(12) STANDARD PATENT

(11) Application No. AU 2012368262 B2

(19) AUSTRALIAN PATENT OFFICE

(54) Title

Asymmetric tibial components for a knee prosthesis

(51) International Patent Classification(s)

A61F 2/38 (2006.01)

A61F 2/46 (2006.01)

A61F 2/30 (2006.01)

(21) Application No: **2012368262**

(22) Date of Filing:

2012.08.24

(87) WIPO No: WO13/115849

(30) Priority Data

(31) Number

(32) Date

(33) Country

61/621,374 61/592,574 2012.04.06 2012.01.30 US US

(43) Publication Date: **2013.08.08**

(44) Accepted Journal Date:

2017.06.29

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(56) Related Art

EP 0956836 A1

EP 2347733 A1

US 2007/0010890 A1

US 5413605 A

US 4959071 A

US 6010534 A

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau





(10) International Publication Number WO 2013/115849 A1

(43) International Publication Date 8 August 2013 (08.08.2013)

(51) International Patent Classification: A61F 2/38 (2006.01) A61F 2/30 (2006.01) A61F 2/46 (2006.01)

(21) International Application Number:

PCT/US2012/052340

(22) International Filing Date:

24 August 2012 (24.08.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/592,574 30 January 2012 (30.01.2012) US 61/621,374 6 April 2012 (06.04.2012) US

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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS

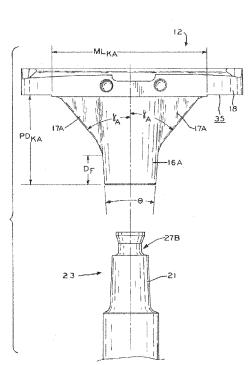


FIG.10

(57) Abstract: An orthopaedic tibial prosthesis includes a tibial baseplate with features designed for use with small-stature knee-replacement patients. The tibial prosthesis may include a shortened tibial keel, tibial keel fins which define a large angle with respect to a longitudinal axis of the keel, and/or tibial keel fins which extend along less than the entire longitudinal extent of the keel.



GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS

BACKGROUND

1. Technical Field.

[0001] The present disclosure relates to orthopaedic prostheses and, specifically, to tibial components in a knee prosthesis.

2. Description of the Related Art.

[0001a] A reference herein to a patent document or other matter which is given as prior art is not to be taken as an admission that that document or matter was known or that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

[0001b] Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other features, integers, steps or components, or group thereto.

[0002] Orthopaedic prostheses are commonly utilized to repair and/or replace damaged bone and tissue in the human body. For example, a knee prosthesis may include a tibial baseplate that is affixed to a resected or natural proximal tibia, a femoral component attached to a resected or natural distal femur, and a tibial bearing component coupled with the tibial baseplate and disposed between the tibial baseplate and femoral component. Knee prostheses frequently seek to provide articulation similar to a natural, anatomical articulation of a knee joint, including providing a wide range of flexion.

[0003] The tibial insert component, sometimes also referred to as a tibial bearing or meniscal component, is used to provide an appropriate level of friction and contact area at the interface between the femoral component and the tibial bearing component. For a knee prosthesis to provide a sufficient range of flexion with a desirable kinematic motion profile, the tibial bearing component and tibial baseplate must be sized and oriented to interact appropriately with the femoral component of the knee prosthesis throughout the flexion range. Substantial design efforts have been focused on providing a range of prosthesis component sizes and shapes to

accommodate the natural variability in bone sizes and shapes in patients with orthopaedic prostheses, while preserving flexion range and desired kinematic motion profile.

[0004] In addition to facilitating implantation and providing enhanced kinematics through manipulation of the size and/or geometry of prosthesis components, protection and/or preservation of soft tissues in the natural knee joint is also desirable.

[0005] A given prosthetic component design (i.e., a tibial baseplate, tibial bearing component, or femoral component) may be provided to a surgeon as a kit including a variety of different sizes, so that the surgeon may choose an appropriate size intraoperatively and/or on the basis of presurgery planning. An individual component may be selected from the kit based upon the surgeon's assessment of fit and kinematics, i.e., how closely the component matches the natural contours of a patient's bone and how smoothly the assembled knee joint prosthesis functions in conjunction with adjacent soft tissues and other anatomical structures. Soft tissue considerations include proper ligament tension and minimization of soft tissue impingement upon prosthetic surfaces, for example.

[0006] In addition to prosthetic sizing, the orientation of a prosthetic component on a resected or natural surface of a bone also impacts surgical outcomes. For example, the rotational orientation of a tibial baseplate and tibial bearing component with respect to a resected proximal tibia will affect the interaction between the corresponding femoral prosthesis and the tibial bearing component. The nature and amount of the coverage of a tibial baseplate over specific areas of the resected proximal tibia will also affect the fixation of the implant to the bone. Thus, substantial design efforts have been focused on providing prosthetic components which are appropriately sized for a variety of patient bone sizes and are adapted to be implanted in a particular, proper orientation to achieve desired prosthesis performance characteristics.

[0006a] According to the present invention there is provided a small-stature tibial baseplate, comprising; a tibial plateau comprising: a distal surface sized and shaped to substantially cover a proximal resected surface of a tibia; a proximal surface opposite said distal surface, said proximal surface having a lateral compartment and a medial compartment opposite said lateral

compartment, the lateral compartment is asymmetric with respect to the medial compartment about a component anteroposterior axis to define a component asymmetry; and a peripheral wall extending between said distal surface and said proximal surface, wherein a total surface area bounded by said peripheral wall of said tibial plateau is between about 1390 mm² and about 1580 mm²; a tibial keel extending distally from said distal surface of said tibial plateau to define a longitudinal tibial keel axis; and a medial fin and a lateral fin spanning a junction between said tibial keel and said distal surface, each of said medial fin and said lateral fin comprising a fin edge having a planar portion defining an angle of about 45 degrees with respect to said longitudinal tibial keel axis, said medial fin and said lateral fin cooperating to define a medial/lateral fin extent of about 40 mm.

[0006b] According to the present invention there is also provided A small-stature tibial baseplate, comprising; a tibial plateau comprising: a distal surface sized and shaped to substantially cover a proximal resected surface of a tibia; a proximal surface opposite said distal surface, said proximal surface having a lateral compartment and a medial compartment opposite said lateral compartment, the lateral compartment is asymmetric with respect to the medial compartment about a component anteroposterior axis to define a component asymmetry; and a peripheral wall extending between said distal surface and said proximal surface, wherein a total surface area bounded by said peripheral wall of said tibial plateau is between about 1390 mm² and about 1580 mm²; a tibial keel extending distally from a junction with said distal surface to an opposing distal tip, said tibial keel positioned so as to substantially coincide with an intramedullary canal of the tibia when said distal surface is placed upon the tibia, said tibial keel comprising a first diameter at said junction between said distal surface and said tibial keel and a second diameter at said distal tip of said tibial keel, each of said first diameter and said second diameter equal to or greater than 13 mm, the first diameter greater than the second diameter; and a medial fin and a lateral fin each spanning a portion of said junction between said tibial keel and said tibial plateau, wherein each of said medial fin and said lateral fin comprising a fin edge having a planar portion defining an angle of about 45 degrees with respect to a longitudinal tibial keel axis, said medial fin mating with said distal surface at said medial compartment, said lateral fin mating with said distal surface at said lateral compartment, wherein said medial and lateral fins cooperate to define a medial/lateral fin extent of about 40 mm.

SUMMARY

[0007] The present disclosure provides an orthopaedic tibial prosthesis which includes a tibial baseplate with features designed for use with small-stature knee-replacement patients. The tibial prosthesis may include a shortened tibial keel, tibial keel fins which define a large angle with respect to a longitudinal axis of the keel, and/or tibial keel fins which extend along less than the entire longitudinal extent of the keel.

[0008] The present disclosure also provides an orthopaedic tibial prosthesis including a tibial baseplate with an asymmetric periphery which promotes proper positioning and orientation on a resected tibia, while also facilitating enhanced kinematics, soft-tissue interaction, and long-term fixation of the complete knee prosthesis. The asymmetric baseplate periphery is sized and shaped to substantially match portions of the periphery of a typical resected proximal tibial surface, such that proper location and orientation is evident by resting the baseplate on the tibia. The baseplate periphery provides strategically positioned relief and/or clearance between the baseplate periphery and bone periphery, such as in the posterior-medial portion to prevent deep-flexion component impingement, and in the anterior-lateral portion to avoid undue interaction between the anatomic iliotibial band and prosthesis components.

[0009] In one form thereof, the present invention provides a small-stature tibial baseplate,

comprising: a tibial plateau comprising: a distal surface sized and shaped to substantially cover a proximal resected surface of a tibia; a proximal surface opposite the distal surface, the proximal surface having a lateral compartment and a medial compartment opposite the lateral compartment; and a peripheral wall extending between the distal surface and the proximal surface; a tibial keel extending distally from the distal surface of the tibial plateau to define a longitudinal tibial keel axis; and at least one fin spanning a junction between the tibial keel and the distal surface, the at least one fin comprising a fin edge defining an angle of about 45 degrees with respect to the longitudinal tibial keel axis. In one aspect, the tibial keel defines a longitudinal extent equal to about 27 mm.

[0010] In another form thereof, the present invention provides a small-stature tibial baseplate, comprising: a tibial plateau comprising: a distal surface sized and shaped to substantially cover a proximal resected surface of a tibia; a proximal surface opposite the distal surface, the proximal surface having a lateral compartment and a medial compartment opposite the lateral compartment; and a peripheral wall extending between the distal surface and the proximal surface; a tibial keel extending distally from a junction with the distal surface to an opposing distal tip, the tibial plateau defining a keel length between the junction and the distal tip equal to about 27 mm, the tibial keel monolithically formed with the tibial plateau and positioned thereupon so as to substantially coincide with an intramedullary canal of the tibia when the distal surface is placed upon the tibia, the tibial keel comprising a first diameter at the junction between the distal surface and the tibial keel and a second diameter at the distal tip of the tibial keel, the first diameter and the second diameter equal to at least 13 mm; and a medial fin and a lateral fin each spanning a portion of the junction between the tibial keel and the tibial plateau, the medial fin mating with the distal surface at the medial compartment, the lateral fin mating with the distal surface at the lateral compartment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0012] Fig. 1A is an exploded, perspective view of a tibial baseplate and tibial bearing component in accordance with the present disclosure;

[0013] Fig. 1B is an assembled, perspective view of the tibial baseplate and tibial bearing component shown in Fig. 1A;

[0014] Fig. 2A is a top plan view of the peripheries of a set of nine tibial baseplates made in accordance with the present disclosure, in which the peripheries are shown to scale according to the illustrated scales in millimeters in the bottom and right-hand margins of the page;

[0015] Fig. 2B is a top plan view of the periphery of a tibial baseplate made in accordance with the present disclosure;

[0016] Fig. 2C is a graph illustrating the asymmetric growth of the posterior-medial compartment for the tibial baseplates shown in Fig. 2A;

[0017] Fig. 2D is a graph illustrating the asymmetric growth of the posterior-lateral compartment for the tibial baseplates shown in Fig. 2A;

[0018] Fig. 3A is top plan view of a periphery of a tibial baseplate made in accordance with the present disclosure, illustrating various arcs defined by the periphery;

[0019] Fig. 3B is a partial, top plan view of the periphery shown in Fig. 3A, illustrating an alternative lateral corner periphery;

[0020] Fig. 3C is a partial, top plan view of the periphery shown in Fig. 3A, illustrating an alternative medial corner periphery;

[0021] Fig. 3D is a top plan view of the periphery of a tibial baseplate made in accordance with the present disclosure, illustrating medial and lateral surface area calculations without a PCL cutout;

[0022] Fig. 4A is a top plan view of a tibial baseplate made in accordance with the present disclosure;

[0023] Fig. 4B is a side elevation view of the tibial baseplate shown in Figs. 4A;

[0024] Fig. 5 is a top plan view of a resected proximal tibial surface with a prosthetic tibial baseplate component and tibial bearing component made in accordance with the present disclosure mounted thereon;

[0025] Fig. 6 is a top plan view of a resected proximal tibial surface with a properly sized tibial trial component thereon;

[0026] Fig. 7 is a side, elevation view of the tibia and trial component shown in Fig. 6;

[0027] Fig. 8 is a side, elevation view of the tibial components shown in Fig. 1A, in conjunction with a femoral component;

[0028] Fig. 9 is a bottom, perspective view of a small stature tibial baseplate made in accordance with the present disclosure;

[0029] Fig. 10 is a front coronal, elevation view of the small stature tibial baseplate shown in Fig. 9, together with a tibial stem extension; and

[0030] Fig. 11 is a rear coronal, perspective view of another small stature tibial baseplate,

shown with the tibial stem extension of Fig. 10.

[0031] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary embodiments of the invention, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION

[0032] The present disclosure provides an asymmetric knee joint prosthesis which facilitates proper rotational and spatial orientation of a tibial baseplate and tibial bearing component upon a resected proximal tibia, while also offering large-area contact with the resected proximal tibia. The prosthesis permits a wide range of flexion motion, protects natural soft tissue proximate the knee joint prosthesis, and optimizes long term fixation characteristics of the prosthesis.

[0033] In order to prepare the tibia and femur for receipt of a knee joint prosthesis of the present disclosure, any suitable methods or apparatuses may be used. As used herein, "proximal" refers to a direction generally toward the torso of a patient, and "distal" refers to the opposite direction of proximal, i.e., away from the torso of the patient.

[0034] As used herein, the "periphery" of a tibial prosthesis refers to any periphery as viewed in a top plan view, e.g., in a generally transverse anatomical plane. Alternatively, the periphery of a tibial prosthesis may be any periphery as viewed in bottom plan view, e.g., in a generally transverse plane and looking at the distal surface adapted to contact a resected proximal surface of a tibial bone.

[0035] As used herein, the term "centroid" or "geometric center" refers to the intersection of all straight lines that divide a given area into two parts of equal moment about each respective line. Stated another way, a geometric center may be said to be the "average" (i.e., arithmetic mean) of all points of the given area. Stated yet another way, the geometric center is a point in a two dimensional figure from which the sum of the displacement vectors of all points on the figure equals zero.

[0036] As used herein, a "disparity" or "difference" between two numerical values (e.g., one value "larger" or "smaller" than another), typically expressed as a percentage, is the difference between the two values divided by the smaller of the two values. For example, a smaller quantity having value 75 and a larger quantity having value 150 would have a percentage disparity of (150-75)/75, or 100%.

