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#### (54) Title: TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES

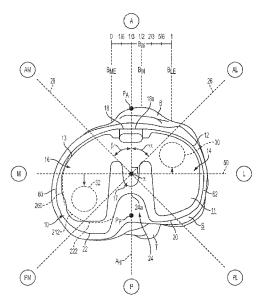
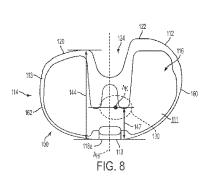


FIG. 1



(57) **Abstract**: An orthopaedic knee prosthesis is provided including a tibial baseplate component having a distal, bone-contacting surface with one or more fixation structures extending distally therefrom, in which the fixation structures are asymmetrically arranged within the baseplate periphery.



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# TIBIAL BASEPLATE WITH ASYMMETRIC PLACEMENT OF FIXATION STRUCTURES

# FIELD OF THE DISCLOSURE

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

# BACKGROUND OF THE DISCLOSURE

[0002] Orthopaedic prostheses are commonly utilized to repair and/or replace damaged bone and tissue in the human body. For a damaged knee, a knee prosthesis may be implanted using a proximal tibial baseplate component, a tibial bearing component, and a distal femoral component. The tibial baseplate component is affixed to a proximal end of the patient's tibia, which is typically resected to accept the baseplate component. The femoral component is implanted on a distal end of the patient's femur, which is also typically resected to accept the femoral component. The tibial bearing component is placed between the tibial baseplate component and the femoral component, and may be fixed or slidably coupled to the tibial baseplate component.

[0003] The tibial baseplate component provides support for the tibial bearing component. Forces generated by use of the knee prosthesis are transferred through the tibial bearing component to the tibial baseplate component, and ultimately to the tibia. In order to ensure long term performance of the knee prosthesis, stable and firm securement of the tibial baseplate component to the proximal end of the patient's tibia is desired.

### **SUMMARY**

[0004] This application is related to U.S. Provisional Patent Application Serial No. 61/562,133, filed November 21, 2011 (Attorney Docket No. ZIM0913), to U.S. Provisional Patent Application Serial No. 61/592,571, filed January 30, 2012 (Attorney Docket No. ZIM0913-01), and to U.S. Provisional Patent Application Serial No. 61/594,030, filed February 2, 2012 (Attorney Docket No. ZIM0913-02), the entire disclosures of which are hereby expressly incorporated by reference herein.

[0005] The present disclosure provides an orthopaedic knee prosthesis including a tibial baseplate component having a distal, bone-contacting surface with one or more fixation structures extending distally therefrom, the fixation structures being asymmetrically arranged within the outer periphery of the baseplate.

[0006] For designs utilizing a plurality of fixation pegs that extend distally from the bone-contacting surface of the tibial baseplate, fixation pegs are asymmetrically arranged in opposite anterior/lateral and posterior/medial regions of the tibial baseplate, thereby maximizing distance between the fixation pegs, avoiding overlap with the intramedullary canal, avoiding areas of low bone density, and avoiding cortical impingement by positioning the fixation pegs in regions of cancellous bone.

**[0007]** For designs utilizing a single keel that extends distally from the bone-contacting surface of the tibial baseplate, the keel is medialized with respect to the outer periphery of the tibial baseplate, where the degree of medialization increases as prosthesis sizes grow progressively.

[8000] According to an embodiment thereof, the present disclosure provides a tibial prosthesis system comprising: a first tibial baseplate comprising: a first proximal surface; a first distal surface opposite the first proximal surface, the first distal surface sized and shaped to substantially cover a proximal resected surface of a tibia; a first medial face; a first lateral face opposite the first medial face; a first total width measured from the first medial face to the first lateral face; and a first keel extending distally from the first distal surface, the first keel spaced from the first medial face by a first medial distance and spaced apart from the first lateral face by a first lateral distance; and a second tibial baseplate comprising: a second proximal surface; a second distal surface opposite the second proximal surface, the second distal surface sized and shaped to substantially cover a proximal resected surface of a tibia; a second medial face; a second lateral face opposite the second medial face; a second total width measured between the second medial face and the second lateral face, the second total width differing from the first total width whereby the first and second tibial baseplates comprise unique nominal sizes; and a second keel extending distally from the second distal surface, the second keel spaced apart from the second medial face by a second medial distance and spaced apart from the second

lateral face by a second lateral distance, a first ratio of the first medial distance to the first total width differing from a second ratio of the second medial distance to the second total width.

[0009] According to another embodiment thereof, the present disclosure provides a tibial baseplate configured for implantation upon a patient's proximal tibia, the tibial baseplate comprising: a medial compartment; a lateral compartment opposite the medial compartment; a proximal surface; a distal surface opposite the proximal surface, the distal surface sized and shaped to substantially cover the patient's proximal tibia; an outer periphery cooperatively defined by an anterior face, a medial face, a lateral face, and at least one posterior face; a first, anterior-posterior axis located between the medial face and the lateral face and intersecting the anterior face, the first axis extending centrally between the medial and lateral compartments throughout its length; a plurality of fixation pegs extending distally from the distal surface, each of the plurality of fixation pegs being positioned inward of the outer periphery for implantation into the patient's proximal tibia, the plurality of fixation pegs comprising: a medial fixation peg located at the medial compartment; and a lateral fixation peg located at the lateral compartment, the lateral fixation peg being positioned more anteriorly than each other fixation peg among the plurality of fixation pegs.

[0010] According to yet another embodiment thereof, the present disclosure provides a tibial baseplate configured for implantation upon a patient's proximal tibia, the tibial baseplate comprising: a medial compartment; a lateral compartment opposite the medial compartment; a proximal surface; a distal surface opposite the proximal surface, the distal surface sized and shaped to substantially cover the patient's proximal tibia; an outer periphery cooperatively defined by an anterior face, a medial face, a lateral face, and at least one posterior face; at most one medial fixation peg associated with the medial compartment, the medial fixation peg extending distally from the distal surface and positioned for implantation into the patient's proximal tibia; and at most one lateral fixation peg associated with the lateral compartment, the lateral fixation peg extending distally from the distal surface and positioned for implantation into the patient's proximal tibia, the lateral fixation peg being located closer to the anterior face than the medial fixation peg.

