dividing AP2/ML. Tray 100 has a medial aspect ratio of 0.651 and a lateral aspect ratio of 0.515.

As a result of the asymmetrical sizing of medial section 110 and lateral section 120 the 102 is asymmetrical.

Tibial tray 100 is categorised as size A1 and has a different size and different asymmetrical sizing aspect ratio to tibial tray 200 shown in FIG. 1B which is categorised as size A2.

Tibial tray 200 has the same mediolateral length as tray 100, but different an AP1 of 46 mm and an AP2 of 39 mm which gives a medial aspect ratio of 0.697 and a lateral aspect ratio of 0.591.

The tibial tray of the invention may be sized to fit an individual. The tibial tray of the invention may comprise a mediolateral length of between approximately or about 60 and 90mm. The medial section anteroposterior width may be between approximately or about 40 and 65 mm. The lateral section anteroposterior width may be between approximately or about 30 and 55 mm. The medial aspect ratio may be between approximately or about 0.6 to 0.75. The lateral aspect ratio may be between approximately or about 0.5 and 0.65.

Both tray sizes A1 and A2 are classified as small. The asymmetrical tibial tray according to the invention may also be manufactured in medium and large sizes.

Medium size trays are categorized as sizes B1 and B2.

A size B1 tray comprises a mediolateral length of 71 mm, a medial section anteroposterior width of 44mm, a lateral section anteroposterior width of 40mm, a medial aspect ratio of 0.62mm and a lateral aspect ratio of 0.563mm.

A size B2 tray comprises a mediolateral length of 71mm, a medial section anteroposterior width of 51mm, a lateral section anteroposterior width of 44mm, a medial aspect ratio of 0.718mm and a lateral aspect ratio of 0.62mm.

Large size trays are categorized as sizes C1 and C2.

A size C1 tray comprises a mediolateral length of 80mm, a medial section anteroposterior width of 50mm, a lateral section anteroposterior width of 42mm, a medial aspect ratio of 0.625mm and a lateral aspect ratio of 0.525mm.

A size C2 tray comprises a mediolateral length of 80mm, a medial section anteroposterior width of 55mm, a lateral section anteroposterior width of 48mm, a medial aspect ratio of 0.688mm and a lateral aspect ratio of 0.6mm.

The invention also provides a method for making a tibial tray including forming the asymmetrical body comprising the medial section and the lateral section.

Further, the invention provides a method for knee arthroplasty including inserting a tibial tray according to the invention.

The inventors have also provided a kit comprising the tibial tray according to the invention. The kit of the invention may also comprise instructions for use.

The invention also provides a method for designing a surgical implant or prosthesis including interrogating a data set comprising sizing information for the population into which the surgical implant is to be implanted to obtain one or more dimensions for the surgical implant.

Once the one or more dimensions is obtained the surgical implant may be designed.

The method may further include a step of interrogating imaging data to obtain the sizing information. The imaging data may be medical imaging data such as, magnetic resonance imaging, x-ray imaging, positron emission imaging or any suitable imaging method.

The method may further include a virtual testing step in which the designed surgical implant is applied to the data set. The application to the data set may comprise superimposing the designed surgical implant or prosthesis on the data set.

Another method provided by the inventors is for designing a size range to cover or partially cover a normally distributed population. This method may include the steps of interrogating a data set comprising sizing information on a normally distributed population to obtain one or more dimensions and determining an upper value and a lower value from the obtained one or more dimensions.

The range between the upper value and the lower value may then be divided into a number of sizes to thereby design the size range.

The method for designing the sizing range may also include a step of interrogating imaging data to obtain the data set. The imaging data may be magnetic resonance imaging, x-ray imaging, positron emission imaging or any suitable imaging method.

The sizing profile may use the Zimmer concept of odd and even sizing. According to the Zimmer concept odd sizes have a small aspect ratio, i.e. a smaller anteroposterior sizing and even sizes have a larger aspect ratio.