[0037] Referring to Fig. 5, tibia T includes tibial tubercle B having mediolateral width W, with tubercle midpoint P_T located on tubercle B approximately halfway across width W. While

tubercle B is shown as having midpoint P_T at the "peak" or point of maximum anterior eminence, it is recognized that midpoint P_T of tibia T may be spaced from such a peak. Tibia T also includes attachment point C_P representing the geometric center of the attachment area between the anatomic posterior cruciate ligament (PCL) and tibia T. Recognizing that the PCL typically attaches to a tibia in two ligament "bundles," one of which is relatively anterior, lateral and proximal and the other of which relatively posterior, medial and distal, attachment point C_P is contemplated as representing the anterior/lateral attachment area in an exemplary embodiment. However, it is contemplated that the posterior/medial attachment area, or the entire attachment area, could be used.

[0038] As used herein, "anterior" refers to a direction generally toward the front of a patient. "Posterior" refers to the opposite direction of anterior, i.e., toward the back of the patient.

[0039] In the context of patient anatomy, "home axis" A_H refers to a generally anteroposterior axis extending from posterior point C_P to an anterior point C_A , in which anterior point C_A is disposed on tubercle B and medially spaced from tubercle midpoint P_T by an amount equal to W/6. Stated another way, anterior point C_A is laterally spaced by an amount equal to W/3 from the medial end of mediolateral width W, such that point C_A lies on the "medial third" of the anterior tibial tubercle.

[0040] In the context of a prosthesis, such as tibial baseplate 12 described below, "home axis" A_H refers to an axis oriented with respect to baseplate 12 such that the baseplate home axis A_H of baseplate 12 is aligned with home axis A_H of tibia T after implantation of baseplate 12 in a proper rotational and spatial orientation (as shown in Fig. 5). In the illustrative embodiments shown in Fig. 3 and described in detail below, home axis A_H bisects PCL cutout 28 at the posterior edge of periphery 200 of tibial plateau 18 (Fig. 5), and bisects anterior edge 202 at the anterior edge of periphery 200 of tibial plateau 18. It is contemplated that home axis A_H may be oriented to other baseplate features, it being understood home axis A_H of baseplate 12 is positioned such that that proper alignment and orientation of baseplate 12 upon tibia T positions the home axis A_H of baseplate 12 coincident with home axis A_H of tibia T.

[0041] Home axis A_H of tibial baseplate 12 may be said to be an anteroposterior axis, as home axis A_H extends generally anteriorly and posteriorly when baseplate 12 is implanted upon tibia T. Tibial baseplate also defines mediolateral axis A_{ML} , which lies along the longest line segment contained within periphery 200 that is also perpendicular to home axis A_H of baseplate 12. As described below, home axis A_H and mediolateral axis A_{ML} cooperate to define a coordinate system useful for quantifying certain baseplate features in accordance with the present disclosure.

[0042] The embodiments shown and described with regard to Figs. 1A, 1B, 3A, 4A, 4B, 5 and 6 illustrate a left knee and associated features of a right-knee prosthesis, while the embodiments shown and described in Figs. 2A, 2B and 3D illustrate the periphery of a right knee prosthesis. Right and left knee configurations are mirror images of one another about a sagittal plane. Thus, it will be appreciated that all aspects of the prosthesis described herein are equally applicable to a left- or right-knee configuration.

1. Asymmetry of the Tibial Prosthesis.

[0043] Referring now to Figs 1A and 1B, tibial prosthesis 10 includes tibial baseplate 12 and tibial bearing component 14. Tibial baseplate 12 may include a stem or keel 16 (Fig. 4B) extending distally from proximal tibial plateau 18, or may utilize other fixation structures for securing baseplate 12 to tibia T, such as distally extending pegs. Portions of the outer periphery defined by tibial plateau 18 closely correspond in size and shape with a resected proximal surface of tibia T, as described in detail below.

[0044] Tibial bearing component 14 and tibial baseplate 12 have a particular asymmetry, with respect to home axis A_H (shown in Fig. 2A and described above), that is designed to maximize tibial coverage for a large proportion of knee-replacement candidates. This high level of coverage allows a surgeon to cover the largest possible area on the proximal resected surface of the tibia, which in turn offers maximum coverage of cortical bone. Advantageously, the maximized coverage of cortical bone facilitates superior support of tibial baseplate 12. A firm, enduring fixation of tibial baseplate 12 to tibia T is facilitated by large-area contact between the cortical and cancellous bone of tibia T and distal surface 35 of tibial plateau 18 (Fig. 4B), which may be coated with porous ingrowth material and/or bone cement.

[0045] In an analysis of a several human specimens, variations in size and geometry for a variety of anatomic tibial features were observed and characterized. Geometrical commonalities between anatomic features, or lack thereof, were noted. Mean tibial peripheral geometries were calculated based on statistical analysis and extrapolation of the collected anatomical data, in view of the observed geometrical commonalities organized around anatomic home axis A_H. These calculated mean geometries were categorized by tibial size.

[0046] A comparison between the asymmetric peripheries for the present family of prostheses and the calculated mean tibial geometries was conducted. Based on the results of this comparison, it has been found that substantial tibial coverage can be achieved for a large proportion of patients using tibial components having asymmetric peripheries in accordance with the present disclosure. Moreover, this coverage can be achieved with a relatively small

number of sizes, even where particular portions of the prosthesis periphery is intentionally "pulled back" from the tibial periphery in order to confer other orthopaedic benefits. Further, the particular asymmetry of tibial baseplate 12 can be expected to offer such coverage without overhanging any portion of the resected surface.

[0047] Thus, periphery 200 including the particular asymmetric profile as described below confers the benefits of maximum coverage, facilitation of proper rotation (discussed below), and long-term fixation as described herein. Such asymmetry may be demonstrated in various ways, including: by a comparison of adjacent radii in the medial and lateral compartments of the asymmetric periphery; by a comparison of the edge length in anterior-medial and anterior lateral corners of the periphery, for a comparable lateral and medial angular sweep; and by a comparison of the location of radius centers for the anterior-medial and anterior-lateral corners with respect to a mediolateral axis. Various comparisons and quantifications are presented in detail below. Specific data and other geometric details of the peripheries for the various prosthesis sizes, from which the below-identified comparisons and quantifications are derived, may be obtained from the draw-to-scale peripheries shown in Fig. 2A.

[0048] Advantageously, the asymmetry of tibial component 12 encourages proper rotational orientation of baseplate 12 upon implantation thereof onto tibia T. As described in detail below, the asymmetry of periphery 200 (Fig. 2A) of tibial plateau 18 is designed to provide a close match in selected areas of the lateral and medial compartments as compared to the anatomic bone. As such, a surgeon can select the largest possible component from among a family of different component sizes, such that the component substantially covers the resected tibia T with minimal gaps between the tibial periphery and component periphery 200, as well as little or no overhang over any portions of the tibial periphery. Because the high congruence between prosthesis periphery 200 and the tibial periphery produces only a minimal gap between the peripheries (as shown in Fig. 5), tibial baseplate 12 cannot be rotated significantly without causing tibial plateau 18 to overhang beyond the periphery of the resected tibial surface. Thus, proper rotation of baseplate 12 can be ascertained by the visual acuity between prosthesis periphery 200 and the resected tibial surface.

[0049] The following examples and data are presented with respect to tibial baseplate 12. However, as described in more detail below, tibial bearing component 14 defines perimeter wall 54 which follows peripheral wall 25 of baseplate 12 except where noted. Thus, it is appreciated that the conclusions, trends and design features gleaned from data relating to the asymmetric periphery of tibial baseplate 12 also applies to the asymmetric periphery of tibial bearing component 14, except where stated otherwise.

[0050] Lateral compartment 20 and medial compartment 22 of tibial plateau 18 are dissimilar in size and shape, giving rise to the asymmetry thereof. This asymmetry is designed so that peripheral wall 25 traces the perimeter of the resected proximal surface of tibia T, such that tibial plateau 18 covers a large proportion of the resected proximal tibial surface as shown in Fig. 5. To achieve this large tibial coverage, tibial plateau 18 closely matches the periphery of tibia T in most areas as noted above. Nevertheless, as shown in Fig. 5, for example, a small gap between periphery 200 of tibial plateau 18 and tibia T is formed to allow some freedom of positioning and rotational orientation. The gap is designed to have a substantially continuous width in most areas, including the anterior edge, anterior-medial corner, medial edge, lateral edge and lateral-posterior corner (all described in detail below).

[0051] However, certain aspects of the asymmetric shape are designed to intentionally deviate from the calculated anatomical shape to confer particular features and advantages in the context of a complete, implanted knee prosthesis. Referring to Fig. 5, for example, tibial baseplate 12 and tibial bearing component 14 have anterior-lateral "corners" (described in detail below) which are "pulled back" to create gap 56 between tibia T and prosthesis 10 in the anterior-lateral area of the resected surface of tibia T. Advantageously, gap 56 creates extra space for "soft-tissue friendly" edges of prosthesis 10, thereby minimizing impingement of the iliotibial band. In an exemplary embodiment, gap 56 may range from 0.5 mm for a small-size prosthesis (such as size 1 / A described below), to 1 mm for a medium-sized prosthesis (such as size 5 / E described below), to 2 mm for a large-sized prosthesis (such as size 9 / J described below).

[0052] Similarly, the posterior edge of the medial compartment may be "pulled back" from the adjacent edge of tibia T to define gap 58. Gap 58 allows extra space for adjacent soft tissues, particularly in deep flexion as described below. Gap 58 also allows prosthesis 10 to be rotated about a lateral pivot by a small amount, thereby offering a surgeon the freedom to displace medial compartment 22 posteriorly as required or desired for a particular patient. In an exemplary embodiment, gap 58 is about 4 mm.

[0053] As described in detail below, the asymmetrical periphery also provides a large overall area for proximal surface 34 of baseplate 12, which creates sufficient space for large contact areas between tibial bearing component 14 and femoral component 60 (Fig. 8).

a. <u>Medial/Lateral Peripheral Curvatures</u>

[0054] The particular asymmetric shape of tibial plateau 18 (and of tibial bearing component 14, which defines a similar periphery as described below) gives rise to a generally "boxy" or

angular periphery in lateral compartment 20, and a "rounded" or soft periphery in medial compartment 22.

[0055] Turning to Fig. 3A, the periphery 200 of tibial plateau 18 surrounds lateral compartment 20 and medial compartment 22, each of which define a plurality of lateral and medial arcs extending between anterior edge 202 and lateral and medial posterior edges 204, 206 respectively. In the illustrative embodiment of Fig. 3A, anterior edge 202, lateral posterior edge 204 and medial posterior edge 206 are substantially planar and parallel for ease of reference. However, it is contemplated that edges 202, 204, 206 may take on other shapes and configurations within the scope of the present disclosure, such as angled or arcuate.

[0056] In the exemplary embodiment of Fig. 3A, lateral compartment 20 includes five separate arcs including lateral anterior edge arc 208, anterior-lateral corner arc 210, lateral edge arc 212, posterior-lateral corner arc 214, and lateral posterior edge arc 216. Each of lateral arcs 208, 210, 212, 214 and 216 defines angular sweep 1L, 2L, 3L, 4L and 5L, respectively, having radii R1L, R2L, R3L, R4L and R5L respectively. A radius of a particular angular sweep extends from the respective radius center (i.e., one of centers C1L, C2L, C3L, C4L and C5L) to periphery 200. Radii R1L, R2L, R3L, R4L and R5L each remain unchanged throughout the extent of angular sweeps 1L, 2L, 3L, 4L and 5L, respectively.

[0057] Similarly, medial compartment 22 includes three separate arcs including anterior-medial corner arc 220, medial edge arc 222 and posterior-lateral corner arc 224, defining angular sweeps 1R, 2R and 3R, respectively having radii R1R, R2R and R3R respectively.

[0058] In Fig. 2A, peripheries 200_X are shown for each of nine progressively larger component sizes, with 200_1 being the periphery of the smallest size (size "1" or "A") and 200_9 being the periphery of the largest size (size "9" or "J"). For purposes of the present disclosure, several quantities and features of tibial baseplate 12 may be described with the subscript "X" appearing after the reference numeral corresponding to a component size as set for in the Tables, Figures and description below. The subscript "X" indicates that the reference numeral applies to all nine differently-sized embodiments described and shown herein.

[0059] In exemplary embodiments, medial and lateral radii may be any value within the following ranges: for medial radius $R1R_X$, between about 27 mm and about 47 mm; for medial radius $R2R_X$, between about 21 mm and about 49 mm; for medial radius $R3R_X$, between about 14 mm and about 31 mm; for lateral radius $R1L_X$, between about 46 mm and about 59 mm; for lateral radius $R2L_X$, between about 27 mm; for lateral radius $R3L_X$ between about 27 mm and about 46 mm; for lateral radius $R4L_X$ between about 6 mm and about 14 mm;

and for lateral radius R5L_X between about 22 mm and about 35 mm.

[0060] In exemplary embodiments, medial and lateral angular extents or sweeps may be any value within the following ranges: for medial angle $1R_X$, between about 13 degrees and about 71 degrees; for medial angle $2R_X$, between about 23 degrees and about 67 degrees; for medial angle $3R_X$, between about 23 degrees and about 90 degrees; for lateral angle $1L_X$, between about 11 degrees and about 32 degrees; for lateral angle $2L_X$, between about 42 degrees and about 63 degrees; for lateral angle $3L_X$, between about 23 degrees and about 47 degrees; for lateral angle $4L_X$, between about 36 degrees and about 46 degrees; and for lateral angle $5L_X$, between about 28 degrees and about 67 degrees;

[0061] The unique asymmetry of periphery 200 defined by tibial plateau 18 can be quantified in multiple ways with respect to the curvatures of lateral and medial compartments 20 and 22 as defined by the arrangement and geometry of lateral arcs 208, 210, 212, 214, 216 and medial arcs 220, 222, 224.

[0062] One measure of the asymmetry of periphery 200 is found in a simple comparison of radii R2L and R1R, which are the anterior "corner" radii of lateral and medial compartments 20 and 22 respectively. Generally speaking, a corner of a baseplate periphery may be said to be that portion of the periphery where a transition from an anterior or posterior edge to a lateral or medial edge occurs. For example, in the illustrative embodiment of Fig. 3A, the anterior-lateral corner is principally occupied by anterior-lateral corner arc 210, which defines a substantially medial-lateral tangent at the anterior end of arc 210 and a substantially anteroposterior tangent at the lateral end of arc 210. Similarly, the medial corner of periphery 200 is principally occupied by anterior-medial corner arc 220, which defines a substantially medial-lateral tangent at the anterior end of arc 220 and a more anteroposterior tangent at the lateral end of arc 220. For some purposes, the anterior-medial corner of periphery 200 may be said to include a portion of medial edge arc 222, as described below.