[0011] According to still another embodiment thereof, the present disclosure provides a tibial baseplate configured for implantation upon a patient's proximal tibia, the tibial baseplate comprising: a medial compartment; a lateral compartment opposite the medial compartment; a proximal surface; a distal surface opposite the proximal surface, the distal

surface sized and shaped to substantially cover the patient's proximal tibia; an outer periphery cooperatively defined by an anterior face, a medial face, a lateral face, and at least one posterior face; a first, anterior-posterior axis located between the medial face and the lateral face and intersecting the anterior face, the first axis extending centrally between the medial and lateral compartments throughout its length; a first fixation peg extending distally from the distal surface, the first fixation peg being inset from the outer periphery for implantation into the patient's proximal tibia, the first fixation peg being medially spaced from the first axis by a first distance; and a second fixation peg extending distally from the distal surface, the second fixation peg being inset from the outer periphery for implantation into the patient's proximal tibia, the second fixation peg being laterally spaced from the first axis by a second distance, the second distance less than the first distance.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The above-mentioned and other features and advantages of this disclosure, 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:

[0013] FIG. 1 is a proximal plan view of a tibial baseplate made in accordance with the present disclosure, the baseplate having a lateral fixation peg and a medial fixation peg, the baseplate shown implanted upon the resected proximal surface of a patient's tibia, the baseplate shown having an asymmetric outer periphery in solid lines and a symmetric outer periphery in phantom;

[0014] FIG. 2A is a first, distal plan view of the baseplate of FIG. 1, showing medial/lateral positioning of the fixation pegs and the overall medial bias thereof;

[0015] FIG. 2B is a second, distal plan view of the baseplate of FIG. 1 similar to FIG. 2A, showing anterior/posterior positioning of the fixation pegs;

[0016] FIG. 2C is a third, distal plan view of the baseplate of FIG. 1 similar to FIGS. 2A and 2B, also showing anterior/posterior positioning of the fixation pegs;

[0017] FIG. 3 is a lateral elevational view of the baseplate of FIG. 1;

[0018] FIG. 4 is a distal plan view of an alternative baseplate;

[0019] FIG. 5 is a distal plan view of another alternative baseplate;

[0020] FIG. 6 is a graph illustrating the anterior/posterior positioning of the fixation pegs of FIGS. 1-3 across a range of prosthesis sizes;

[0021] FIG. 7 is a posterior perspective view of the baseplate of FIG. 1, shown with a tibial bearing component mounted thereon;

[0022] FIG. 8 is a proximal plan view of another tibial baseplate made in accordance with the present disclosure, the baseplate having a single fixation keel for fixation to the patient's tibia;

[0023] FIG. 9A is an anterior elevational view of the baseplate of FIG. 8;

[0024] FIG. 9B is another anterior elevational view of the baseplate of FIG. 8;

[0025] FIG. 10 is a graph illustrating the medialization of the fixation keel of FIGS. 8 and 9 across a range of prosthesis sizes;

[0026] FIG. 11 is another graph illustrating the medialization of the fixation keel of FIGS. 8 and 9 across a range of prosthesis sizes;

[0027] FIG. 12 is a graph illustrating the anterior/posterior positioning of the fixation keel of FIGS. 8 and 9 across a range of prosthesis sizes; and

[0028] FIG. 13 is a distal plan view of another baseplate similar to the baseplate shown in FIGS. 2A-2C, but having another lateral fixation peg and another medial fixation peg; and

[0029] Fig. 14 is a perspective view of a posterior-stabilized femoral component in accordance with the present disclosure.

[0030] 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**

[0031] The present disclosure provides a tibial baseplate component for a knee prosthesis including asymmetrically arranged distal fixation structures which promote secure and stable long term fixation of the tibial baseplate to a patient's proximal tibia.

[0032] In order to prepare the tibia and femur for receipt of a knee joint prosthesis of the present disclosure, any suitable methods or apparatuses for preparation of the knee joint may be used. The surgical procedure may involve, for example, forming an incision in the patient's skin near the knee joint, resecting the distal end of the patient's femur (not shown), and resecting the proximal end of the patient's tibia T (FIG. 1). Resecting the proximal end of the patient's tibia T (FIG. 1), in particular, may involve guiding a saw blade through an appropriate cutting guide slot to form a substantially planar resected surface S of tibia T, as shown in FIG. 1.

[0033] Exemplary surgical procedures and associated surgical instruments are disclosed in Zimmer's "LPS-Flex Fixed Bearing Knee, Surgical Technique" bearing copyright dates of 2004, 2007 and 2008, "NexGen® Complete Knee Solution, Surgical Technique for the CR-Flex Fixed Bearing Knee" bearing a copyright date of 2003, "NexGen® Complete Knee Solution Extramedullary/Intramedullary Tibial Resector, Surgical Technique" bearing copyright dates of 2000, 2008 and 2009, "NexGen® Trabecular Metal<sup>TM</sup> Monoblock Tibial Components, Surgical Technique Addendum," bearing copyright dates of 2005 and 2007, "NexGen® Trabecular Metal<sup>TM</sup> Tibial Tray, Surgical Technique," bearing copyright dates of 2007 and 2009, and "Trabecular Metal<sup>TM</sup> Monoblock Tibial Components," bearing a copyright date of 2007 (collectively, the "Zimmer Surgical Techniques"), the entire disclosures of which are hereby expressly incorporated herein by reference, copies of which are submitted on even date herewith in an Information Disclosure Statement.

[0034] 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 a patient). "Anterior" refers to a direction generally toward the front of a patient or knee, and "posterior" refers to the opposite direction of anterior (i.e., toward the back of the patient or knee). "Lateral" refers to a direction generally away from the middle of the patient and the sagittal plane, and "medial" refers to the opposite direction of lateral (i.e., toward the middle of the patient and the sagittal plane). When referring to one of the patient's knees, "lateral" refers

to the direction generally away from the other knee, and "medial" refers to the direction generally toward the other knee.

These anatomical regions are labeled in certain drawings for clarity. In FIG. 1, for example, the anterior region of tibia T is labeled "A," the posterior region of tibia T is labeled "P," the lateral region of tibia T is labeled "L," and the medial region of tibia T is labeled "M." Therebetween and moving in a clock-wise direction, the anterior/lateral region of tibia T is labeled "AL," the posterior/lateral region of tibia T is labeled "PL," the posterior/medial region of tibia T is labeled "PM," and the anterior/medial region of tibia T is labeled "AM." The AL, PL, PM, and AM regions can be described as dividing tibia T into four corners or quadrants. These labels are referenced throughout the following paragraphs.

[0036] The embodiments shown and described herein illustrate components for a right knee prosthesis. Right and left knee prosthesis configurations are generally mirror images of one another about a sagittal plane. Thus, it will be appreciated that the aspects of the prosthesis described herein for a right knee configuration are equally applicable to a left knee configuration.

# 1. <u>Tibial Baseplate</u>

Referring now to FIG. 1, tibial baseplate 10 is shown disposed atop a proximal resected surface S of a patient's tibia T. The upper or proximal surface 11 of baseplate 10 is shown in FIG. 1. This proximal surface 11 of baseplate 10 is configured to receive a tibial bearing component 53 (FIG. 7) in a fixed or a sliding relationship, for example. To arrange baseplate 10 and the tibial bearing component 53 in a fixed relationship, the tibial bearing component 53 may be adhered to, mechanically fastened to, molded directly onto (as discussed further below), or otherwise fixedly coupled to baseplate 10. The illustrative baseplate 10 includes a raised rim 13 around proximal surface 11 to receive, surround, and hold the tibial bearing component 53 therein, but it is contemplated that other structures may be provided on baseplate 10 to receive and hold the tibial bearing component 53 on baseplate 10. In turn, tibial bearing component 53 is configured to interact with the patient's distal femur or a prosthetic femoral component, such as femoral component 70 shown in Fig. 14 and described below.