The following non-limiting examples illustrate the tibial tray and methods of the invention. These examples should not be construed as limiting: the examples are included for the purposes of illustration only. The tibial trays and methods discussed in the Examples will be understood to represent an exemplification of the invention.

Examples

Example 1: Study of Tibial Tray Sizing and Bone Coverage

A retrospective magnetic resonance imaging (MRI) study of 101 patients with suspected soft tissue injuries was conducted. The mean age was 31.8 with a range of 17-60 and a male : female ratio of 74 : 27.

Proton density fat suppressed magnetic resonance (MR) images were previously acquired and studied using a GE Hdx 1.5T MRI system (General Electric, Waukesha, WI) and an Osirix Dicom Viewer (version 3.6.1, Osirix Foundation, Geneva). Axial images of tibia identified 8-10mm from the lateral compartment articular surface.

Total knee arthroplasty baseplates were digitally scanned with magnification marker (HP Photosmart C4500 series, Hewlett Packard, Palo Alto, CA). The digital images were superimposed on axial MR cut. There was no anterior, medial or lateral tray oversizing and orientation was on or near Insall's line. Insall's line is a line originating from the junction of the medial 1/3 and lateral 2/3 of the tibial tubercle and extending to the tibial insertion of the posterior cruciate ligament.

Percent Tibial Coverage was calculated as per below:

$$\% \text{ Tibial Coverage} = (CSA_{BASEPLATE} - CSA_{OVERHANG})/CSA_{TIBIAL\ SURFACE}$$

CSA = cross sectional area.

Statistical Analysis was performed with SAS version 9.1 (Cary, NC) using chi-squared testes for comparisons of proportions and paired and unpaired t-tests for comparisons of continuous variables.

Tibial component bone coverage results were as shown in Table 1 below.

There was no correlation between the number of available sites and total coverage ($p=0.3$).

Posterolateral tibial component position results demonstrated that 28.2 % demonstrated an optimal fit (+/- 1mm). The NextGen implant had the least number of

oversized trays in the relative (1-3mm) and absolute (>3mm) groups. The Genesis II implant had the most in both categories. 48.8% had theoretical impingement on the popliteus tendon.

Posteromedial tibial components position results demonstrated that only 7.6% had an optimal fit. Genesis II had significantly more optimal fit compared to all other prostheses used ($p<0.001$). 69.9% had absolute undersizing (>3mm).

This study showed that asymmetric tibial trays (Genesis II) compared to symmetric designs are rotationally aligned and this leads to improved bone coverage and a greater incidence of oversizing.

Example 2: Asymmetric Tibial Tray Design

An asymmetric tibial tray was designed based upon proximal tibial anatomy.

The dimensions and aspect ratios of 346 magnetic resonance images of a knee of 136 females and 210 males with a mean age of 41 (female) and 37 (male) were studied.

The images were classified into three different mediolateral groups: small, medium and large. The Zimmer concept of odd and even sizing was used.

The design was then tested on the 101 knees used in the tibial tray study above.

The results are shown in Table 2 below.

Based on the mediolateral distance (ML) values three groups were identified. In the cohort ML values ranged from 62.3 to 88.6 the difference (26.3) divided by 3 is 8.8. Beginning from 62.3 and increasing in 9mm increments gives ML values of:

1. Small: 62 to 71; 104 patients, mean ML = 68mm
2. Medium: 71 to 80; 140 patients, mean ML = 76.1mm
3. Large: 80 to 89; 102 patients, mean ML = 82.7mm.

The 346 knees were split into three groups to show negligible differences in the aspect ratios. The results are shown in Table 3 below.

This led to formulation of six sizes A1, A2, B1, B2, C1 and C2 with the sizes shown in Table 4 below. Sizes A1 and A2 are small. Sizes B1 and B2 are medium and sizes C1 and C2 are large.

The fit of the tibial trays of the invention are as shown in Table 5 below.