[0063] A periphery corner may also be defined by a particular angular sweep with respect to an anteroposterior reference axis. Such reference axis may extend posteriorly from an anterior-most point of a tibial prosthesis (e.g., from the center of anterior edge 202 of periphery 200) to divide the prosthesis into medial and lateral halves. In a symmetrical prosthesis, the anteroposterior reference axis is the axis of symmetry.

[0064] In the illustrative embodiment of Fig. 3A, the anteroposterior reference axis may be home axis A_H , such that the anterior-medial corner of periphery 200 occupies some or all of the 90-degree clockwise angular sweep between home axis A_H (at zero degrees, i.e., the beginning of the clockwise sweep) and mediolateral axis A_{ML} (at 90 degrees, i.e., the end of the sweep).

Similarly, the anterior-lateral corner of periphery 200 occupies some or all of the 90-degree counter-clockwise angular sweep between home axis A_H and mediolateral axis A_{ML}. For example, the anterior-medial and anterior-lateral corners may each occupy the central 45 degree angular sweep of their respective 90-degree angular sweeps as described above. Thus, the anterior-lateral corner of periphery 200 would begin at a position rotated 22.5 degrees counter-clockwise from home axis A_H as described above, and would end at 67.5 degrees counter-clockwise from home axis A_H. Similarly, the anterior-medial corner would begin at a 22.5-degree clockwise rotation and end at a 67.5 degree clockwise rotation. [0066] It is contemplated that the anterior-lateral and anterior-medial corners may occupy any angular sweep as required or desired for a particular design. For purposes of comparison between two corners in a given prosthesis periphery, however, a comparable angular sweep for the lateral and medial sides is envisioned, i.e., the extent and location of the compared angles may be "mirror images" of one another about an anteroposterior axis. For example, in a comparison of anterior-lateral and anterior-medial radii R2L, R1R, it is contemplated that such comparison is calculated across lateral and medial angular sweeps which each begin and end at similar angular end points with respect to the chosen reference axis (e.g., home axis A_H). As best seen in Figs. 3A and 5, one aspect of the asymmetric periphery of baseplate 12 arises from R1R_X being substantially larger than R2L_X. Table 1, below, also includes a comparison of radii R1R_X and R2L_X across nine exemplary component sizes, demonstrating that difference Δ -12RL between radius R1R_X and radius R2L_X may be as little as 48%, 76% or 78%, and may be as much as 102%, 103% or 149%. It is contemplated that radius R1R_X may be larger than radius R2L_X by any percentage value within any range defined by the listed values.

<u>Table 1</u>
Comparisons of Values of Respective Medial and Lateral Anterior Corner Radii

SIZE	Δ-12RL R1R vs. R2L	
1 / A	103.0%	
2/B	149.2%	
3 / C	82.4%	
4 / D	74.6%	

5 / E	90.9%	
6/F	78.6%	
7 / G	102.2%	
8 / H	86.5%	
9 / J	48.1%	
AVG	90.6%	

All Δ values are expressed as the difference between a given pair of radii, expressed as a percentage of the smaller of the two radii

[0068] Stated another way, the smaller $R2L_X$ makes a sharper turn, thereby imparting a relatively more "boxy" appearance to the anterior corner of lateral compartment 20, while the relatively larger radius $R1R_X$ makes a more gradual turn that imparts a more "rounded" appearance to the anterior corner of medial compartment 22. In the exemplary nine sizes illustrated in Fig. 2A and shown in Table 1, an average disparity between the lateral and medial anterior corner radii $R2L_X$ and $R1R_X$ is greater than 90%. In some sizes of periphery 200_X , the anterior-medial "corner" making the more gradual turn may also includes medial edge arc 222. [0069] As described in detail below, this "rounded-medial/boxy-lateral" asymmetry of the

anterior corners of tibial plateau facilitates and encourages proper rotational orientation and positioning of baseplate 12 upon tibia T upon implantation by allowing periphery 200 to closely match the periphery of a typical resected tibia T (Fig. 5), while also maximizing the surface area of proximal surface 34 of tibial plateau to allow for use of a tibial bearing component 14 with a concomitantly large proximal surface area.

[0070] As noted above, the small-radius "corner" defined by angle 2L may be considered to have a similar angular sweep as a large-radius "corner" defined by angles 1R, 2R (or a combination of portions thereof) for purposes of comparing the two radii. Given this comparable angular sweep, another measure of the asymmetry defined by the medial and lateral anterior corners is the arc length of the corners. More particularly, because medial radii $R1R_X$ and $R2R_X$ are larger than lateral radius $R2L_X$ (as described above), it follows that the medial corner has a larger arc length as compared to the lateral corner arc length for a given angular sweep.

[0071] Moreover, while the peripheries of lateral and medial compartments 20, 22 are shown as being generally rounded and therefore defining respective radii, it is contemplated

that an asymmetric periphery in accordance with the present disclosure need not define a radius per se, but rather could include one or more straight line segments which, on the whole, define asymmetric corner edge lengths in the medial and lateral compartments. Referring to Figs. 3B, for example, it is contemplated that an alternative anterior lateral corner 210' could be comprised of three line segments 210A, 210B, 210C which cooperate to span angular extent 2L. Similarly, an alternative anterior medial corner 220' could be comprised of three line segments 220A, 220B, 220C which cooperate to span angular extent 1R. Any of the other arcs which define periphery 200 could be similarly configured as one or more line segments. In the variant illustrated by Figs. 3B and 3C, the difference between corner radii would not be an appropriate measure of asymmetry because the straight line segments would not define radii. Asymmetry of the medial and lateral anterior corners would instead be quantified by comparison of the respective lengths of the medial and lateral corner edges across comparable medial and lateral angular extents.

[0072] Yet another way to quantify the asymmetry of the anterior corner arcs (i.e., anterior-lateral corner arc 210 and anterior-medial corner arc 220) is to compare the distance of the lateral and medial radius centers C2L and C1R respectively, from anterior edge 202 and/or mediolateral axis A_{ML} (Fig. 3A). In the boxy anterior-lateral corner, center $C2L_X$ of radius $R2L_X$ is anterior of mediolateral axis A_{ML} and relatively close to anterior edge 202. For the rounded, anterior-medial corner, centers C1R_X and C2R_X of radii R1R_X and R2R_X, respectively, are posterior of mediolateral axis A_{ML} and relatively far from anterior edge 202. [0073] Another metric for quantifying the "boxy vs. rounded" asymmetry of periphery 200 is a comparison between ratios of adjacent radii. In the more boxy lateral compartment 20, pairs of adjacent radii define large ratios because the large edge radii (i.e., of lateral anterior edge arc 208, lateral edge arc 212 and lateral posterior edge arc 216) are much larger than the adjacent corner radii (i.e., of anterior-lateral corner are 210 and posterior-lateral corner are 214). On the other hand, in the more rounded medial compartment 22, pairs of adjacent radii define small ratios (i.e., nearly 1:1) because the radii of the medial arcs (i.e., anterior-medial corner arc 220, medial edge arc 222 and posterior-medial corner arc 224) are of similar magnitude. In the illustrated embodiment of Fig. 3A, lateral edge arc 212 is considered an "edge" because arc 212 defines tangent 212A which is substantially perpendicular to anterior edge 202. Just as a "corner" may be considered to be the portion of periphery 200 which makes a transition from anterior or posterior to medial or lateral, an edge is that portion of periphery 200 which encompasses the anterior, posterior, medial or lateral terminus of periphery 200. [0075]Similarly, medial edge arc 222 defines tangent 222A which is also substantially

perpendicular to anterior edge 202. The medial "edge" of periphery 200 may be part of the same arc that extends around the anterior-medial corner and/or the anterior-lateral corner, as the medial arcs are similar. Indeed, as noted herein, medial compartment 22 may have a single arc which extends from anterior edge 202 to medial posterior edge 206.

[0076] Table 2 shows a comparison between adjacent-radii ratios for lateral and medial compartments 20 and 22. For each adjacent pair of radii, the difference between the radii magnitudes are expressed as a percentage of the smaller radius of the pair, as noted above.

Table 2

Comparisons of Values of Respective Pairs of Baseplate Peripheral Radii

SIZE	Δ-12R R1R vs. R2R	Δ-23R R2R vs. R3R	Δ-12L R1L vs. R2L	Δ-23L R2L vs. R3L	Δ-34L R3L vs. R4L	Δ-45L R4L vs. R5L
1 / A	18.3%	58.6%	337.3%	141.8%	323.5%	194.1%
2 / B	49.0%	62.0%	254.1%	96.7%	361.5%	315.4%
3 / C	24.0%	48.8%	247.1%	58.8%	203.4%	214.6%
4 / D	44.2%	34.4%	207.0%	59.2%	213.9%	244.4%
5/E	23.3%	57.9%	151.5%	80.6%	250.0%	250.0%
6/F	46.5%	37.6%	122.6%	42.9%	222.6%	260.2%
7/G	25.3%	38.9%	110.8%	64.5%	264.3%	176.2%
8 / H	73.6%	21.3%	109.0%	80.9%	198.1%	142.6%
9/J	21.9%	61.2%	70.4%	68.5%	264.0%	172.0%
AVG	36.2%	46.7%	178.9%	77.1%	255.7%	218.8%

All Δ values are expressed as the difference between a given pair of radii, expressed as a percentage of the smaller of the two radii

[0077] As illustrated in Table 2, the "boxy" periphery of lateral compartment 20 gives rise to disparity values Δ -12L, Δ -23L, Δ -34L and Δ -45L that are at least 42%, 48% or 59%, and as great as 323%, 337% or 362%. It is contemplated that the disparity between a pair of adjacent radii in the boxy periphery of lateral compartment 20 may be any percentage value within any range defined by any of the listed values. It is also contemplated that the lateral disparity values may be substantially higher, as required or desired for a particular application.

[0078] Meanwhile, the "rounded" periphery of medial compartment 22 gives rise to disparity values Δ -12R and Δ -23R that are as small as 21%, 23% or 25%, and no greater than

61%, 62% or 74%. It is contemplated that the disparity between a pair of adjacent radii in the rounded periphery of medial compartment 22 may be any value within any range defined by any of the listed values. It is also contemplated that the medial disparity values may be less than 21%, and as little as zero %, as required or desired for a particular application.

[0079] Moreover, the boxy shape of lateral compartment 20 and rounded shape of medial compartment 22 is also demonstrated by the number of arcs used to define the portion of periphery 200 in lateral and medial compartments 20, 22. In lateral compartment 20, five arcs (i.e., arcs 208, 210, 212, 204, 216) are used to define the lateral periphery, which is indicative of anterior, lateral and posterior "sides" of a box joined by the relatively sharp transitions of corner arcs 210, 214. On the other hand, medial compartment 22 uses only three radii (i.e., 220, 222, 224), leaving no clear definition of any box "sides" or other transitions. Indeed, it is contemplated that medial compartment 22 could join anterior edge 202 to medial posterior edge 206 by a single radius within the scope of the present disclosure.

b. Surface Area of Medial and Lateral Baseplate Compartments

[0080] Referring still to Fig. 3A, yet another characterization of the asymmetry of periphery 200 arises from disparities in surface area for lateral and medial compartments 20, 22. For purposes of the present disclosure, surface area of lateral compartment SAL is that area contained within periphery 200, and on the lateral side of home axis $A_{\rm H}$. Similarly, the surface area of medial compartment 22 is that area contained within periphery 200, and on the medial side of home axis $A_{\rm H}$.

[0081] In an exemplary embodiment, lateral surface area SAL_X may be as little as 844 mm² or may be as much as 1892 mm^2 , or may be any area within the range defined by the foregoing values. In an exemplary embodiment, medial surface area SAM_X may be as little as 899 mm^2 or may be as much as 2140 mm^2 , or may be any area within the range defined by the foregoing values.

[0082] Surfaces areas SAL and SAM do not include any of the area occupied by PCL cutout 28, as any such area is not within periphery 200. However, the asymmetry of surface areas SAL and SAM arises primarily from the differences in the geometry and placement of arcs 208, 210, 212, 214, 216, 220, 222, 224 rather than from any asymmetry of PCL cutout 28. In the illustrative embodiments of Fig. 2A, for example, PCL cutout 28_X is symmetrical with respect to home axis A_H , but extends further posteriorly in medial compartment 22.

[0083] Thus, it is contemplated that the asymmetry of surfaces areas SAL, SAM are little changed by exclusion of the PCL cutout 28 from the area calculation. As illustrated in Fig. 3D,

PCL cutout 28 is effectively excluded from calculation by extrapolating the line formed by lateral posterior edge 204 and medial posterior edge 206 inwardly to intersect with home axis A_H. In lateral compartment 20, such extrapolation cooperates with the lateral side of PCL cutout 28 to define lateral fill area 80. In medial compartment 22, such extrapolation cooperates with the medial side of PCL cutout 28 to define medial fill area 82.

[0084] In the illustrative embodiment of Fig. 3D, lateral surface area SAL_X ' may be as little as 892 mm² or may be as much as 2066 mm², or may be any area within the range defined by the foregoing values. In an exemplary embodiment, medial surface area SAM_X ' may be as little as 986 mm² or may be as much as 2404 mm², or may be any area within the range defined by the foregoing values.

[0085] Tables 3 and 4 below illustrate that medial surface area SAM_X occupies a greater percentage of the total surface area contained within periphery 200_X, regardless of whether PCL cutout 28 is included in the calculation. That is to say, medial fill area 82 is larger than lateral fill area 80 by approximately the same proportion as medial and lateral surfaces areas SAM_X, SAL_X. In the exemplary embodiments of Fig. 3A, medial surface area SAM_X occupies between 52% and 53% of the total surface area regardless, while lateral surface area SAM_X occupies the remainder. If the PCL cutout is excluded from the calculation as shown in Fig. 3D, medial surface area SAM_X' occupies between 52% and 54% of the total surface area, while lateral surface area SAM_X' occupies the remainder. With or without the PCL cutout included in the calculation, it is contemplated that medial surface areas SAM_X, SAM_X' may occupy as little as 51% of the total surface area, and as much as 60% of the total surface area.