[0038] Baseplate 10 may be partially or entirely constructed of 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 Metal<sup>TM</sup> Technology generally available from Zimmer, Inc., of Warsaw, Indiana. Trabecular Metal<sup>TM</sup> 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 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.

[0039] 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 baseplate 10 to the patient's bone.

[0040] 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.

[0041] Bearing component 53 may be molded directly onto baseplate 10, specifically proximal surface 11 of baseplate 10. If baseplate 10 is constructed of a highly porous biomaterial, as discussed above, the material that is used to construct bearing component 53 (e.g., polyethylene) may interdigitate into the pores of baseplate 10 during the molding process. The pores may be located at and beneath proximal surface 11 of baseplate 10, so the resulting molded bearing component 53 may also be located at and beneath proximal surface 11 of baseplate 10. The resulting structure may be a monoblock component having a strong,

wear-resistant connection between baseplate 10 and bearing component 53, especially along proximal surface 11 of baseplate 10.

Baseplate 10 includes outer periphery 12, which may be visible in a top plan view (FIG. 1) or a bottom plan view (FIGS. 2A-2C) with baseplate 10 positioned in a generally transverse anatomical plane. As shown in FIG. 1, outer periphery 12 is cooperatively defined by anterior face 18, posterior/lateral face 20, posterior/medial face 22, PCL cutout area 24, lateral face 62, and medial face 60. Each of these surfaces is described further below.

[0043] Baseplate 10 also includes lateral compartment 14, medial compartment 16, and interior compartment 17 therebetween. Lateral compartment 14 and medial compartment 16 are separated by an anterior-posterior home axis A<sub>H</sub>, which is discussed further below. Because FIG. 1 is a proximal view of the patient's right tibia T, lateral compartment 14 of baseplate 10 is located on the right side of FIG. 1 and medial compartment 16 of baseplate 10 is located on the left side of FIG. 1.

With bearing component 53 in place against baseplate 10 (FIG. 7) to articulate with adjacent femoral component 70, for example, lateral compartment 14 of baseplate 10 will be positioned generally beneath lateral condyle 74 of femoral component 70 to support and articulate with lateral condyle 74, and medial compartment 16 of baseplate 10 will be positioned generally beneath medial condyle 72 of femoral component 70 to support medial condyle 72. Tibial bearing component 53 (Fig. 7) may be disposed between medial and lateral condyles 72, 74 of femoral component 70 and medial and lateral compartments 16, 14 to provide a low-friction articular interface, as described below. In the illustrative embodiment, femoral component 70 includes cam 76 adapted to articulate with a spine of a tibial bearing component, e.g., spine 58 of tibial bearing component 53 (Fig. 7). However, it is contemplated that femoral component 70 may omit spine 76 to provide an uninterrupted space between medial and lateral condyles 72, 74 in some prosthesis designs.

[0045] Anterior face 18 of the illustrative baseplate 10 is disposed anteriorly on periphery 12 of baseplate 10 (i.e., in the A region of tibia T). Anterior face 18 is generally centrally located between lateral and medial compartments 14, 16. More specifically, as shown in FIG. 1, anterior face 18 includes a linear or flat portion 18a that is generally centrally located between lateral and medial compartments 14, 16. In this illustrated embodiment, flat portion 18a of anterior face 18 defines the anterior-most extent of baseplate 10.

[0046] Posterior/lateral face 20 of the illustrative baseplate 10 is disposed generally opposite anterior face 18 in the posterior region of lateral compartment 14 (i.e., near the PL region of tibia T). Posterior/medial face 22 of the illustrative baseplate 10 is disposed generally opposite anterior face 18 in the posterior region of medial compartment 16 (i.e., near the PM region of tibia T). The PCL cutout area 24 is disposed between posterior/lateral face 20 and posterior/medial face 22 (i.e., near the P region of tibia T). From both posterior/lateral face 20 and posterior/medial face 22, the PCL cutout area 24 extends generally anteriorly until reaching apex 24a.

[0047] Lateral face 62 of the illustrative baseplate 10 is disposed laterally of lateral compartment 14 on periphery 12 of baseplate 10 (i.e., near the L region of tibia T). Medial face 60 of the illustrative baseplate 10 is located medially of medial compartment 16 on periphery 12 of baseplate 10 (i.e., near the M region of tibia T).

#### 2. Home Axis and Other Reference Axes of Tibial Baseplate

[0048] In the context of patient anatomy, such as tibia T described herein, "home axis"  $A_H$  of tibia T extends anteriorly from a posterior point  $P_P$  on tibia T to an anterior point  $P_A$  on tibia T. The posterior point  $P_P$  and the anterior point  $P_A$  of tibia T are discussed further below.

[0049] The posterior point  $P_P$  is generally disposed in the area where the patient's posterior cruciate ligament (PCL) attaches to tibia T. More specifically, the posterior point  $P_P$  is generally disposed at the geometric center of the attachment between the patient's PCL and tibia T. The patient's PCL typically attaches to tibia T in two ligament "bundles," the first bundle having a more anterolateral attachment location and the second bundle having a more posteromedial attachment location. In FIG. 1, the posterior point  $P_P$  is shown at the geometric center of the first bundle. It is also within the scope of the present disclosure that the posterior point  $P_P$  may be located at the geometric center of the second bundle or at the geometric center of the first and second bundles, together.

[0050] The anterior point  $P_A$  is disposed on the patient's anterior tibial tubercle B. In FIG. 1, the anterior point  $P_A$  is medially spaced from the tubercle midpoint  $B_M$  (at marking 1/2) by an amount equal to 1/6 of the overall medial/lateral tubercle width  $B_W$  (which spans between markings 0 and 1). Stated another way, the anterior point  $P_A$  is laterally spaced from the tubercle medial end  $B_{ME}$  (at marking 0) by an amount equal to 1/3 of the overall

medial/lateral tubercle width  $B_W$  (which spans between markings 0 and 1), such that the anterior point  $P_A$  lies on the "medial third" of the anterior tibial tubercle B (at marking 1/3).

[0051] In the context of a prosthesis, such as tibial baseplate 10 described herein, "home axis"  $A_H$  of baseplate 10 refers to an anterior-posterior extending axis of baseplate 10 that aligns with home axis  $A_H$  of tibia T upon implantation of baseplate 10 onto resected surface S of tibia T in a proper rotational and spatial orientation (as shown in FIG. 1). According to an exemplary embodiment of the present disclosure, and as shown in FIG. 1, home axis  $A_H$  of baseplate 10 is centrally located between the inner-most portion of lateral compartment 14 and the inner-most portion of medial compartment 16 of baseplate 10 throughout its length. In other words, home axis  $A_H$  of baseplate 10 is equidistant from the inner-most portion of lateral compartment 14 and the inner-most portion of medial compartment 16 of baseplate 10 to divide the interior compartment 17 therebetween into substantially equal halves.