Tibial trays 100 and 200 shown in FIGS. 1A and 1B show the ML, AP1 and AP2 lengths of tibial trays of sizes A1 and A2, respectively.

The percent coverage of the asymmetric tibial tray according to the invention, labeled SKS1, is shown in FIG. 2 as compared to conventional tibial trays.

Comparative posterolateral and posteromedial fits of tibial trays according to the invention, labeled SKS1, are shown in Table 6 below.

The asymmetric tray of the invention is of significant advantage at least because it has an increased coverage compared to other tibial trays. Additionally, posterolateral overhang is reduced well below that achieved with other tibial trays.

Throughout the specification the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. It will therefore be appreciated by those of skill in the art that, in light of the instant disclosure, various modifications and changes can be made in the particular embodiments exemplified without departing from the scope of the present invention.

All computer programs, algorithms, patent and scientific literature referred to herein is incorporated herein by reference.

Table 1: Tibial Component Bone Coverage:

Implant	% Tibial Coverage	Number of sites available
Genesis II	88*	8
LCS	85	8
PPC	85	5
Scorpio	83	7
Triathlon	83	6
NextGen	80	6

* P <0.0001 compared to all other designs in paired t-tests.

Table 2: 210 Male (M) and 136 Female (F) anatomical data

		Mediolateral distance (mm)	Medial plateau anteroposterior distance (AP1) (mm)	Lateral plateau anteroposterior distance (AP2) (mm)	Medial Ratio (AP1/ML)	Lateral Ratio (AP2/ML)
Mean	F	70.9	47.7	41.2	0.673	0.581
	M	78.69	52.2	45.9	0.664	0.585

Min	F	62.3	39.2	34.2	0.592	0.485
	M	63	40.3	32.6	0.580	0.496
Max	F	84.9	60.1	52.8	0.761	0.664
	M	88.6	61.6	53.8	0.739	0.678
SD	F	5.07	3.8	4.0	0.0316	0.0341
	M	4.6	3.7	3.54	0.030	0.0312

Table 3: Differences in Aspect Ratios

	SMALL (ML = 62-71)		MEDIUM (ML = 71-80)		LARGE (ML = 80-89)	
	medial ratio	lateral ratio	medial ratio	lateral ratio	medial ratio	lateral ratio
MEAN	0.676	0.580	0.667	0.586	0.660	0.583
MIN	0.590	0.485	0.592	0.487	0.580	0.496
MAX	0.750	0.664	0.761	0.678	0.737	0.648
STDEV	0.02983	0.03375	0.030	0.0327	0.0316	0.03052

Table 4: Sizes and Aspect Ratios of Tibial Plate

Size on medial and lateral tibial plateau						
Size	A1	A2	B1	B2	C1	C2
Mediolateral width (mm)	66	66	71	71	80	80
Medial plateau anteroposterior depth (mm)	43	46	44	51	50	55
Lateral plateau anteroposterior depth (mm)	34	39	40	44	42	48
Medial Aspect Ratio	0.652	0.697	0.62	0.718	0.625	0.688
Lateral Aspect Ratio	0.515	0.591	0.563	0.62	0.525	0.6

Table 5: Fit of Tibial Tray

Size		Fit	Size		Fit	Size		Fit
A1	ML	88/104 in small	B1	ML	140/140 in medium	C1	ML	102/102 in large
	AP1	96/104 in small		AP1	139/140 in medium		AP1	97/102 in large
	AP2	103/104 in small		AP2	133/140 in medium		AP2	101/102 in large
A2	ML	88/104 in small	B2	ML	140/140 in medium	C2	ML	102/102 in large
	AP1	47/104 in small		AP1	71/140 in medium		AP1	48/102 in large
	AP2	59/104 in small		AP2	81/140 in medium		AP2	60/102 in large

Table 6: Comparative posterolateral (PL) and posteromedial (PM) fit:

	Absolute undersizing		Relative undersizing		Optimal sizing		Relative oversizing		Absolute oversizing	
	PL	PM	PL	PM	PL	PM	PL	PM	PL	PM
NextGen	8	90	33	8	34	2	22	1	5	0
LCS	2	71	13	21	32	7	37	2	17	0
PFC	10	87	18	12	29	1	33	1	10	0
Scorpio	4	76	19	20	26	3	32	2	20	0
Triathlon	3	68	17	22	25	9	35	2	21	0
Genesis II	1	30	11	32	25	24	38	14	26	1
NK	14	43	27	32	29	19	22	7	9	0
SKS1	28	49	37	37	31	14	4	1	1	0

CLAIMS

1. A tibial tray comprising:

an asymmetrical body comprising a medial section and a lateral section;

the medial section comprising a medial overlay and a posteromedial shoulder;

the lateral section comprising a lateral overlay and a posterolateral shoulder;

both the medial section and lateral section comprising a shape and size to increase tibial coverage and reduce posterolateral overhang.

2. A method for making a tibial tray including:

forming an asymmetrical body comprising a medial section and a lateral section;

the medial section comprising a medial overlay and a posteromedial shoulder;

the lateral section comprising a lateral overlay and a posterolateral shoulder;

both the medial section and lateral section comprising a shape and size to increase tibial coverage and reduce posterolateral overhang, to thereby make the tibial tray.

3. The tibial tray of Claim 1 or the method of Claim 2, wherein the posteromedial and/or posterolateral shoulder profiles may comprise a curved and/or a substantially straight section.

4. The tibial tray of Claim 1 or Claim 3 or the method of Claim 2 or Claim 3, wherein the medial and/or lateral overlays may comprise a curved or straight section.

5. The tibial tray or method of Claim 3 or Claim 4, wherein the curved or substantially straight section(s) of the shoulder profiles and/or the overlays may comprises a radius of curvature be selected to increase tibial coverage and/or reduce posterolateral overhang.

6. The tibial tray or method of Claim 5, wherein the radius of curvature is in a range of approximately or about 4.0-12.0 cm.

7. The tibial tray or method of any preceding claim, wherein the tibial comprises a mediolateral length of between approximately or about 60 and 90mm.

8. The tibial tray or method of any preceding claim, wherein the medial section comprises a medial section anteroposterior width of between approximately or about

40 and 65 mm.

9. The tibial tray or method of any preceding claim wherein the lateral section comprises a lateral section anteroposterior width of between approximately or about 30 and 55 mm.

10. The tibial tray or method of any preceding claim having a medial aspect ratio between approximately or about 0.60 and 0.75.

11. The tibial tray or method of any preceding claim having a lateral aspect ratio between approximately or about 0.50 and 0.65.

12. The tibial tray or method of any preceding claim, the tibial tray having: (i) a mediolateral length of approximately or about 66mm, a medial section anteroposterior width of approximately or about 43mm, a lateral section anteroposterior width of approximately or about 34mm, a medial aspect ratio of approximately or about 0.652 and a lateral aspect ratio of approximately or about 0.515: (ii) a mediolateral length of approximately or about 66mm, a medial section anteroposterior width of 46mm, a lateral section anteroposterior width of approximately or about 39mm, a medial aspect ratio of approximately or about 0.697 and a lateral aspect ratio of approximately or about 0.591; (iii) a mediolateral length of approximately or about 71 mm, a medial section anteroposterior width of approximately or about 44mm, a lateral section anteroposterior width of approximately or about 40mm, a medial aspect ratio of approximately or about 0.62 and a lateral aspect ratio of approximately or about 0.563; (iv) a mediolateral length of approximately or about 71mm, a medial section anteroposterior width of approximately or about 51mm, a lateral section anteroposterior width of 44mm, a medial aspect ratio of approximately or about 0.718 and a lateral aspect ratio of approximately or about 0.62;(v) a mediolateral length of approximately or about 80mm, a medial section anteroposterior width of approximately or about 50mm, a lateral section anteroposterior width of 42mm, a medial aspect ratio of approximately or about 0.625 and a lateral aspect ratio of approximately or about 0.525; or (vi) a mediolateral length of approximately or about 80mm, a medial section anteroposterior width of approximately or about 55mm, a lateral section anteroposterior width of approximately or about 48mm, a medial aspect ratio of

approximately or about 0.688 and a lateral aspect ratio of approximately or about 0.6.