Table 3

Medial vs. Lateral Tibial Baseplate Surface Areas for Baseplates with a PCL Cutout (Figs. 2A and 3A)

With PCL Notch		
Size	Medial Surface Area SAM _X as % of Total Surface Area	
1 / A	52%	
2/B	52%	
3 / C	52%	
4 / D	52%	
5 / E	52%	

6/F	52%
7 / G	53%
8 / H	53%
9/J	53%

Table 4

Medial vs. Lateral Tibial Baseplate Surface Areas for Baseplates without a PCL Cutout (Fig. 3D)

Without PCL Notch		
Size	Medial Surface Area SAM _x ' as % of Total Surface Area	
1 / A	53%	
2/B	52%	
3 / C	53%	
4 / D	53%	
5/E	53%	
6/F	53%	
7 / G	53%	
8 / H	54%	
9 / J	54%	

c. Anteroposterior Extent of Medial and Lateral Compartments

[0086] Still another way to characterize and quantify the asymmetry of tibial periphery 200 is to compare the overall anteroposterior extent of lateral and medial compartments 20, 22. [0087] Turning to Fig. 2A (which is drawn to scale, according to scales 230 and 232) and Fig. 2B, lateral compartment 20 of tibial plateau 18 defines overall lateral anteroposterior extent DAPL_X, while medial compartment 22 of tibial plateau 18 defines overall medial anteroposterior extent DAPM_X, where X is an integer between 1 and 9 corresponding to a particular component size as shown in Fig. 2A, as noted above. As illustrated in Table 5 below, lateral anteroposterior extent DAPL_X is less than medial anteroposterior extent DAPM_X, for all component sizes.

[0088] This disparity in anteroposterior extent can be said to result from medial compartment 22 extending posteriorly further than lateral compartment 20. In the illustrative embodiment of Fig. 2B, lateral anteroposterior extent DAPL_X extends from anterior edge 202 to lateral posterior edge 204, while medial anteroposterior extent DAPM_X extends from

anterior edge 202 to medial posterior edge 206. Thus, if one takes anterior edge 202 to be the anteroposterior "zero point," the additional anteroposterior extent defined by medial compartment 22 is due entirely to the further posterior position of medial posterior edge 206. [0089] As set forth in the right-hand column of Table 5, exemplary embodiments of tibial baseplate 12 may define medial anteroposterior extent DAPM_X that is larger than lateral anteroposterior extent DAPL_X by as little as 12.1%, 12.2% or 12.4%, and as much as 13.7%, 14.2% or 14.5%. It is contemplated that such disparity between medial and lateral anteroposterior extents DAPM_X, DAPL_X may be any percentage within any range defined by the listed values of Table 5. Advantageously, the particular asymmetric arrangement of tibial baseplate 12 with respect to anteroposterior extent of lateral and medial compartments 20, 22 facilitates substantially complete coverage of tibia T, without overhanging the edge of tibia T, in a wide variety of patients.

Table 5

Overall A/P and M/L Dimensions for Tibial Baseplates (Figs. 2A and 2B)

Size (X)	Growth in A/P Medial Dimension (DAPM), from next-smaller size, mm	Growth in A/P Lateral Dimension (DAPL), from next-smaller size, mm	Additional A/P Extent of DAPM vs. DAPL, % of DAPL
1 / A			14.5%
2 / B	2.3	2.13	14.2%
3 / C	2.4	2.25	13.7%
4 / D	2.3	2.27	13.1%
5/E	3	2.8	12.7%
6/F	3.1	2.85	12.4%
7 / G	3.2	2.81	12.5%
8 / H	3.3	3.11	12.2%
9 / J	3.73	3.34	12.1%

[0090] For example, in an exemplary family of prosthesis sizes, at least 60% and as much as 90% coverage of the resected proximal surface is provided by tibial plateau 18 of tibial baseplate 12 when rotation is limited to +/- 5 degrees from home axis A_H. In a majority of all patients, such coverage is between 75-85%. Coverage of up to 100% may be achieved within the scope of the present disclosure, such as by fully extending the posterior-medial and anterior-lateral coverage of tibial plateau (which intentionally leave gaps between tibial plateau 18 and the periphery of tibia T as noted herein).

[0091] The additional posteromedial material of tibial plateau 18 includes chamfer 32,

described in detail below with respect to the assembly of tibial baseplate 12 to tibial bearing component 14. Chamfer 32 is formed in peripheral wall 25, such that chamfer 32 forms angle α (Fig. 8) with the distal or bone-contacting surface 35 of tibial plateau 18. In the illustrated embodiment, chamfer 32 defines a substantially linear sagittal cross-sectional profile, with angle α between about 35 degrees and about 55 degrees. In addition, it is contemplated that chamfer 32 may have an arcuate profile in a sagittal, coronal and/or transverse plane, and may include convex or concave curvature as required or desired for a particular application.

2. Progressive Peripheral Growth Between Implant Sizes

[0092] In addition to the asymmetry of each individual size/embodiment of tibial baseplate 12, described in detail above, the present disclosure also provides asymmetry in the way periphery 200 grows from one size to the next. Advantageously, this asymmetric peripheral growth accommodates observed growth trends in tibias T of differently-sized patients, while also preserving the optimal fit and coverage provided by baseplate 12, and offering the other advantages of designs in accordance with the present disclosure as described herein.

[0093] In symmetrical peripheral growth, a larger size of baseplate is a scaled-up version of a smaller size and vice-versa. In the present asymmetrical peripheral growth, by contrast, certain parameters of tibial baseplate 12 grow faster than others as the overall size of the baseplate gets larger (i.e., from smallest size 1 / A through largest size 9 / J). Thus, differently-sized components made in accordance with the present disclosure are not proportional to one another in all respects, in that a larger tibial prosthesis is not proportionally larger than a smaller tibial prosthesis in all aspects.

[0094] Referring now to Fig. 2B, periphery 200_X defines centroid C_X , which is medially biased with respect to home axis A_H owing to medial surface area SAM being larger than lateral surface area SAL (as described in detail above). Posterior-medial distance DMP $_X$ extends from centroid C_X toward the posterior-medial "corner" of periphery 200_X (i.e., toward posterior-medial corner are 224, shown in Fig. 3A and described above) at an angle of 130 counter-clockwise degrees from home axis A_H . Similarly, posterior-lateral distance DLP $_X$ extends from centroid C_X toward the posterior-lateral "corner" of periphery 200_X (i.e., toward posterior-lateral corner are 214, shown in Fig. 3A and described above) at an angle of 120 clockwise degrees from home axis A_H . The posterior-lateral and posterior-medial corners are defined in a similar fashion as the anterior-lateral and anterior-medial corners, described in detail above. Moreover, while the asymmetric posterior-medial and posterior lateral growth among consecutive sizes is described below with respect to distances DLP $_X$, DMP $_X$, such

[0095] As illustrated in Fig. 2A and shown in Table 6 below, lateral- and medial-posterior distances DLP_X, DMP_X do not grow linearly as smallest size 1 / A progresses among consecutive sizes to eventually reach largest size 9 / J. Rather, lateral- and medial-posterior distances DLP_X, DMP_X exhibit an increase in the magnitude of growth as the sizes progress consecutively from size 1 / A to size 9 / J. This non-linear, asymmetric growth is illustrated in the graphs of Figs. 2C and 2D and in Table 6 below.

Table 6

Growth of the Posterior-Medial and Posterior-Lateral Corners of Baseplate Periphery (Figs. 2A and 2B)

Size (X)	Growth in medial-posterior distance DMP_X from centroid (C_X) , compared to next-smaller size, mm	Growth in lateral-posterior distance (DLP _x) from centroid (C _x), compared to next-smaller size, mm
1		
2	2.42	2.48
3	2.56	2.8
4	2.76	2.55
5	2.86	3.26
6	3.71	2.64
7	3.28	2.83
8	3.52	2.28
9	3.76	3.29

[0096] In Fig. 2C, the amount of growth in DMP_X is plotted against size no. X. As illustrated, the family of tibial baseplates 12 illustrated in Fig. 2A exhibit a steadily increasing growth in DMP_X , with nearly 20% average increase in growth from one size to the next consecutive size (as represented by the slope of the linear trend line having equation y = 0.1975x + 2.0225).

[0097] In Fig. 2D, the amount of growth in DLP_X is plotted against size no. X, and illustrates a smaller, but still positive growth increase across baseplate sizes. More specifically, the family of tibial baseplates 12 illustrated in Fig. 2A exhibit a nearly 4% average increase in growth from one size to the next consecutive size (as represented by the slope of the linear trend line having equation y = 0.0392x + 2.5508).

[0098] As used herein, a "family" of prostheses refers to a set or kit of prostheses sharing

common geometrical and/or performance characteristics. For example, the family of nine tibial baseplates whose peripheries 200_X are shown in Fig. 2A share a common asymmetry as described herein, such that each tibial baseplate is adapted to provide substantial tibial coverage, facilitate proper implant rotation and avoid impingement with various soft tissues of the knee. Typically, a family of prostheses includes a plurality of differently-sized components, with consecutively larger/smaller components sized to accommodate a variety of differently-sized bones. In the exemplary embodiments of the present disclosure, a size "1" or "A" prosthesis is the smallest prosthesis of the family, a size "9" or "J" prosthesis is the largest prosthesis of the family, and each of the intermediate sizes "2" or "B" through "8" or "H" are consecutively larger sizes.

[0099] Advantageously, in the family or kit of prosthesis peripheries shown in Fig. 2A, each tibial baseplate 12 (Fig. 1A) having periphery 200_X provides a close match to a particular subset of patient tibias T having a unique size and shape. Particular features of periphery 200_X have been designed with non-linear growth which is calculated to provide the closest possible fit for the largest number of particular natural geometries found in anatomic tibias T, as described in detail herein. This close fit allows for maximum coverage of the resected proximal tibial periphery 200_X , by accommodating the non-linear changes which may occur across anatomic tibial periphery sizes. Lateral- and medial-posterior distances DLP_X , DMP_X are exemplary non-linear growth parameters found in a family of tibial baseplates 12, and are reflective of non-linear growth in mediolateral extent DML_X and anteroposterior extents $DAPM_X$ and $DAPL_X$ across the various sizes.

3. Tibial Baseplates for Small-Stature Patients

[00100] As noted above, tibial baseplate 12 may be provided in a variety of sizes each defining a unique periphery 200_X. Periphery 200_X is described for an exemplary family of baseplate sizes in U.S. Patent Application Publication No. 2012/0022659, filed July 22, 2011 and entitled ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS, U.S. Patent Application Publication No. 2012/0022660, filed July 22, 2011 and entitled ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS and U.S. Patent Application Publication No. 2012/0022658, filed July 22, 2011 and entitled ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS, each of which claims the benefit under Title 35, U.S.C. §119(e) of U.S. Provisional Patent Application Serial No. 61/381,800, filed on September 10, 2010 and entitled TIBIAL PROSTHESIS FACILITATING ROTATIONAL ALIGNMENT, U.S. Provisional Patent Application Serial No. 61/367,375,

filed on July 24, 2010 and entitled TIBIAL PROSTHESIS. The entire disclosures of the aforementioned applications are hereby expressly incorporated by reference herein.

[00101] As described in detail below, the smallest two sizes of tibial baseplate 12 include other unique features to accommodate the special needs of smaller stature patients. More particularly, these small sizes of tibial baseplate 12 are not scaled down versions of the larger sizes, but instead include unique geometries suited to the smaller bones for which they are designed. Further, because the small stature tibial baseplates 12 have less material overall, special geometries are employed to selectively strengthen tibial baseplate 12 in areas where such strengthening would not be required for larger baseplate sizes.

[00102] In an exemplary embodiment, tibial baseplate 12 is considered "small stature" for nominal sizes 1 and 2. For example, nominal size 1 of tibial baseplate 12 may define a medial/lateral extent DML₁ of about 57 mm, a maximum anterior/posterior extent DAPM₁ of about 40 mm, and a surface area of about 1390 mm³ within periphery 200₁. Nominal size 2 of tibial baseplate 12 may define a medial/lateral extent DML₂ of about 61 mm, a maximum anterior/posterior extent DAPM₂ of about 43 mm, and a surface area of about 1580 mm³ within periphery 200₂.

One special feature of the small-stature sizes of tibial baseplate 12 is the shape of [00103]the outer surface of keel 16A extending distally from proximal tibial plateau 18. In larger size tibial baseplate 12, such as baseplate 12 shown in Fig. 4B, keel 16 defines a substantially cylindrical outer profile. By contrast, Fig. 10 illustrates that keel 16A of the small-stature size of tibial baseplate 12 has a generally conical, tapered outer profile defining taper angle θ . In an exemplary embodiment, angle θ may be about 9°. This 9° taper may be formed, for example, by tapering keel 16A from a circular outer diameter of about 17.1 mm at the proximal terminus of keel 16A (i.e., at the junction between keel 16A and distal surface 35 of tibial plateau 18) to a circular diameter of approximately 13.4 mm at the distal terminus of keel 16A. Keel 16, on the other hand, maintains a diameter between about 14 mm and about 16 mm that remains constant across the longitudinal extent. Moreover, prior art tibial baseplates include constant-diameter keels in this diameter range, such as the Zimmer NexGen Stemmed Tibial Plates and Natural Knee II Modular Cemented Tibial Plates. The NexGen Stemmed Tibial Plates and Natural Knee II Modular Cemented Tibial Plates are shown at pages 14 and 28, respectively, of the "Zimmer® Tibial Baseplate, Pocket Guide United States Version," the entire disclosure of which is hereby expressly incorporated herein by reference, a copy of which is submitted on even date herewith in an Information Disclosure Statement.

[00104] In an exemplary embodiment, keels 16, 16A are monolithically or integrally formed

with tibial plateau 18, though it is contemplated that keels 16, 16A may be separately attachable to tibial plateau 18. Further, in an exemplary embodiment keels 16, 16A themselves are monolithically formed as a single piece, rather than being assembled from multiple partial pieces to form a complete keel.

[00105] Referring to Figs. 9 and 10, another unique feature of small-stature sizes of tibial baseplate 12 is the geometry and arrangement of keel fins 17A as compared to keel fins 17 (Fig. 4B) of larger-stature sizes of baseplate 12. More particularly, fins 17A extend along less than the entire longitudinal extent of keel 16A, as best shown in Fig. 10, such that fins 17A terminate into the conical outer surface of keel 16A at a distance D_F above the distal tip of keel 16A. In an exemplary embodiment, distance D_F is about 7 mm, or about 26% of overall longitudinal extent PD_{KA} of keel 16A, such that fins 17A extend along the remaining 74% of longitudinal extent PD_{KA}.