In the illustrative embodiment of FIG. 1, home axis  $A_{\rm H}$  of baseplate 10 bisects anterior face 18 of baseplate 10 (which is located anteriorly on periphery 12 of baseplate 10) and is generally perpendicular to flat portion 18a of anterior surface 18. Also, home axis  $A_{\rm H}$  of baseplate 10 bisects PCL cutout area 24 of baseplate 10 (which is located posteriorly on periphery 12 of baseplate 10) and is generally perpendicular to apex 24a of PCL cutout area 24. It is contemplated that home axis  $A_{\rm H}$  of baseplate 10 may be oriented to other features of baseplate 10, it being understood that proper alignment and orientation of baseplate 10 upon resected surface S of tibia T will position home axis  $A_{\rm H}$  of baseplate 10 coincident with home axis  $A_{\rm H}$  of tibia T.

[0053] The home axes A<sub>H</sub> of tibia T and baseplate 10 are further described in U.S. Patent Application Publication No. 2012/0022659, filed July 22, 2011, entitled "ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS," the entire disclosure of which is hereby expressly incorporated herein by reference.

[0054] A pair of reference axes 26, 28 is presented in FIG. 1. A first reference axis 26 extends diagonally across baseplate 10 from the back-left PM region of tibia T to the front-right AL region of tibia T, intersecting home axis  $A_H$  to define a first angle  $\alpha$  with home axis  $A_H$ , as shown in FIG. 1. A second reference axis 28 extends diagonally across baseplate 10 and perpendicularly to the first axis 26 from the back-right PL region of tibia T to the front-left AM

region of tibia T, intersecting home axis  $A_H$  to define a second angle  $\beta$  with home axis  $A_H$ , as shown in FIG. 1. The first and second angles  $\alpha$  and  $\beta$  are each approximately 45 degrees such that, when combined, the first and second angles  $\alpha$  and  $\beta$  together total approximately 90 degrees.

[0055] The first and second reference axes 26, 28 illustratively intersect one another and home axis  $A_H$  at a common point X within periphery 12 of baseplate 10. According to an exemplary embodiment of the present disclosure, point X is generally centered within periphery 12 of baseplate 10 to maximize the aggregated extent of each reference axis 26, 28 that is located within periphery 12 of baseplate 10 while maintaining the desired first and second angles  $\alpha$  and  $\beta$ , as discussed above. Point X is illustratively positioned along home axis  $A_H$  between flat portion 18a of anterior face 18 and apex 24a of PCL cutout area 24.

[0056] Illustratively, a medial-lateral axis 50 also extends through point X in a direction perpendicular to home axis A<sub>H</sub>. Together, the medial-lateral axis 50 (e.g., the x-axis) and the anterior-posterior home axis A<sub>H</sub> (e.g., the y-axis) cooperate to define a component coordinate system (e.g., an x-y coordinate system) useful for quantifying and identifying certain features of baseplate 10.

# 3. <u>Shape of Outer Periphery of Tibial Baseplate</u>

[0057] According to an exemplary embodiment of the present disclosure, and as shown in FIG. 1, baseplate 10 has an asymmetric outer periphery 12. The asymmetric outer periphery 12 may be designed to closely match the corresponding periphery of resected surface S of tibia T. In the illustrated embodiment of FIG. 1, for example, medial compartment 16 is larger than lateral compartment 14. Medial compartment 16 is wider than lateral compartment 14, so medial face 60 is spaced further apart from the anterior-posterior home axis A<sub>H</sub> than lateral face 62. Medial compartment 16 is also deeper than lateral compartment 14, so posterior/medial face 22 is spaced further apart posteriorly from the medial-lateral axis 50 than posterior/lateral face 20. For at least these reasons, the outer periphery 12 of baseplate 10 is asymmetric.

[0058] The asymmetric shape of baseplate 10 is further described in U.S. Patent Application Publication No. 2012/0022659, filed July 22, 2011, entitled "ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS," the entire disclosure of which is hereby expressly incorporated herein by reference.

[0059] It is also within the scope of the present disclosure that baseplate 10 may have a symmetric outer periphery 212, as shown in phantom in FIG. 1. In this embodiment, lateral compartment 14 and medial compartment 16 are the same shape and size. Lateral compartment 14 and medial compartment 16 are the same width, so lateral face 62 and the modified medial face 260 (shown in phantom) are equidistant from the anterior-posterior home axis A<sub>H</sub>. In this manner, an anterior-posterior axis of symmetry through outer periphery 212 of symmetric baseplate 10 may overlay "home axis" A<sub>H</sub> and may serve as a reference for lateral compartment 14, medial compartment 16, lateral face 62, medial face 260, lateral and fixation pegs 30, 32 (described below) and other components of baseplate 10. Thus, in addition to being centered within interior compartment 17 between lateral compartment 14 and medial compartment 16 of the symmetric embodiment of baseplate 10, the anterior-posterior home axis A<sub>H</sub> would also be centered between lateral face 62 and the modified medial face 260 (shown in phantom). Lateral compartment 14 and medial compartment 16 also define a common anterior/posterior depth, so posterior/lateral face 20 and the modified posterior/medial face 222 (shown in phantom) are equidistant from the medial-lateral axis 50. Generally, a symmetric outer periphery 212 allows the same baseplate 10 to be implanted onto either a patient's right tibia or left tibia.

#### 4. Fixation Pegs

[0060] Referring next to FIGS. 2A-2C and 3, the underside or distal surface 34 of baseplate 10 is shown. Distal surface 34 is the surface which contacts resected surface S of tibia T (FIG. 1) after implantation of baseplate 10. As shown in FIG. 3, distal surface 34 is located opposite proximal surface 11. Baseplate 10 includes a plurality of fixation structures, illustratively lateral fixation peg 30 and medial fixation peg 32, that extend distally from distal surface 34 and into tibia T (FIG. 1).

[0061] Each fixation peg 30, 32 is inset from outer periphery 12 of baseplate 10. Each fixation peg 30, 32 may have a minimum inset distance 39 (FIG. 2A) that exceeds 0 mm, such as 1 mm, 3 mm, 5 mm, or more, for example. For purposes of the present disclosure, and as shown in FIG. 2A, the minimum inset distance 39 is the smallest distance measured between outer periphery 12 of baseplate 10 and the outer perimeter of each fixation peg 30, 32.

[0062] According to an exemplary embodiment of the present disclosure, fixation pegs 30, 32 of baseplate 10 are constructed of a highly porous biomaterial, such as the

above-described porous tantalum material. Distal surface 34 of baseplate 10 may also be constructed of a highly porous biomaterial. With distal surface 34 of baseplate 10 resting against resected surface S of tibia T and fixation pegs 30, 32 of baseplate 10 extending distally into tibia T, the highly porous biomaterial may provide a matrix into which cancellous bone may grow to provide fixation of baseplate 10 to tibia T.