13. A method for knee arthroplasty or reconstruction including inserting a tibial tray according to any one of Claims 1-12 or produced according to the method of any one of Claims 2-12, into a knee joint in need of arthroplasty or reconstruction, to thereby perform the knee arthroplasty or knee reconstruction.

14. A kit comprising a tibial tray according to any one of Claims 1-12 or produced according to the method of any one of Claims 2-12 and instructions for use.

15. A method for designing a surgical implant or prosthesis, the method including:

interrogating a data set comprising sizing information for the population into which the surgical implant is to be implanted to obtain one or more dimensions for the surgical implant; and

based on the obtained one or more dimensions designing the surgical implant.

16. The method of Claim 15 which further includes the step of interrogating imaging data set to obtain the sizing information.

17. The method of Claim 15 or Claim 16, wherein the surgical implant or prosthesis is the tibial tray of any one of Claims 1-12.

18. A method for designing a sizing profile for a surgical implant or prosthesis to cover or partially cover a normally distributed population, the method including:

interrogating a data set comprising sizing information on a normally distributed population to obtain one or more dimension;

determining an upper value and lower value from the obtained one or more dimension;

dividing the range between the upper value and the lower value into a number of sizes to thereby design the size range.

19. The method of Claim 18, wherein the surgical implant or prosthesis is the tibial tray of any one of Claims 1-12.

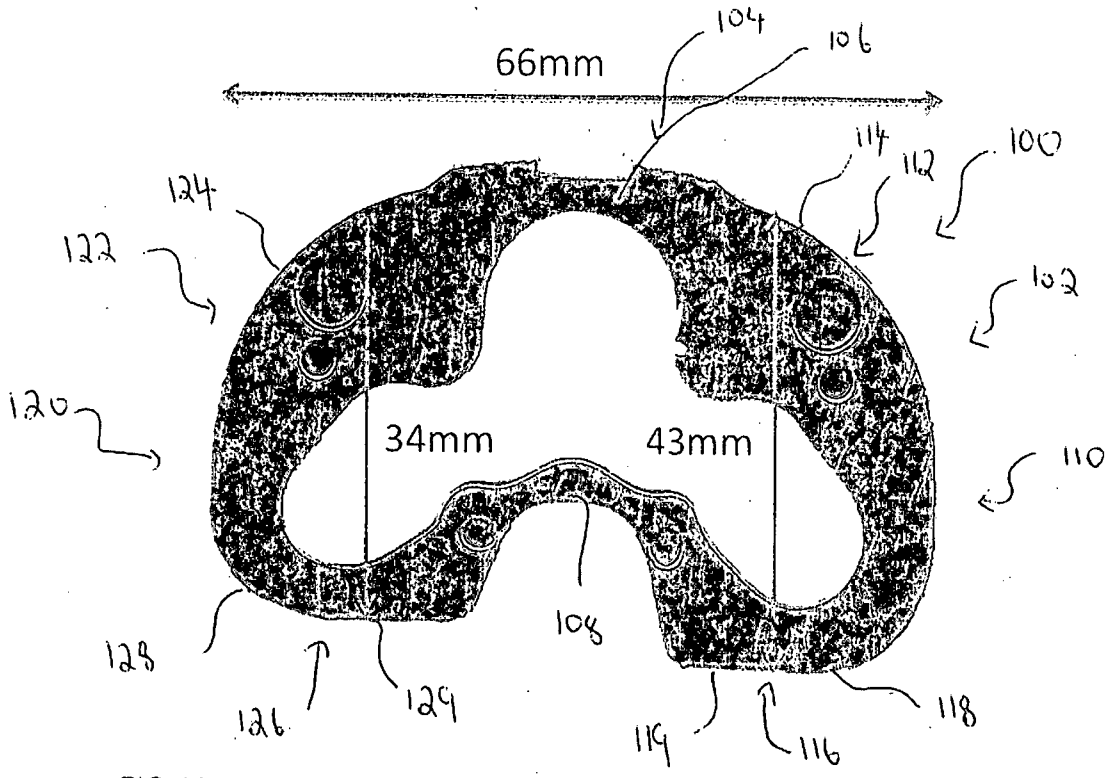
66mm
104
106
114
112
100
124
122
102
120
34mm
43mm
110
108
128
126
129
119
116
118