[00106] Keel fins 17A of small-stature sizes of tibial baseplate 12 also define keel fin angle γ_A (Fig. 10) with respect to the longitudinal axis of keel 16A, which is larger than keel fin angle γ_A (Fig. 4B) defined by fins 17 of larger size tibial baseplate 12. In an exemplary embodiment, keel fin angle γ_A is equal to about 45°, as compared to keel fin angle γ of about 22-27° defined by larger sizes of baseplate 12 and by prior art devices including the Zimmer NexGen MIS Stemmed baseplates shown at pages 4-5 of the "Zimmer® Tibial Baseplate, Pocket Guide United States Version," the entire disclosure of which is hereby expressly incorporated herein by reference, a copy of which is submitted on even date herewith in an Information Disclosure Statement. The increased magnitude of keel fin angle γ_A concomitantly increases the overall medial/lateral extent in ML_{KA} of keel fins 17A at the junction with tibial plateau 18 at distal surface 35 for a given proximal/distal extent of keel fins 17A. As illustrated in Figs. 9 and 10, medial/lateral extent in ML_{KA} is the maximum medial/lateral distance defined by the medial and lateral fins 17A at the junction thereof with tibial plateau 18. In the illustrated embodiment, medial and lateral fins 17A are the only fins provided as part of small-stature tibial baseplate 12.

[00107] Provided that fins 17A extend along a substantial portion of the longitudinal extent PD_{KA} of keel 16A (e.g., across 74% of longitudinal extent PD_{KA} , as noted above), medial/lateral keel extent ML_{KA} may be equal to about 40 mm, which is commensurate with the corresponding medial/lateral keel extent ML_{K} (Fig. 4B) of larger sizes of tibial baseplate 12. Advantageously, the increased medial/lateral extent ML_{KA} defined by fins 17A of keel 16A present high resistance to rotation of tibial baseplate 12 in vivo, and enhance the overall strength of baseplate 12.

[00108] Yet another unique feature of keel 16A in small stature sizes of tibial baseplate 12 is its overall longitudinal extent PD_{KA} , which extends in a generally proximal/distal direction as shown in Fig. 10. Longitudinal extent PD_{KA} of the small-stature sizes of tibial baseplate 12 is substantially reduced with respect to longitudinal extent PD_K (Fig. 4B) of keel 16 in the larger sizes of tibial baseplate 12, and with respect to small baseplate sizes in other, alternative tibial baseplate designs. In an exemplary embodiment, longitudinal extend PD_{KA} of small stature tibial keel 16A may be about 27 mm, while longitudinal extent PD_K of larger tibial keel 16 may range from about 39 mm to about 48 mm.

[00109] Advantageously, the above-described special geometries and features of small stature tibial keel 16A prevent impingement of the conical outer surface of the body of keel 16A and/or fins 17A upon cortical bone when implanted upon the tibia of a small stature patient for which the small stature sizes of tibial baseplate 12 are intended. More particularly, Applicant has found that cortical bone impingement, is most likely to occur (if at all) at or near the distal tip of a tibial keel in small stature patients. To minimize the probability of such impingement, small stature tibial keel 16A of tibial baseplate 12 includes the above-described unique features while also retaining a large fixation area for attachment to the surrounding tissues, and maintaining a high minimum material thickness to ensure appropriate strength throughout the material of tibial baseplate 12. For example, the high value of keel fin angle γ_A (described in detail above) increases the surface area for fixation of tibial baseplate 12 to the surrounding bone, while the tapered outer surface of keel 16A ensures that a nominal minimum wall thickness of 1.5 mm is maintained throughout the material of tibial baseplate 12 while presenting a relatively small radius at the distal tip of keel 16A.

[00110] The probability of cortical bone impingement by keel 16A is also minimized by medially biasing the position of keel 16A with respect to the tibial baseplate periphery (i.e., peripheries 200₁ and 200₂). More particularly, small-stature sizes of tibial baseplate 12 have keel 16A offset approximately 1 mm from a centered position on distal surface 35 of tibial plateau 18, thereby enhancing the probability of proper alignment with the anatomic intramedullary canal and concomitantly minimizing the probably of cortical bone impingement. Medialization of keel 16A (and of keel 16 for larger sizes of baseplate 12) is described in detail in U.S. Provisional Patent Application Serial No. 61/562,133, filed November 21, 2011 and entitled TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES (Attorney Docket No. ZIM0913), and in U.S. Provisional Patent Application Serial No. 61/592,571, entitled TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES and filed January 30, 2012 (Attorney Docket No.

ZIM0913-01), and in U.S. Provisional Patent Application Serial No. 61/594,030, entitled TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES and filed February 2, 2012 (Attorney Docket No. ZIM0913-02), and in U.S. Provisional Patent Application Serial No. 61/621,369, entitled TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES and filed on April 6, 2012 (Attorney Docket No. ZIM0913-03), and in U.S. Patent Application Serial No. 13/593,339, entitled TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES and filed on August 23, 2012 (Attorney Docket No. ZIM0913-04), the entire disclosures of which are hereby expressly incorporated herein by reference.

[00111] Small stature tibial keel 16A also includes some features common to tibial keel 16 of larger sizes of tibial baseplate 12. For example, small stature tibial keel 16A includes a tapered bore 19 (Fig. 9) extending proximally into keel 16A from the distal tip thereof, which is designed to mate with a corresponding locking-taper surface 21 of tibial stem extension 23. The locking taper formed between the inner surface of bore 19 and surface 21 may define an angle of approximately 5° with respect to the shared longitudinal axis of keel 16A and stem extension 23 upon assembly. Further, a secondary locking mechanism may be provided in the form of set screw aperture 27A (Fig. 11) formed in a posterior portion of the outer wall of keel 16A. Set screw aperture 27A is positioned to align with annular groove 27B formed in stem extension 23 when tapered surface 21 is fully, lockingly seated with the correspondingly tapered inner surface bore 19. A set screw may then be threaded into aperture 27A to engage annular groove 27B, thereby offering secondary prevention of relative axial movement between stem extension 23 and tibial baseplate 12.

4. PCL Cutout Aligned with Home Axis and Associated Technique

[00112] In the illustrated embodiment, tibial plateau 18 includes PCL cutout 28 disposed between compartments 20, 22, as described above. PCL cutout leaves PCL attachment point C_P accessible, thereby allowing the PCL to pass therethrough during and after implantation of tibial baseplate 12. Tibial bearing component 14 (Fig. 5) may similarly include cutout 30. [00113] Thus, the illustrated embodiment of tibial prosthesis 10 is adapted for a cruciate retaining (CR) surgical procedure, in which the posterior cruciate ligament is not resected during implantation of tibial prosthesis 10. Further, as noted above, home axis A_H includes reference to PCL attachment point C_P when tibial baseplate 12 is mounted upon tibia T. In order to facilitate alignment of home axis A_H with respect to tibial baseplate 12 and tibia T, alignment indicia 70A, 70P (Figs. 4A and 4B) may be marked on proximal surface 34 and/or

peripheral wall 25. When tibial baseplate 12 is implanted (as described below), anterior alignment indicia 70A (Figs. 4A and 4B) is aligned with anterior point C_A at the "medial third" of the anterior tibial tubercle T, and posterior alignment indicia 70P is aligned with the natural PCL attachment point C_P of tibia T.

[00114] However, it is contemplated that a prosthesis in accordance with the present disclosure may be made for a design in which the posterior cruciate ligament is resected during surgery, such as "posterior stabilized" (PS) or "ultra congruent" (UC) designs. The PS and UC designs may exclude PCL cutout 30 in bearing component 14, thereby obviating the need for PCL cutout 28 in tibial baseplate 12. Continuous material may instead occupy cutout 28 (as schematically shown in Fig. 3D). Moreover, it is contemplated that PCL cutouts 28, 30 may have any shape and/or size within the scope of the present disclosure. For example, PCL cutouts 28, 30 may be asymmetrical with respect to an anteroposterior axis. For purposes of the present disclosure "bisecting" an asymmetric PCL cutout with an anteroposterior axis refers to dividing such cutout into two equal areas for a given anteroposterior section of the anteroposterior axis

5. Tibial Bearing Component and Deep Flexion Enablement

[00115] Turning again to Fig. 1A, tibial bearing component 14 includes lateral portion 39, medial portion 41, inferior surface 36 adapted to couple to tibial baseplate 12, and superior surface 38 adapted to articulate with condyles of a femoral component (such as femoral component 60 shown in Fig. 8 and described in detail below). Superior surface 38 includes lateral articular surface 40 in lateral portion 39 and medial articular surface 42 in medial portion 41, with eminence 44 (Fig. 5) disposed between articular surfaces 40. 42. Referring to Fig. 5, eminence 44 generally corresponds in shape and size with a natural tibial eminence of tibia T prior to resection.

[00116] Referring now to Fig. 1A, tibial plateau 18 of tibial baseplate 12 further includes a distal or bone contacting surface 35 and an opposing proximal or superior surface 34, with superior surface 34 having raised perimeter 24 and locking mechanism 26 formed between lateral and medial compartments 20, 22. Raised perimeter 24 and locking mechanism 26 cooperate to retain tibial bearing component 14 upon tibial baseplate 12, as described in detail below.

[00117] Inferior surface 36 of tibial bearing component 14 includes recess 46 at the periphery thereof and a tibial bearing locking mechanism (not shown) disposed between lateral and medial articular surfaces 40, 42. Recess 46 is sized and positioned to correspond with

raised perimeter 24 of tibial plateau 18, and the tibial bearing locking mechanism cooperates with locking mechanism 26 of tibial plateau 18 to fix tibial bearing component 14 to tibial baseplate 12 in a desired position and orientation as described in detail below. However, it is contemplated that tibial bearing component 14 may be affixed to baseplate 12 by any suitable mechanism or method within the scope of the present disclosure, such as by adhesive, dovetail tongue/groove arrangements, snap-action mechanisms, and the like.

[00118] Exemplary baseplate and tibial bearing locking mechanisms are described in U.S. Patent Application Publication No. 2012/0035737, filed July 22, 2011 and entitled TIBIAL PROSTHESIS (Attorney Docket No. ZIM0806-02), and in U.S. Patent Application Publication No. 2012/0035735, filed July 22, 2011 and entitled TIBIAL PROSTHESIS (Attorney Docket No. ZIM0806-03), the entire disclosures of which are hereby expressly incorporated by reference herein.

[00119] As best seen in Figs. 1B, 5 and 8, the outer periphery of tibial bearing component 14 generally corresponds with the outer periphery of tibial plateau 18, except for the posteromedial extent of plateau 18 as compared with tibial bearing component 14. The anterolateral "corner" of tibial bearing component 14 defines radius R₃ (Fig. 5) having a generally common center with radius R2L of baseplate 12 in a transverse plane, i.e., radii R2L and R₃ are substantially coincident in a plan view. Similarly, the anteromedial "corner" of tibial bearing component 14 defines radius R₄ having a generally common center with radius R1R of baseplate 12 in a transverse plane, i.e., radii R1R and R₄ are substantially coincident in a plan view.

[00120] R₃ defines a slightly smaller radial length as compared to R2L, and R₄ defines a slightly smaller radial length as compared to R1R, such that the anterior portion of perimeter wall 54 of tibial bearing component 14 is set back from the anterior portion of peripheral wall 25 (i.e., from anterior edge 202 and adjacent arcs, as described above) of tibial baseplate 12. As with the above-described comparison between radii R2L and R1R, anteromedial radius R₄ is substantially larger than anterolateral radius R₃.

[00121] Given that medial portion 41 of tibial bearing component 14 has a lesser anteroposterior extent compared to medial compartment 22 of tibial plateau 18, medial portion 41 must be biased anteriorly in order for the anterior-medial "corners" of tibial bearing component 14 and tibial plateau 18 to coincide as shown in Fig. 5. In view of this anterior bias, it may be said that tibial bearing component 14 is asymmetrically oriented upon tibial plateau 18. More particularly, although lateral articular surface 40 is generally centered with respect to lateral compartment 20 of tibial plateau 18, medial articular surface 42 is anteriorly biased with

respect to medial compartment 22 of tibial plateau 18 in order to leave chamfer 32 exposed at the posterior-lateral corner. This asymmetric mounting of tibial bearing component 14 upon tibial plateau 18 ensures a desired articular interaction between tibial prosthesis 10 and femoral component 60, as described in detail below.

[00122] Tibial plateau 18 of tibial baseplate 12 deviates from the periphery of tibial bearing component 14 in the posteromedial portion of each component, leaving medial portion 41 incongruent with medial compartment 22 of tibial baseplate 12. More particularly, tibial plateau 18 extends posteromedially to substantially cover the proximal resected surface of tibia T, as shown in Fig. 5 and described in above, while tibial bearing component 14 does not extend posteromedially beyond the superior terminus of chamfer 32 (i.e., tibial bearing component 14 does not "overhang" chamfer 32). In addition, tibial bearing component 14 includes chamfer 50 formed in peripheral wall 54, with chamfer 50 having a profile and geometrical arrangement corresponding with chamfer 32 of tibial plateau 18. More particularly, when tibial bearing component 14 is assembled to tibial baseplate 12 as shown in Figs. 1B and 8, the anterior orientation or "bias" of the medial portion of tibial bearing component 14 (as described above) aligns chamfers 32, 50, which in turn cooperate to create a substantially continuous chamfer extending from tibia T to medial articular surface 42. Referring to Fig. 8, chamfers 32, 50 further cooperate to define void 52 formed between femur F and tibial plateau 18 when tibial prosthesis 10 is in a deep flexion orientation. In the illustrated embodiment of Fig. 8, the deep flexion orientation is defined by angle β between anatomic tibia axis A_T and anatomic femoral axis A_F of up to about 25 degrees to about 40 degrees, for example (i.e., about 140 degrees to 155 degrees of flexion or more).

[00123] Advantageously, void 52 cooperates with the "pulled back" or incongruent posterior medial edge 206 and posterior medial corner 224, as compared to a typical tibial periphery (described above), to allow the deep flexion orientation to be achieved without impingement of femoral component 60 and/or femur F upon tibial plateau 18 and/or tibial bearing component 14. Soft tissues in the region of void 52 are therefore also accommodated with little or no impingement on the surrounding components.