[0063] As shown in FIG. 3, the illustrative fixation pegs 30, 32 are hexagonal in cross-section near distal surface 34 of baseplate 10. As fixation pegs 30, 32 continue extending distally away from distal surface 34 of baseplate 10, fixation pegs 30, 32 transition to a circular cross-section. The hexagonal to circular transition of fixation pegs 30, 32 is also evident in FIGS. 2A-2C. In FIG. 1, by contrast, each fixation peg 30, 32 is represented by a phantom circle to schematically show the general location of each fixation peg 30, 32, not necessarily the size or shape of each fixation peg 30, 32. Exemplary fixation pegs 30, 32 are shown at pages 16-19 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.

[0064] According to an exemplary embodiment of the present disclosure, and as discussed further below, lateral and medial fixation pegs 30, 32 are asymmetrically arranged on distal surface 34 of baseplate 10. In one exemplary embodiment, fixation pegs 30, 32 are asymmetrically arranged about the anterior-posterior home axis  $A_H$ , such that the anterior-posterior home axis  $A_H$  is not an axis of symmetry of fixation pegs 30, 32. In another embodiment, fixation pegs 30, 32 are asymmetrically arranged about the medial-lateral axis 50, such that the medial-lateral axis 50 is not an axis of symmetry of fixation pegs 30, 32. In yet another embodiment, fixation pegs 30, 32 are asymmetrically arranged about both the anterior-posterior home axis  $A_H$  and the medial-lateral axis 50, such that neither the anterior-posterior home axis  $A_H$  nor the medial-lateral axis 50 is an axis of symmetry of fixation pegs 30, 32.

### 5. Anterior/Lateral (AL) and Posterior/Medial (PM) Positioning of Fixation Pegs

[0065] Returning now to FIG. 1, lateral fixation peg 30 in lateral compartment 14 of baseplate 10 is positioned anteriorly relative to the medial-lateral axis 50 and anteriorly of medial fixation peg 32. Thus, lateral fixation peg 30 is more generally positioned in the AL region of tibia T while being substantially distanced from the PL region of tibia T. The AL bias

of lateral fixation peg 30 is evident in FIG. 1, because from the center point X, the first axis 26 extends toward the AL region and approaches or even intersects lateral fixation peg 30, while the second axis 28 extends toward the PL region extends further away from lateral fixation peg 30.

[0066] In the medial compartment 16 of baseplate 10, medial fixation peg 32 is positioned posteriorly relative to the medial-lateral axis 50 and posteriorly of lateral fixation peg 30. Thus, medial fixation peg 32 is more generally positioned in the PM region of tibia T while being substantially distanced from the AM region of tibia T. The PM bias of medial fixation peg 32 is evident in FIG. 1, because from the center point X, the first axis 26 extends toward the PM region and approaches or even intersects medial fixation peg 32, while the second axis 28 extends toward the AM region and travels away from medial fixation peg 32. In this exemplary embodiment, both fixation pegs 30, 32 are generally positioned along the same first reference axis 26 which spans the PM and AL regions.

[0067] An alternative baseplate 10' is shown in FIG. 4 for contrast. Outer periphery 12' of the alternative baseplate 10' of FIG. 4 is generally the same as outer periphery 12 of baseplate 10 (shown in solid lines in FIG. 1) – both are asymmetric in shape. However, unlike fixation pegs 30, 32 of FIGS. 2A-2C, which are located on opposite sides of the medial-lateral axis 50, fixation pegs 30', 32' of FIG. 4 are aligned along and intersect with medial-lateral axis 50'. With respect to baseplate 10', both the anterior-posterior home axis A<sub>H</sub>' and the medial-lateral axis 50' are axes of symmetry for fixation pegs 30', 32', such that fixation pegs 30', 32' may be said to be symmetrically oriented with respect to the component coordinate system.

[0068] Another alternative baseplate 10" is shown in FIG. 5 for contrast. Outer periphery 12" of the alternative baseplate 10" of FIG. 5 is generally the same as outer periphery 212 of baseplate 10 (shown in phantom in FIG. 1) – both are symmetric in shape. Lateral compartment 14" of the alternative baseplate 10" is generally the same size and shape as medial compartment 16" of the alternative baseplate 10". Therefore, the anterior-posterior home axis A<sub>H</sub>" is an axis of symmetry for outer periphery 12" of baseplate 10". Like fixation pegs 30', 32' of FIG. 4, fixation pegs 30", 32" of FIG. 5 are aligned along and intersect with medial-lateral axis 50". With respect to baseplate 10", both the anterior-posterior home axis A<sub>H</sub>" and the medial-lateral axis 50" are axes of symmetry for fixation pegs 30", 32", such that that fixation

pegs 30", 32" may be said to be symmetrically oriented with respect to the component coordinate system.

Returning again to FIG. 1, the asymmetric positioning of lateral and medial fixation pegs 30, 32 near opposite AL and PM corners or quadrants, respectively, allows fixation pegs 30, 32 to be widely spaced apart across distal surface 34 of baseplate 10.

Advantageously, this wide spacing facilitates avoidance of the anatomic intramedullary canal of tibia T upon implantation (which may be located near the intersection point X), particularly where baseplate 10 is used for a small-stature patient. By avoiding placement of fixation pegs 30, 32 within the intramedullary canal of tibia T, the associated areas of low bone density are avoided and, instead, fixation pegs 30, 32 may be implanted into areas of higher bone density, thereby promoting firm and stable long-term fixation of tibial baseplate 10 to tibia T. If fixation pegs 30, 32 are constructed of a highly porous biomaterial, as discussed above, this firm and stable long-term fixation may be achieved by cancellous bone growth into the porous fixation pegs 30, 32. Also advantageously, the wide spacing between fixation pegs 30, 32 are too close together, there may not be enough space for bone to grow therebetween.

[0070] Also, the asymmetric arrangement of lateral and medial fixation pegs 30, 32 on opposite sides of the medial-lateral axis 50 may enhance the torsional stability of baseplate 10 when implanted upon tibia T (FIG. 1). During normal use, a significant portion of the forces generated on baseplate 10 are directed anteriorly or posteriorly. Activities which primarily generate such anteriorly-directed or posteriorly-directed forces include walking, running, squatting, and climbing stairs, for example. As shown in FIG. 3, such anteriorly-directed and posteriorly-directed forces give rise to anterior torsional moments M<sub>A</sub> and posterior torsional moments M<sub>P</sub>, respectively, which urge rotation of baseplate 10 anteriorly and posteriorly about the medial-lateral axis 50. Having lateral and medial fixation pegs 30, 32 positioned on opposite sides of the medial-lateral axis 50 (i.e., the axis of rotation), as illustrated in FIG. 3 and discussed in detail above, presents greater resistance to such rotation.