FIG.1A

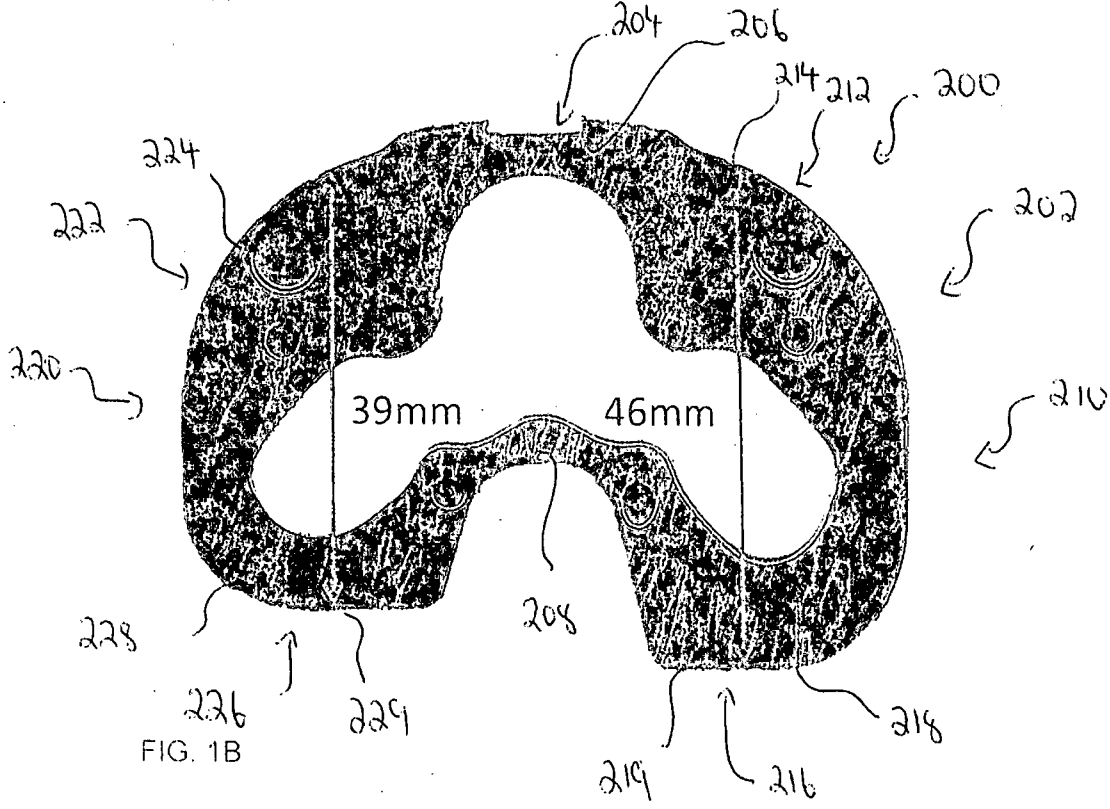
204
206
214
212
200
224
222
202
220
39mm
46mm
210
208
228
226
229
219
216
218