[00124] In addition, the relatively large size of tibial plateau 18 (covering a large proportion of the resected proximal surface of tibia T) also allows tibial bearing component 14 to be relatively large, so that tibial bearing component 14 provides sufficient non-articular surface area at chamfers 32, 50 and around the periphery of lateral and medial articular surfaces 40, 42 to allow relatively large-radius, rounded transitions between articular surfaces 40, 42 and peripheral wall 54 of tibial bearing component 14. These gradual, large-radius transitions

prevent undue friction between tibial prosthesis 10 and any surrounding soft tissues which may remain in place after implantation of the prosthesis, such as the iliotibial (IT) band.

[00125] In certain ranges of prosthesis articulation, for example, the human iliotibial (IT) band may touch the anterolateral "corner", i.e., the portion of tibial bearing component 14 having radius R₃. Because the anterolateral extent of tibial bearing component 14 follows the anterolateral extent of tibial plateau 18 (as described above), the transition between lateral articular surface 40 and peripheral wall 54 at the point of contact between an IT band and tibial bearing component 14 can have a relatively large convex portion while still leaving sufficient concave space for articular surface 40. This large convex portion results in a large contact area if the IT band does contact tibial bearing component 14, which in turn results in relatively low pressures on the IT band. Further, the anterolateral "pull back" or incongruence between the anterior-lateral corner are 210 of periphery 200 and a typical tibial periphery, described in detail above, allows the corresponding anterior-lateral corner of bearing component 14 to maintain separation from the IT band through a wide range of flexion, and low contact pressures where contact does occur.

[00126] However, to any such contact between the IT band and tibial bearing component 14 may be avoided or minimized by designing periphery 200 such that anterior-lateral corner arc 210 and/or lateral edge arc 212 is brought away from the expected periphery of a typical tibia T (as calculated from anatomical data, described above). This extra spacing designed into periphery 200 provides extra clearance for the iliotibial band. In addition, this extra clearance assures that the substantial proportion of prospective patients lacking Gerdy's tubercle, which is an eminence located at the anterior-lateral portion of tibia T, will not experience any "overhang" of tibial plateau 18 beyond the anatomic periphery of resected tibia T.

[00127] Thus, generally speaking, tibial prosthesis 10 can be considered "soft tissue friendly" because the edges of tibial bearing component 14 and tibial plateau 18, including chamfers 32, 50, are smooth and rounded, so that any soft tissue coming into contact with these edges will be less likely to chafe or abrade.

[00128] Advantageously, the relatively large inferior/distal surface area of tibial plateau 18 facilitates a large amount of bone ingrowth where bone ingrowth material is provided in tibial baseplate 12. For example, baseplate 12 may also be constructed of, or may be coated with, a highly porous biomaterial. A highly porous biomaterial is useful as a bone substitute and as cell and tissue receptive material. A highly porous biomaterial may have a porosity as low as 55%, 65%, or 75% or as high as 80%, 85%, or 90%. An example of such a material is produced using Trabecular MetalTM Technology generally available from Zimmer, Inc., of Warsaw,

Indiana. Trabecular MetalTM is a trademark of Zimmer, Inc. Such a material may be formed from a reticulated vitreous carbon foam substrate which is infiltrated and coated with a biocompatible metal, such as tantalum, by a chemical vapor deposition ("CVD") process in the manner disclosed in detail in U.S. Patent No. 5,282,861 to Kaplan, the entire disclosure of which is hereby expressly incorporated herein by reference. In addition to tantalum, other metals such as niobium, or alloys of tantalum and niobium with one another or with other metals may also be used.

[00129] Generally, the porous tantalum structure includes a large plurality of ligaments defining open spaces therebetween, with each ligament generally including a carbon core covered by a thin film of metal such as tantalum, for example. The open spaces between the ligaments form a matrix of continuous channels having no dead ends, such that growth of cancellous bone through the porous tantalum structure is uninhibited. The porous tantalum may include up to 75%, 85%, or more void space therein. Thus, porous tantalum is a lightweight, strong porous structure which is substantially uniform and consistent in composition, and closely resembles the structure of natural cancellous bone, thereby providing a matrix into which cancellous bone may grow to provide fixation of implant [#] to the patient's bone.

[00130] The porous tantalum structure may be made in a variety of densities in order to selectively tailor the structure for particular applications. In particular, as discussed in the above-incorporated U.S. Patent No. 5,282,861, the porous tantalum may be fabricated to virtually any desired porosity and pore size, and can thus be matched with the surrounding natural bone in order to provide an improved matrix for bone ingrowth and mineralization.

6. <u>Trial Tibial Components</u>

[00131] Tibial prosthesis 10 may be provided in a variety of sizes and configurations to accommodate different bone sizes and geometries. The choice of one particular size may be planned preoperatively such as through preoperative imaging and other planning procedures. Alternatively, an implant size may be chosen, or a previous size choice modified, intraoperatively. To facilitate proper intraoperative selection of a particular size for tibial prosthesis 10 from among the family of sizes shown in Fig. 2A, and to promote proper orientation of the chosen prosthesis 10, tibial prosthesis 10 may be part of a kit including one or more template or "sizing" components.

[00132] Referring now to Figs. 6 and 7, trial prosthesis 100 may be temporarily coupled to tibia T for intraoperative sizing evaluation of tibial prosthesis 10 and initial steps in the

implantation of tibial prosthesis 10. Trial prosthesis 100 is one of a set of trial prostheses provided as a kit, with each trial prosthesis having a different size and geometrical configuration. Each trial prosthesis in the set of trial prostheses corresponds to a permanent prosthesis 10, such as sizes 1/A-9/J of tibial baseplate 12 as described above.

[00133] For example, as shown in Fig. 6, trial prosthesis 100 defines superior surface 112 generally corresponding in size and shape to proximal surface 34 of tibial plateau 18, and including lateral portion 102 and medial portion 104. Superior surface 112 is asymmetrical about home axis A_H, with lateral portion 102 having a generally shorter overall anteroposterior extent as compared to medial portion 104 (which includes void indicator 106, discussed below). In addition, the anterolateral "corner" of lateral portion 102 defines radius R2L, which is identical to radius R2L of tibial plateau 18, while the anteromedial "corner" of medial portion 104 defines radius R1R, which is identical to radius R1R of tibial plateau 18 and greater than radius R2L.

[00134] Moreover, perimeter wall 114 of trial prosthesis 100 is substantially identical to peripheral wall 25 of tibial plateau 18, and therefore defines periphery 200 with the same features and shapes of perimeter 200 described above with respect to tibial plateau 18. Thus, trial prosthesis 100 is asymmetrical about home axis A_H in a similar manner to tibial plateau 18 of tibial baseplate 12, with the nature of this asymmetry changing across the various other sizes of tibial prosthesis provided in the kit including trial prosthesis 100.

[00135] In an alternative embodiment, a trial prosthesis may be provided which extends completely to the posterior-medial edge of the natural tibial resection periphery. Thus, such a trial would substantially completely cover the resected tibial surface, thereby aiding in determination of a proper rotational orientation of the trial (and, therefore, of the final tibial baseplate 12). In this alternative embodiment, the trial prosthesis lacks the posterior-medial "pull back" of tibial plateau 18, described above.

[00136] Trial prosthesis 100 includes void indicator 106 disposed at the posterior portion of medial portion 104, consuming a given posteromedial area of superior surface 34 and peripheral wall 25. Void indicator 106 indicates where void 52 (discussed above) will be located with respect to tibia T after implantation of tibial prosthesis 10. Void indicator 106 facilitates proper rotational and spatial orientation of trial prosthesis 100 on the resected proximal surface of tibia T by allowing a surgeon to visually match tibial bearing component 14 with trial prosthesis 100, as described in detail below. In the illustrated embodiment, void indicator 106 is an area of visual and/or tactile contrast with the remainder of tibial plateau 18. This contrast may include, for example, a contrasting color, texture, surface finish, or the like,

or may be formed by a geometric discrepancy such as a step or lip, for example.

[00137] Referring specifically to Fig. 6, trial prosthesis 100 further includes a plurality of peg hole locators 108 corresponding to the proper location for peg holes in tibia T to receive pegs (not shown) extending inferiorly from tibial plateau 18 of tibial baseplate 12.

Advantageously, peg hole locators 108 allow a surgeon to demarcate the proper center for peg holes in tibia T once the proper size and orientation for trial prosthesis 100 has been found, as discussed in detail below. Alternatively, peg hole locators 108 may be used as drill guides to drill appropriately positioned peg holes while trial prosthesis is still positioned on tibia T.

7. <u>Tibial Prosthesis Implantation</u>

[00138] In use, a surgeon first performs a resection of tibia T using conventional procedures and tools, as are well-known in the art. In an exemplary embodiment, a surgeon will resect the proximal tibia to leave a planar surface prepared for receipt of a tibial baseplate. This planar surface may define a tibial slope, which is chosen by the surgeon. For example, the surgeon may wish to perform a resection resulting in positive tibial slope in which the resected tibial surface slopes proximally from posterior to anterior (i.e., the resected surface runs "uphill" from posterior to anterior). Alternatively, the surgeon may instead opt for negative tibial slope in which the resected tibial surface slopes distally from posterior to anterior (i.e., the resected surface runs "downhill" from posterior to anterior). Varus or valgus slopes may also be employed, in which the resected surface slopes proximally or distally from medial to lateral. The choice of a tibial and/or varus/valgus slope, and the amount or angle of such slopes, may depend upon a variety of factors including correction of deformities, mimicry of the native/preoperative tibial slope, and the like.

[00139] In an exemplary embodiment, keel 16 (Fig. 4B) defines a 5-degree, anteriorly-extending angle with respect to bone-contacting surface 35 of tibial plateau 18. Tibial baseplate 12 is appropriate for use with a positive tibial slope of as little as zero degrees and as much as 9 degrees, and with a varus or valgus slope of up to 3 degrees. However, it is contemplated that a tibial baseplate made in accordance with the present disclosure may be used with any combination of tibial and/or varus/valgus slopes, such as by changing the angular configuration of the keel with respect to the bone-contacting surface.

[00140] With a properly resected proximal tibial surface, the surgeon selects trial prosthesis 100 from a kit of trial prostheses, with each prosthesis in the kit having a different size and geometrical configuration (as discussed above). Trial prosthesis 100 is overlaid on the resected surface of tibia T. If trial prosthesis 100 is appropriately sized, a small buffer zone 110 of

exposed bone of resected tibia T will be visible around the periphery of trial prosthesis 100. Buffer 110 is large enough to allow a surgeon to rotate and/or reposition trial prosthesis 100 within a small range, thereby offering the surgeon some flexibility in the final positioning and kinematic profile of tibial prosthesis 10. However, buffer 110 is small enough to prevent trial prosthesis 100 from being rotated or moved to an improper location or orientation, or from being implanted in such as way as to produce excessive overhang of the edge of trial prosthesis 100 past the periphery of the resected tibial surface. In one exemplary embodiment, for example, trial prosthesis may be rotated from a centered orientation by up to +/- 5 degrees (i.e., in either direction), though it is contemplated that such rotation may be as much as +/- 10 degrees or +/- 15 degrees.

[00141] To aid in rotational orientation, trial prosthesis may include anterior and posterior alignment indicia 70A, 70P, which are the same marks in the same location as indicia 70A, 70P provided on tibial plateau 18 as described above. The surgeon can align indicia 70A with anterior point C_A and indicia 70P with PCL attachment point C_P, in similar fashion as described above, to ensure the anatomical and component home axes A_H are properly aligned. Alternatively, a surgeon may use indicia 70A, 70P to indicate a desired deviance from alignment with home axis A_H. As noted above, deviation of up to 5 degrees is envisioned with the exemplary embodiments described herein. A surgeon may choose to orient indicia 70A, 70P to another tibial landmark, such as the middle of the patella or the medial end of tibial tubercle B.

[00142] Thus, the large coverage of trial prosthesis 100 (and, concomitantly, of tibial plateau 18) ensures that tibial baseplate 12 will be properly positioned and oriented on tibia T upon implantation, thereby ensuring proper kinematic interaction between tibial prosthesis 10 and femoral component 60. If buffer zone 110 is either nonexistent or too large, another trial prosthesis 100 is selected from the kit and compared in a similar fashion. This process is repeated iteratively until the surgeon has a proper fit, such as the fit illustrated in Figs. 6 and 7 between trial prosthesis 100 and tibia T.

[00143] With the proper size for trial prosthesis 100 selected and its orientation on tibia T settled, trial prosthesis 100 is secured to tibia T, such as by pins, screws, temporary adhesive, or any other conventional attachment methods. Once trial prosthesis is so secured, other trial components, such as trial femoral components and trial tibial bearing components (not shown) may be positioned and used to articulate the leg through a range of motion to ensure a desired kinematic profile. During such articulation, void indicator 106 indicates to the surgeon that any impingement of femoral component 60 and/or femur F upon trial prosthesis 100 at void

indicator 106 will not occur when tibial prosthesis 10 is implanted. Once the surgeon is satisfied with the location, orientation and kinematic profile of trial prosthesis 100, peg hole locators 108 may be used to demarcate the appropriate location of peg holes in tibia T for tibial baseplate 12. Such peg holes may be drilled in tibia T with trial prosthesis 100 attached, or trial prosthesis 100 may be removed prior to drilling the holes.

[00144] With tibia T prepared for receipt of tibial prosthesis 10, tibial baseplate 12 may be provided by the surgeon (such as from a kit or surgical inventory), and is implanted on tibia T, with pegs fitting into holes previously identified and demarcated using peg hole locators 108 of trial prosthesis 100. Tibial baseplate 12 is selected from the family of tibial baseplates illustrated in Fig. 2A to correspond with the trial component 100 chosen, which ensures that tibial plateau 18 will cover a large proportion of the resected proximal surface of tibia T, as trial prosthesis 100 did prior to removal. Tibial baseplate is affixed to tibia T by any suitable method, such as by keel 16 (Fig. 4B), adhesive, bone-ingrowth material, and the like.

[00145] With tibial baseplate 12 installed, tibial bearing component 14 may be coupled with tibial baseplate 12 to complete tibial prosthesis 10. However, once attached, tibial bearing component 14 does not fully cover tibial plateau 18 of tibial baseplate 12. Rather, tibial bearing component 14 leaves a posteromedial portion of tibial baseplate 12 uncovered to create void 52 (as shown in Fig. 8 and discussed above). Thus, a surgeon may wish to verify that this anterior-biased, "asymmetrical" orientation of medial articular surface 42 is proper prior to permanent affixation of tibial bearing component 14 to tibial baseplate 12.