[0071] Furthermore, positioning lateral and medial fixation pegs 30, 32 in the AL and PM regions of tibia T, rather than the PL and AM regions of tibia T, may avoid impingement of pegs 30, 32 on adjacent cortical bone upon implantation of baseplate 10. Advantageously, the AL and PM regions of tibia T (where fixation pegs 30, 32 are located) are typically populated with substantial areas of cancellous bone, thereby promoting firm and stable long-term fixation

of tibial baseplate 10 to tibia T and promoting bone ingrowth. By contrast, the PL and AM regions of tibia T (where fixation pegs 30, 32 are not located) are typically populated with substantial areas of cortical bone. By avoiding the PL and AM regions of tibia T, the potential for impingement of fixation pegs 30, 32 upon cortical bone is minimized.

# 6. Lateral/Medial Positioning of Fixation Pegs

[0072] Because lateral fixation peg 30 extends from lateral compartment 14 and medial fixation peg 32 extends from medial compartment 16, as discussed above, lateral fixation peg 30 can be said to be positioned "more laterally" on distal surface 34 of baseplate 10 than medial fixation peg 32. Similarly, medial fixation peg 32 is positioned "more medially" on distal surface 34 of baseplate 10 than lateral fixation peg 30. Thus, as shown in FIG. 2A, fixation pegs 30, 32 are spaced apart by a medial-lateral separation distance 36. For purposes of the present disclosure, the medial-lateral separation distance 36 is measured on center between fixation pegs 30, 32 along a direction perpendicular to home axis A<sub>H</sub> and parallel to medial-lateral axis 50 (FIG. 2B). In an exemplary embodiment, the medial-lateral separation distance 36 is between 20 mm and 55 mm, with smaller separation distances 36 corresponding to smaller nominal prosthesis sizes, and larger separation distances 36 corresponding to larger nominal prosthesis sizes.

fixation peg 30 and/or medial fixation peg 32 are medially biased in their respective compartments 14, 16. In lateral compartment 14, the illustrative lateral fixation peg 30 is medially biased toward home axis A<sub>H</sub>. In medial compartment 16, the illustrative medial fixation peg 32 is medially biased away from home axis A<sub>H</sub>. The medial bias of fixation pegs 30, 32, is evident in FIG. 2A, for example, where central peg axis 38 (which is centered along the medial-lateral separation distance 36 between fixation pegs 30, 32) is medially biased toward medial compartment 16 and away from home axis A<sub>H</sub>. Because central peg axis 38 is centered along medial-lateral separation distance 36, central peg axis 38 divides medial-lateral separation distance 36 into equal halves – one half being located between lateral fixation peg 30 and central peg axis 38 and the other half being located between medial fixation peg 32 and central peg axis 38.

[0074] If fixation pegs 30, 32 were equally spaced apart from home axis A<sub>H</sub>, central peg axis 38 would coincide with home axis A<sub>H</sub>. However, in FIG. 2A, pegs 30, 32 are not

equally spaced apart from home axis A<sub>H</sub>. Instead, lateral fixation peg 30 is located closer to home axis A<sub>H</sub> than medial fixation peg 32. As a result, central peg axis 38 between fixation pegs 30, 32 is medially spaced or offset toward medial compartment 16 and away from home axis A<sub>H</sub> by offset distance 40. Therefore, fixation pegs 30, 32 may be said to be asymmetrically, medially biased relative to home axis A<sub>H</sub>. In an exemplary embodiment, offset distance 40 is between 3 mm and 6 mm. Smaller prosthesis sizes may have smaller values for offset distance 40, while larger prosthesis sizes may have larger values for offset distance 40.

# 7. Anterior/Posterior Positioning of Fixation Pegs

[0075] As discussed above, lateral fixation peg 30 is positioned relatively more anteriorly on distal surface 34 of baseplate 10 than medial fixation peg 32. Stated differently, medial fixation peg 32 is positioned relatively more posteriorly on distal surface 34 of baseplate 10 than lateral fixation peg 30. Thus, as shown in FIG. 2B, pegs 30, 32 are spaced apart by an anterior-posterior separation distance 42. For purposes of the present disclosure, the anterior-posterior separation distance 42 is measured on center between fixation pegs 30, 32 along a direction parallel to home axis A<sub>H</sub>. In an exemplary embodiment, the anterior-posterior separation distance 42 is between 5 mm and 11 mm, with smaller separation distances 42 corresponding to smaller prosthesis sizes, and larger separation distances 42 corresponding to larger prosthesis sizes.

[0076] The alternative baseplates 10', 10" of FIGS. 4 and 5 are provided for contrast. Because lateral and medial fixation pegs 30', 32' of the alternative baseplate 10' of FIG. 4, for example, are aligned in an anterior-posterior direction, lateral and medial fixation pegs 30', 32' lack an anterior-posterior separation distance analogous to the anterior-posterior separation distance 42 of FIG. 2B. Or stated differently, lateral and medial fixation pegs 30', 32' have an anterior-posterior separation distance equal to 0 mm. Similarly, lateral and medial fixation pegs 30", 32" of the alternative baseplate 10" of FIG. 5 are aligned in an anterior-posterior direction and, therefore, have an anterior-posterior separation distance equal to 0 mm.

[0077] Turning now to FIG. 2C, another way of quantifying the anterior/posterior asymmetry of fixation pegs 30, 32 is by contrasting their different positions relative to a common reference marker. In FIG. 2C, for example, the common reference marker is flat portion 18a of anterior face 18 of baseplate 10, with measurements being taken posteriorly

therefrom in a direction parallel to home axis A<sub>H</sub>. Lateral fixation peg 30 is spaced posteriorly from anterior face 18 by a relatively smaller lateral peg distance 46, while medial fixation peg 32 is spaced posteriorly from anterior face 18 by a relatively larger medial peg distance 48. The lateral anterior/posterior depth 44 of lateral compartment 14 of baseplate 10 is also shown being measured from anterior face 18 to posterior/lateral face 20 of baseplate 10, and this lateral anterior/posterior depth 44 exceeds both peg distances 46, 48. Similarly, medial anterior/posterior depth 45 of medial compartment 16 of baseplate 10 is also shown being measured from anterior face 18 to posterior/medial face 22 of baseplate 10, and medial anterior/posterior depth 45 exceeds both peg distances 46, 48, as well as lateral anterior/posterior depth 44. If baseplate 10 had a symmetric outer periphery 212 (shown in phantom in FIG. 1) instead of the asymmetric outer periphery 12 of FIG. 2C, lateral depth 44 and medial depth 45 would be the same.

[0078] The alternative baseplates 10', 10" of FIGS. 4 and 5 are provided for contrast. Because lateral and medial fixation pegs 30', 32' of the alternative baseplate 10' of FIG. 4, for example, are aligned in an anterior-posterior direction, the lateral peg distance 46' from anterior face 18' to lateral fixation peg 30' is the same as the medial peg distance 48' from anterior face 18' to medial fixation peg 32'. The same is also true for lateral peg distance 46" and medial peg distance 48" of the alternative baseplate 10" of FIG. 5. Because the alternative baseplate 10' of FIG. 4 has an asymmetric outer periphery 12', medial depth 45' differs from lateral depth 44'. Because the alternative baseplate 10" of FIG. 5 has a symmetric outer periphery 12", on the other hand, medial depth 45" is the same as lateral depth 44".