FIG. 1B

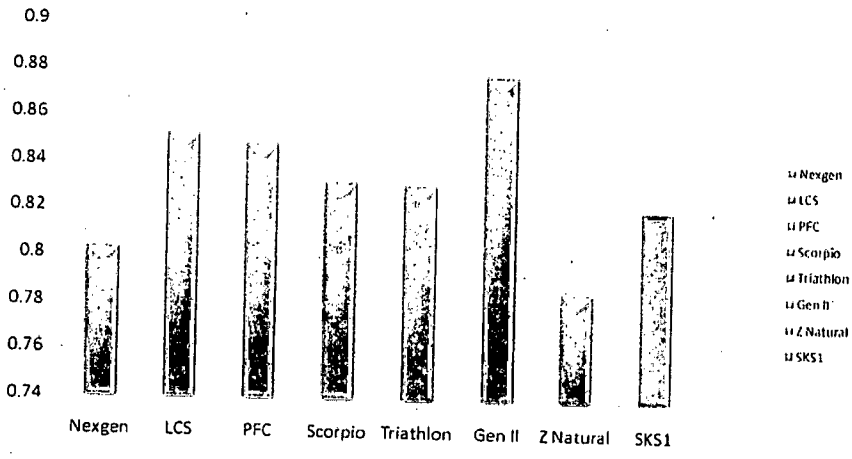
0.9
0.88
0.86
0.84
0.82
0.8
0.78
0.76
0.74
Nexgen
LCS
PFC
Scorpio
Triathlon
Gen II
Z Natural
SKS1

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2013/001217

A. CLASSIFICATION OF SUBJECT MATTER

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)

EPODOC and WPI: Overhang, tibia, tray, asymmetrical

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[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
6 January 2014	06 January 2014

Name and mailing address of the ISA/AU

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Telephone No. 0262832352

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2013/001217**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/018567 A1 (ZIMMER, INC.) 09 February 2012 Figures 2, 3, 5 and 6, and paragraphs [0009], [0041], [0043], [0045], [0056] and [0086].	1-14
X	US 2011/0087332 A1 (BOJARSKI et al.) 14 April 2011 Figures 163, 164, 165A and 165C, paragraphs [0882] - [0884]	1-14
X	US 2012/0035735 A1 (SANFORD et al.) 09 February 2012 Figures 47-55 and 57-62, paragraphs [0018] and [0089] - [0091]	1-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2013/001217

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:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

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:

See Supplemental Box for Details

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.:
1-14

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

Continuation of: **Box 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.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-14 are directed to a tibial tray, or a method of making a tibial tray, shaped and sized to increase tibial coverage and reduce posterolateral overhang. The feature of shaping and sizing a tibial tray is specific to this group of claims.

- Claims 15-19 are directed to any surgical implant or prosthesis designed from an interrogation of population data. The feature of designing any implant or prosthesis according to population data is specific to this group of claims.

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.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied a priori.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

This Annex lists known 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/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
WO 2012/018567 A1	09 Feb 2012	AU 2011286307 A1	14 Mar 2013
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		US 2012022660 A1	26 Jan 2012
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		US 2012022658 A1	26 Jan 2012
		US 8574304 B2	05 Nov 2013
		US 2012101585 A1	26 Apr 2012
		US 8591594 B2	26 Nov 2013
		US 2012022659 A1	26 Jan 2012
		US 8613775 B2	24 Dec 2013
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		WO 2012018565 A1	09 Feb 2012

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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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		WO 2012034033 A1	15 Mar 2012
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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 2011/0087332 A1	14 Apr 2011	AU 2002310193 B2	29 Mar 2007
		AU 2003284035 A1	04 May 2004
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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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		JP 2007514470 A	07 Jun 2007
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		JP 5148284 B2	20 Feb 2013
		JP 2008521493 A	26 Jun 2008
		JP 5198069 B2	15 May 2013
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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		US 2010160917 A1	24 Jun 2010

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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2013/001217**

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