[00146] To accomplish such verification, tibial bearing component 14 is placed side-by-side with trial prosthesis 100, with inferior surface 36 of tibial bearing component 14 in contact with superior surface 112 of trial prosthesis 100. Tibial bearing component 14 will substantially cover superior surface 112, but will not cover void indicator 106. Put another way, peripheral wall 54 of tibial bearing component 14 will trace perimeter wall 114 of tibial trial prosthesis 100, excluding the posteromedial area defined by void indicator 106. If inferior surface 36 of tibial bearing component 14 is a match with superior surface 112 of trial prosthesis 100 except for void indicator 106 (which is left uncovered by tibial bearing component 14), then tibial bearing component 14 is the proper size component and may be confidently installed upon tibial plateau 18 of tibial baseplate 12.

[00147] Tibial baseplate 12 may then be implanted upon the proximal surface of tibia T in accordance with accepted surgical procedures. Exemplary surgical procedures and associated surgical instruments are disclosed in "Zimmer LPS-Flex Fixed Bearing Knee, Surgical Technique," "NEXGEN COMPLETE KNEE SOLUTION, Surgical Technique for the

CR-Flex Fixed Bearing Knee" and "Zimmer NexGen Complete Knee Solution Extramedullary/Intramedullary Tibial Resector, Surgical Technique" (collectively, the "Zimmer Surgical Techniques"), copies of which are submitted on even date herewith in an information disclosure statement, the entire disclosures of which are hereby expressly incorporated by reference herein.

When the surgeon is satisfied that tibial bearing component 14 is properly matched and fitted to the installed tibial baseplate 12, bearing component 14 is secured using locking mechanism 26 and the corresponding tibial bearing locking mechanism an appropriate instrumentation (not shown). Proper location and rotational orientation of tibial bearing component 14 upon tibial plateau 18 is ensured by raised perimeter 24 cooperating with recess 46, and locking mechanism 26 cooperating with the corresponding tibial bearing locking mechanism (not shown). Such proper orientation results in medial articular surface 42 being generally anteriorly disposed with respect to medial compartment 22 of tibial plateau 18. Femoral component 60 may be affixed to a distal end of femur F, if appropriate, using any conventional methods and/or components. Exemplary surgical procedures and instruments for such affixation are disclosed in the Zimmer Surgical Techniques, incorporated by reference above. Femur F and tibia T may then be articulated with respect to one another to ensure that neither femur F nor femoral component 60 impinges upon tibial baseplate 12 and/or tibial bearing component 14 in deep flexion, such as at a flexion angle β of 155° as shown in Fig. 8. When the surgeon is satisfied with the location, orientation and kinematic profile of tibial prosthesis 10, the knee replacement surgery is completed in accordance with conventional procedures.

[00150] While this invention has been described as having an exemplary design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

- 1. A small-stature tibial baseplate, comprising:
 - a tibial plateau comprising:
- a distal surface sized and shaped to substantially cover a proximal resected surface of a tibia;
- a proximal surface opposite said distal surface, said proximal surface having a lateral compartment and a medial compartment opposite said lateral compartment, the lateral compartment is asymmetric with respect to the medial compartment about a component anteroposterior axis to define a component asymmetry; and
- a peripheral wall extending between said distal surface and said proximal surface, wherein a total surface area bounded by said peripheral wall of said tibial plateau is between about 1390 mm² and about 1580 mm²;
- a tibial keel extending distally from said distal surface of said tibial plateau to define a longitudinal tibial keel axis; and
- a medial fin and a lateral fin spanning a junction between said tibial keel and said distal surface, each of said medial fin and said lateral fin comprising a fin edge having a planar portion defining an angle of about 45 degrees with respect to said longitudinal tibial keel axis, said medial fin and said lateral fin cooperating to define a medial/lateral fin extent of about 40 mm.
- 2. The small-stature tibial baseplate of claim 1, wherein said tibial keel defines a longitudinal extent equal to about 27 mm.
- 3. The small-stature tibial baseplate of claim 1, wherein said at least one fin extends along less than an entire longitudinal extent of said tibial keel.
- 4. The small-stature tibial baseplate of claim 3, wherein said at least one fin extends along about 74% of said entire longitudinal extent of said tibial keel.
- 5. The small-stature tibial baseplate of any one of claims 1 to 4, wherein said tibial keel is formed as a monolithic, one-piece keel.

- 6. The small-stature tibial baseplate of claim 5, wherein said tibial keel is monolithically formed with said tibial plateau.
- 7. The small-stature tibial baseplate of any one of claims 1 to 6, wherein said tibial keel comprises:
- a first diameter at said junction between said distal surface and said tibial keel; and a second diameter at a distal tip of said tibial keel, said first diameter larger than said second diameter.
- 8. The small-stature tibial baseplate of claim 7, wherein said first diameter is about 17.1 mm and said second diameter is about 13.4 mm.
- 9. The small-stature tibial baseplate of claim 7, wherein said tibial keel comprises a tapered outer profile extending between said first diameter and said second diameter.
- 10. The small-stature tibial baseplate of claim 9, wherein said tapered outer profile of said tibial keel defines a taper angle of about 9 degrees.
- 11. The small-stature tibial baseplate of any one of claims 1 to 10, wherein said tibial keel defines a longitudinal extent, said tibial keel having a minimum diameter along said longitudinal extent of at least 13 mm.
- 12. The small-stature tibial baseplate of any one of claims 1 to 11, wherein said tibial keel comprises a tapered bore extending proximally into said tibial keel from a distal tip of said tibial keel, said tapered bore sized to receive a correspondingly tapered proximal end of a tibial stem extension, such that said tapered proximal end of said tibial stem extension forms a locking taper connection with said tapered bore.
- The small-stature tibial baseplate of claim 12, wherein: 13. said tibial keel comprises a set screw aperture extending from an outer surface of said tibial keel to an inner surface defined by said tapered bore; and

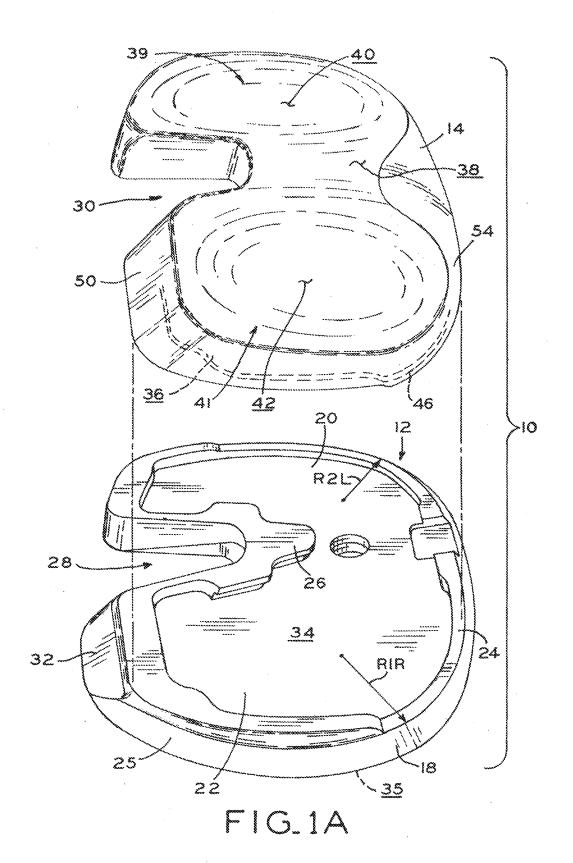
said tapered proximal end of said tibial stem extension comprises an annular groove positioned to align with said set screw aperture when said locking taper connection is formed between said tibial stem extension and said tapered bore.

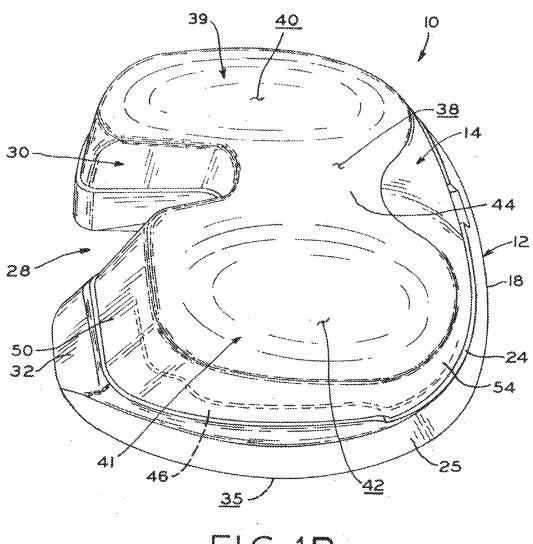
- 14. The small-stature tibial baseplate of claim 13, in combination with a set screw receivable within said set screw aperture, said set screw extending into said annular groove to form a secondary locking mechanism preventing relative axial movement between said tibial stem extension and said tibial keel when said locking taper connection is formed between said tibial stem extension and said tapered bore.
- 15. The small-stature tibial baseplate of any one of claims 1 to 14, wherein said tibial plateau defines an overall medial/lateral extent of between about 57 mm and about 61 mm.
- 16. A small-stature tibial baseplate, comprising:
 - a tibial plateau comprising:
- a distal surface sized and shaped to substantially cover a proximal resected surface of a tibia;
- a proximal surface opposite said distal surface, said proximal surface having a lateral compartment and a medial compartment opposite said lateral compartment, the lateral compartment is asymmetric with respect to the medial compartment about a component anteroposterior axis to define a component asymmetry; and
- a peripheral wall extending between said distal surface and said proximal surface, wherein a total surface area bounded by said peripheral wall of said tibial plateau is between about 1390 mm² and about 1580 mm²;
- a tibial keel extending distally from a junction with said distal surface to an opposing distal tip, said tibial keel positioned so as to substantially coincide with an intramedullary canal of the tibia when said distal surface is placed upon the tibia, said tibial keel comprising a first diameter at said junction between said distal surface and said tibial keel and a second diameter at said distal tip of said tibial keel, each of said first diameter and said second diameter equal to or greater than 13 mm, the first diameter greater than the second diameter; and

a medial fin and a lateral fin each spanning a portion of said junction between said tibial keel and said tibial plateau, wherein each of said medial fin and said lateral fin comprising a fin edge having a planar portion defining an angle of about 45 degrees with respect to a longitudinal tibial keel axis, said medial fin mating with said distal surface at said medial compartment, said lateral fin mating with said distal surface at said lateral compartment, wherein said medial and lateral fins cooperate to define a medial/lateral fin extent of about 40 mm.

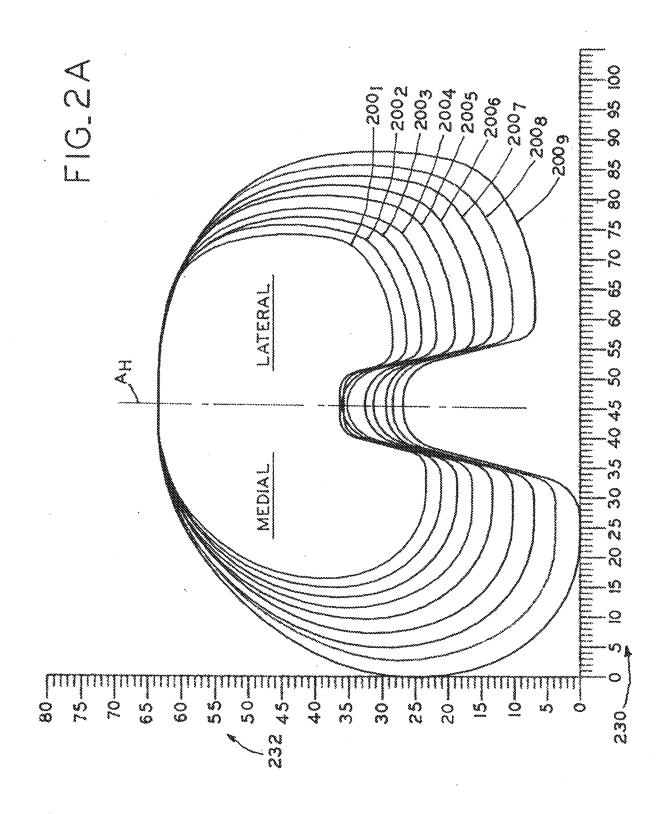
- 17. The small-stature tibial baseplate of claim 16 wherein said tibial keel comprises a tapered outer profile extending between said first diameter and said second diameter.
- 18. The small-stature tibial baseplate of claim 17, wherein said tapered outer profile of said tibial keel defines a taper angle of 9 degrees.
- 19. The small-stature tibial baseplate of claim 16 or 17, wherein said tibial plateau defines an overall medial/lateral extent of between about 57 mm and about 61 mm.
- 20. The small-stature tibial baseplate of claim 19, wherein said tibial plateau defines an overall anterior/posterior extent substantially perpendicular to said overall medial/lateral extent, said overall anterior/posterior extent between about 40 mm and about 43 mm.
- 21. The small-stature tibial baseplate of claim 20, wherein said medial and lateral fins extend along less than an entire longitudinal extent of said tibial keel.
- 22. The small-stature tibial baseplate of claim 21, wherein said medial and lateral fins extend along about 74% of said entire longitudinal extent of said tibial keel.
- 23. The small-stature tibial baseplate of any one of claims 16 to 22, wherein said tibial keel is monolithically formed with said tibial plateau

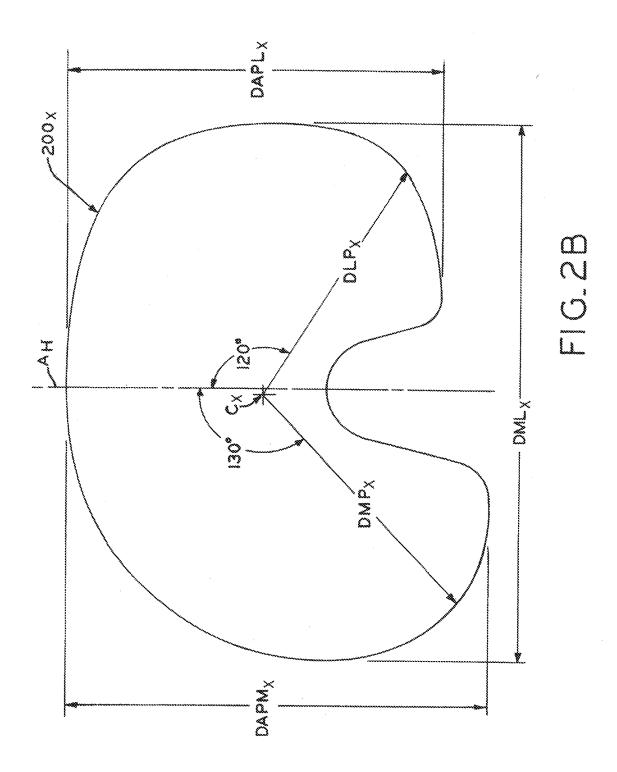
- 24. The small-stature tibial baseplate of any one of claims 16 to 22, wherein said tibial keel is separately attachable to said tibial plateau.
- 25. The small-stature tibial baseplate of any one of claims 16 to 24, wherein said tibial keel comprises a tapered bore extending proximally into said tibial keel from said distal tip of said tibial keel, said tapered bore sized to receive a corresponding tapered proximal end of a stem extension to form a locking taper connection.
- 26. The small-stature tibial baseplate of claim 25, wherein said tibial keel comprises a set screw aperture formed in a posterior portion of an outer wall of said tibial keel, said set screw aperture positioned to align with an annular groove formed in said tapered proximal end of said stem extension when said tapered proximal end is fully, lockingly seated within said tapered bore.