#### 8. Asymmetric Positioning of Fixation Pegs for Set of Prostheses

Baseplate 10 may be provided in a kit or set of different prosthesis sizes. In one embodiment, nine baseplates 10 are provided in the set, with baseplates 10 growing progressively in lateral anterior/posterior depth 44 and/or other dimensions, for example. The progressive growth of periphery 12 of baseplates 10 across the set or family of baseplate sizes is described in detail in U.S. Patent Application Publication No. 2012/0022660 filed July 22, 2011 and entitled ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS (Attorney Docket: ZIM0815-02), the entire disclosure of which is hereby expressly incorporated herein by reference.

[0080] Referring next to FIG. 6, exemplary peg distances 46, 48 are graphically presented for a set of prostheses of different sizes. More specifically, exemplary peg distances 46, 48 are graphically presented for a set of prostheses having different lateral depths 44. The vertical axis of FIG. 6 shows peg distances 46, 48 (in millimeters), while the horizontal axis of FIG. 6 shows various lateral depths 44 (also in millimeters) and the corresponding nominal size indicator (1-9). The data points located farther to the left represent smaller lateral depths 44 (and therefore smaller nominal prosthesis sizes), and data points located farther to the right represent larger lateral depths 44 (and therefore larger nominal prosthesis sizes). In accordance with FIG. 2C, peg distances 46, 48 and lateral depth 44 are measured posteriorly from flat portion 18a of anterior face 18.

[0081] For each given prosthesis size (i.e., each discrete value of lateral depth 44), a pair of points are presented for lateral and medial peg distances 46, 48, respectively, with a space between the pair of points. This space indicates that peg distances 46, 48 are different for each of the nine given prosthesis sizes. Medial peg distances 48 consistently exceed the corresponding lateral peg distances 46 for each of the nine given prosthesis sizes. For example, each medial peg distance 48 may exceed the corresponding lateral peg distance 46 by 7 mm to 11 mm. In this manner, each of the given prostheses has anterior/posterior asymmetry of fixation pegs 30, 32 with respect to anterior face 18.

[0082] FIG. 6 also demonstrates that, as the prosthesis size increases, medial peg distances 48 may increase at a faster rate than lateral peg distances 46. In the illustrated embodiment of FIG. 6, medial peg distances 48 increase at a rate (i.e., slope) of approximately 0.9, while lateral peg distances 46 increase at a rate of approximately 0.6. As a result, the difference between medial peg distance 48 and its corresponding lateral peg distance 46 increases as the prosthesis size increases, causing fixation pegs 30, 32 to become more and more spaced apart as the prosthesis size increases.

[0083] With respect to the alternative baseplate 10' of FIG. 4, by contrast, where the lateral peg distance 46' is the same as the medial peg distance 48', the peg distances 46', 48' would overlap graphically in FIG. 6. Thus, for any given prosthesis size, a single point corresponding to both lateral peg distance 46' and medial peg distance 48' would be presented in FIG. 6, without a space therebetween. Also, because fixation pegs 30', 32' of baseplate 10' are aligned along medial-lateral axis 50', and not forward of or behind medial-lateral axis 50' like fixation pegs 30, 32 of baseplate 10, the overlapping peg distances 46', 48' of the

alternative baseplate 10' would fall somewhere between the spaced-apart peg distances 46, 48 of FIG. 6. The same result would occur with the overlapping peg distances 46", 48" of the alternative baseplate 10" of FIG. 5.

[0084] According to an exemplary embodiment of the present disclosure, the above-described distances, including inset distance 39, medial-lateral separation distance 36, offset distance 40, anterior-posterior separation distance 42, lateral peg distance 46, and medial peg distance 48, are measured along distal surface 34 of baseplate 10. As a result, the distances are measured near the intersection of each peg 30, 32 with distal surface 34 (e.g., near the proximal end of each peg 30, 32). In embodiments where pegs 30, 32 are perpendicular to distal surface 34, the distances could also be measured away from distal surface 34 (e.g., near the distal end of each peg 30, 32) without impacting the measurements. In embodiments where pegs 30, 32 are canted relative to distal surface 34, however, the measurements could vary if taken away from distal surface 34 (e.g., near the distal end of each canted peg 30, 32).

Therefore, for consistency, the measurements are taken along distal surface 34 of baseplate 10.

# 9. Force Testing of Asymmetric Fixation Pegs

[0085] A first prosthesis was manufactured, as shown in FIG. 7, by mounting bearing component 53 onto baseplate 10, with baseplate 10 having an asymmetric outer periphery 12 and asymmetrically arranged lateral and medial fixation pegs 30, 32 (FIGS. 1-3). A second prosthesis (not shown) was manufactured by mounting a similar bearing component 53 onto an alternative baseplate 10', with the alternative baseplate 10' having an asymmetric outer periphery 12' but aligned lateral and medial fixation pegs 30', 32' (FIG. 4). A third prosthesis (not shown) was manufactured by mounting a similar bearing component 53 onto another alternative baseplate 10", with the other alternative baseplate 10" having a symmetric outer periphery 12" and aligned lateral and medial fixation pegs 30", 32" (FIG. 5).

[0086] The illustrative bearing component 53 has lateral articular surface 54, medial articular surface 56, and spine 58 located therebetween. When bearing component 53 is assembled onto baseplate 10, as shown in FIG. 7, lateral articular surface 54 of bearing component 53 aligns with lateral compartment 14 of baseplate 10, medial articular surface 56 of bearing component 53 aligns with medial compartment 16 of baseplate 10, and spine 58 aligns with interior compartment 17 (FIG. 1) of baseplate 10. For the first and second prostheses, bearing component 53 had a thickness T of 20 mm. For the third prosthesis,

bearing component 53 had a thickness T of 17 mm. Bearing component 53 and its associated articular surfaces 54, 56 are described in detail in U.S. Provisional Patent Application Serial No. 61/561,657, filed November 18, 2011 (Attorney Docket No. ZIM0912), and are further described in U.S. Provisional Patent Application Serial No. 61/577,293, filed December 19, 2011 (Attorney Docket No. ZIM0912-01), and are further described in U.S. Provisional Patent Application Serial No. 61/592,576, filed on January 30, 2012 (Attorney Docket No. ZIM0912-02), and are further described in U.S. Provisional Patent Application Serial No. 61/621,361 filed April 6, 2012 (Attorney Docket No. ZIM0912-03), and are further described in U.S. Provisional Patent Application Serial No. 61/621,363 filed April 6, 2012 (Attorney Docket No. ZIM0912-04), and are further described in U.S. Provisional Patent Application Serial No. 61/621,364 filed April 6, 2012 (Attorney Docket No. ZIM0912-05), and are further described in U.S. Provisional Patent Application Serial No. 61/621,366 filed April 6, 2012 (Attorney Docket No. ZIM0912-06), and are further described in U.S. Patent Application Serial No. 13/459,037 filed April 27, 2012 (Attorney Docket No. ZIM0912-07), and are further described in U.S. Patent Application Serial No. 13/459,041 filed April 27, 2012 (Attorney Docket No. ZIM0912-08), and are further described in U.S. Patent Application Serial No. 13/459,048 filed April 27, 2012 (Attorney Docket No. ZIM0912-09), and are further described in U.S. Patent Application Serial No. 13/459,056 filed April 27, 2012 (Attorney Docket No. ZIM0912-10), all entitled "TIBIAL BEARING COMPONENT FOR A KNEE PROSTHESIS WITH IMPROVED ARTICULAR CHARACTERISTICS," the entire disclosures of which are hereby incorporated by reference herein.