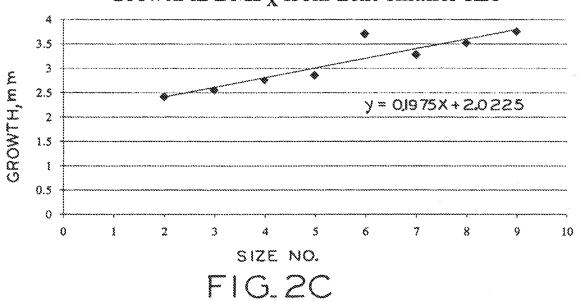


FIG_18

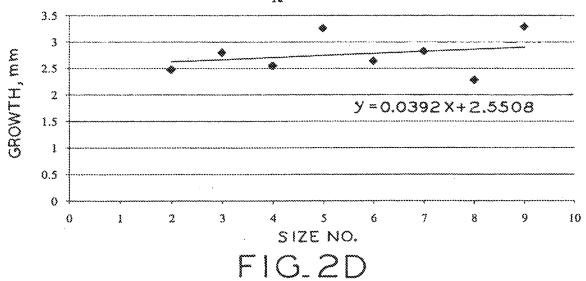


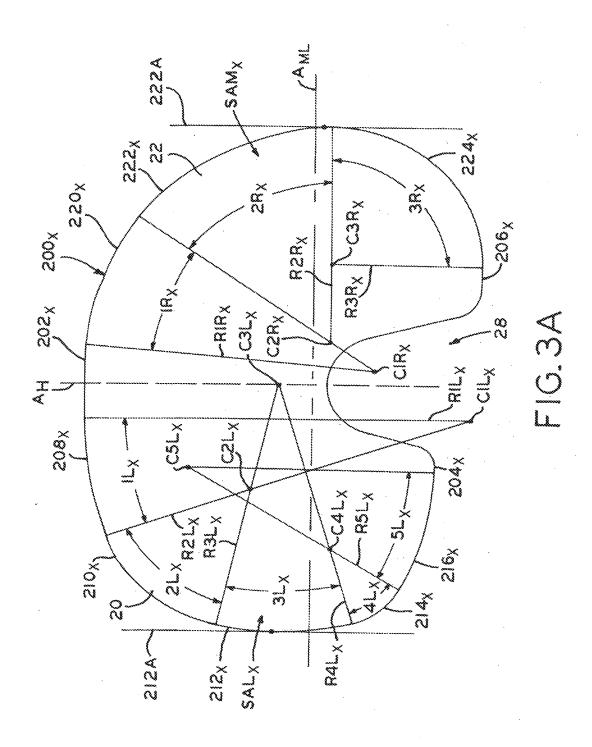


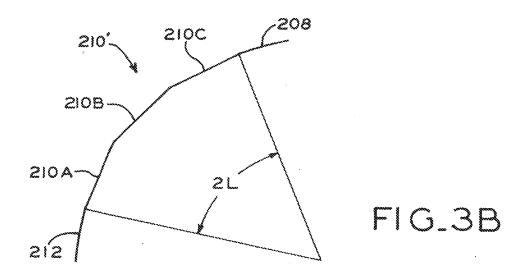


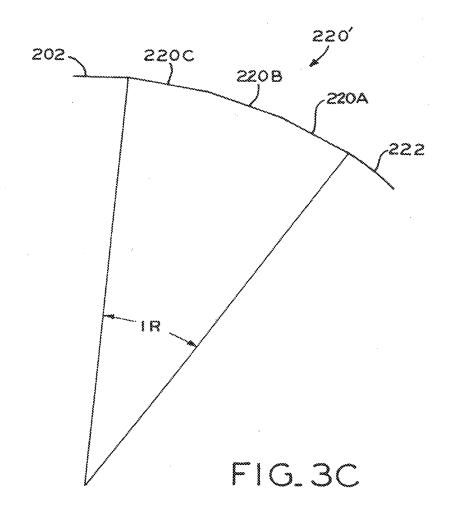


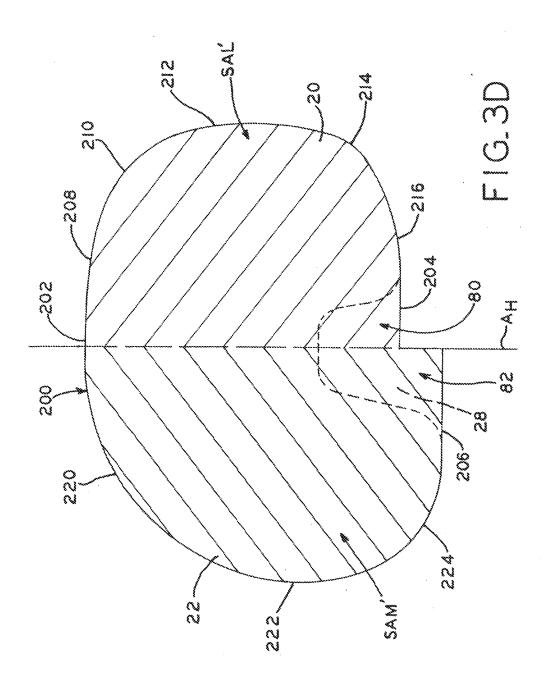
Growth in DLP_X from next-smaller size











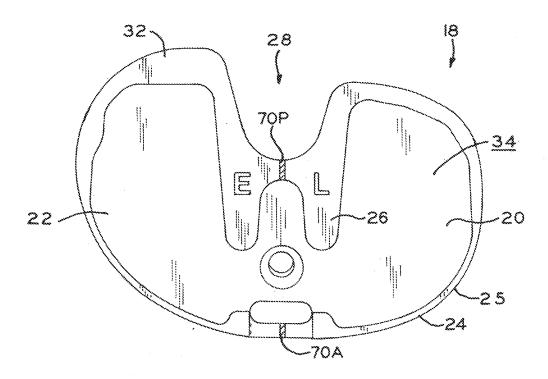


FIG. 4A

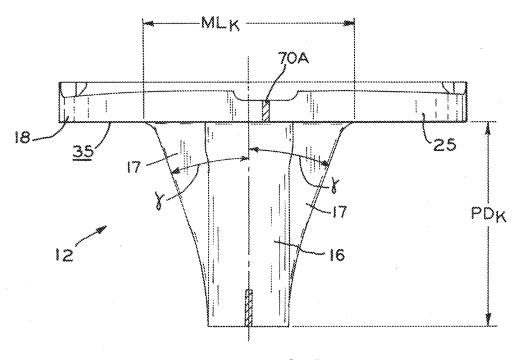
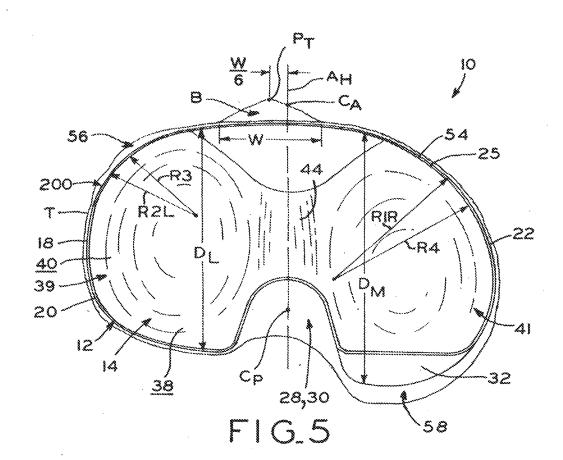
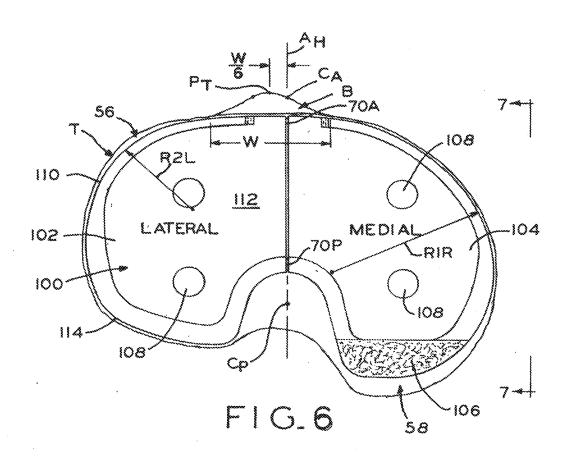


FIG.4B





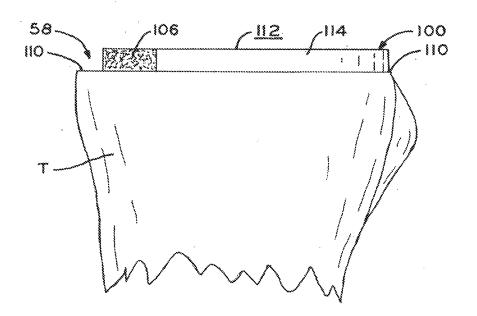
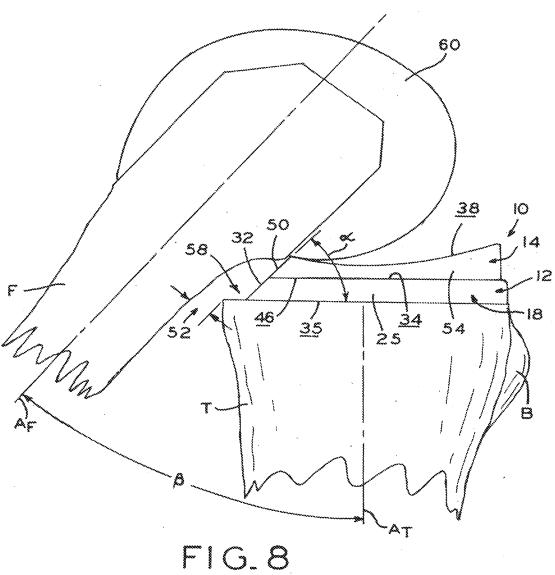


FIG. 7



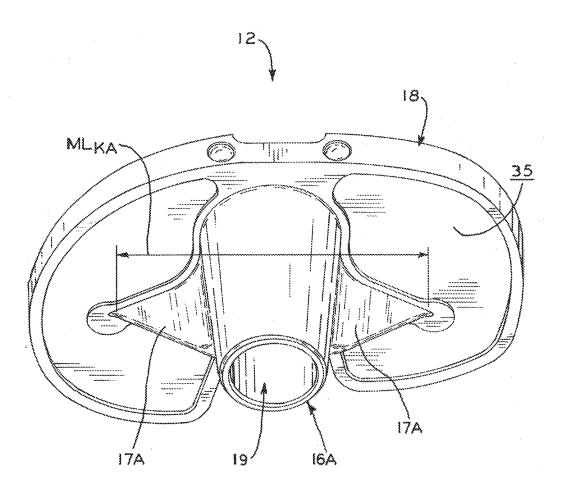


FIG.9

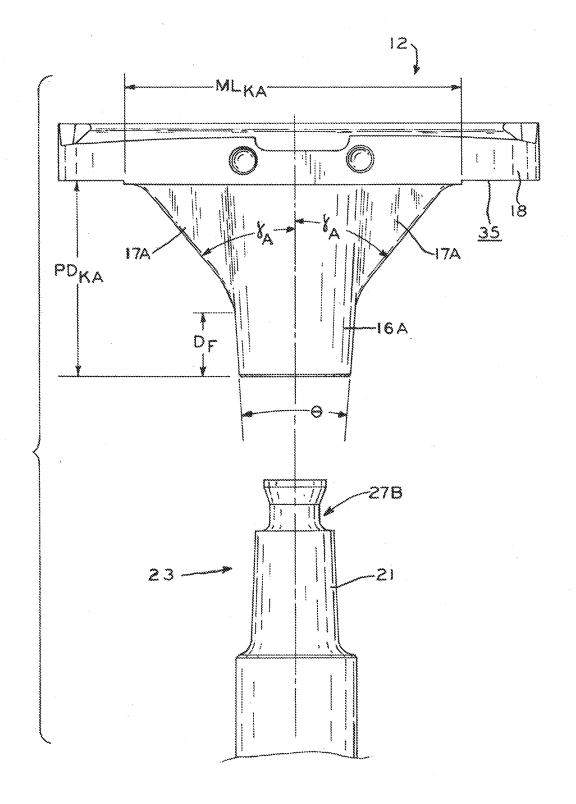
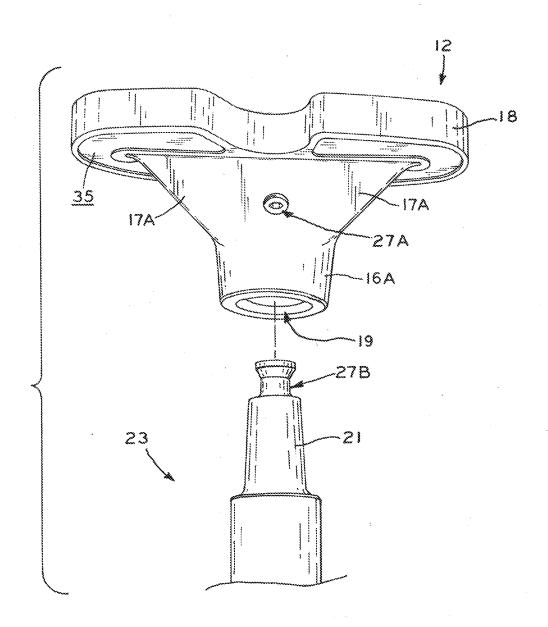


FIG.10

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FIG_11