[0087] As shown in FIG. 7, a lateral compressive force  $F_{CL}$  was applied onto lateral articular surface 54 of each bearing component 53, and a medial compressive force  $F_{CM}$  was applied onto medial articular surface 56 of each bearing component 53. The compressive forces  $F_{CL}$ ,  $F_{CM}$  measured 202 N.

[0088] Simultaneously with application of the compressive forces  $F_{CL}$ ,  $F_{CM}$ , an anterior-facing force  $F_{AP}$  was applied to the distal/posterior base of spine 58, as shown in FIG. 7. The anterior-facing force  $F_{AP}$  measured 725 N for the first and second prostheses and was scaled up to 791 N for the third prosthesis to account for the thinner bearing component 53.

[0089] Forces  $F_{CL}$ ,  $F_{CM}$ , and  $F_{AP}$  were designed in magnitude and area of application to replicate forces exerted on tibial bearing component 53 by a prosthetic femoral component, e.g., femoral component 70, during a kneeling motion. An exemplary femoral component

which articulates with tibial bearing component 53 is described in U.S. Provisional Patent Application Serial No. 61/561,658, filed November 18, 2011 (Attorney Docket No. ZIM0915), and is further described in U.S. Provisional Patent Application Serial No. 61/579,873, filed December 23, 2011 (Attorney Docket No. ZIM0915-01), and is further described in U.S. Provisional Patent Application Serial No. 61/592,575, filed on January 30, 2012 (Attorney Docket No. ZIM0915-02), and is further described in U.S. Provisional Patent Application Serial No. 61/594,113 filed on February 2, 2012 (Attorney Docket: ZIM0915-03), and is further described in and in U.S. Provisional Patent Application Serial No. 61/621,370 filed April 6, 2012 (Attorney Docket: ZIM0915-04), and are further described in U.S. Provisional Patent Application Serial No. 61/621,372 filed April 6, 2012 (Attorney Docket No. ZIM0915-05), and are further described in U.S. Provisional Patent Application Serial No. 61/621,373 filed April 6, 2012 (Attorney Docket No. ZIM0915-06), and are further described in U.S. Patent Application Serial No. 13/459,061 filed April 27, 2012 (Attorney Docket No. ZIM0915-07), and are further described in U.S. Patent Application Serial No. 13/459,064 filed April 27, 2012 (Attorney Docket No. ZIM0915-08), and are further described in U.S. Patent Application Serial No. 13/459,060 filed April 27, 2012 (Attorney Docket No. ZIM0915-09), all entitled "FEMORAL COMPONENT FOR A KNEE PROSTHESIS WITH IMPROVED ARTICULAR CHARACTERISTICS," the entire disclosures of which are hereby expressly incorporated herein by reference.

[0090] Finite element analysis was performed on the first, second, and third prostheses to evaluate and compare stresses experienced at the interface of baseplates 10, 10', 10" and a simulated tibial bone that was well fixed to each respective baseplate. Peak stresses experienced in the above-described loading scenario were substantially reduced for the first baseplate 10 having asymmetrically arranged fixation pegs 30, 32 as compared to the second baseplate 10' having aligned fixation pegs 30', 32' and the third baseplate 10" having aligned fixation pegs 30", 32". More particularly, a 51% reduction in peak stress was observed in the first baseplate 10 as compared to the second baseplate 10', and a 46% reduction in peak stress was observed in the first baseplate 10 as compared to the third baseplate 10".

### 10. Additional Fixation Pegs

[0091] In addition to lateral fixation peg 30 described above, lateral compartment 14 of tibial baseplate 100 may further include at least one additional lateral fixation peg 330. As shown in FIG. 13, the additional lateral fixation peg 330 is substantially centered within the PL

quadrant. The illustrative lateral fixation peg 330 is positioned anteriorly/posteriorly between lateral fixation peg 30 and medial fixation peg 32, such that lateral fixation peg 30 is the anterior-most fixation peg on tibial baseplate 100 and medial fixation peg 32 is the posterior-most fixation peg on tibial baseplate 100. As a result of lateral fixation peg 30 being medially biased toward home axis A<sub>H</sub>, as described above, the illustrative lateral fixation peg 330 is located laterally outward of lateral fixation peg 30 and is the lateral-most fixation peg on tibial baseplate 100.

[0092] In addition to medial fixation peg 32 described above, medial compartment 16 of tibial baseplate 100 may further include at least one additional medial fixation peg 332. As shown in FIG. 13, the additional medial fixation peg 332 is substantially centered within the AM quadrant. The illustrative medial fixation peg 332 is positioned anteriorly/posteriorly between lateral fixation peg 30 and medial fixation peg 32, such that lateral fixation peg 30 is the anterior-most fixation peg on tibial baseplate 100 and medial fixation peg 32 is the posterior-most fixation peg on tibial baseplate 100. As a result of medial fixation peg 32 being medially biased away from home axis A<sub>H</sub>, as described above, the illustrative medial fixation peg 332 is located laterally inward of medial fixation peg 32.

# 11. <u>Fixation Keel</u>

Turning to FIGS. 8 and 9, tibial baseplate 100 is provided that is substantially similar to baseplate 10 of FIGS. 1-3, except that baseplate 100 includes a single fixation structure, illustratively keel 130, that extends distally from distal surface 134 and into tibia T (FIG. 1). Keel 130 may be monolithically or integrally formed as part of tibial baseplate 100, or keel 130 may be separately attachable to distal surface 134 of tibial baseplate 100. Structures of baseplate 100 that correspond to structures of baseplate 10 have corresponding reference numerals, with the number 100 being added to the reference numerals of baseplate 10 to arrive at the corresponding reference numerals of baseplate 100, except as otherwise noted.

[0094] The illustrative keel 130 of FIG. 9A has a cylindrical core 131 defining longitudinal axis  $A_K$  (i.e., the axis of the cylinder defined by cylindrical core 131) and having two or more fins 133 extending radially outwardly therefrom, the fins being arranged symmetrically relative to the cylindrical core 131. More particularly, fins 133 extend along substantially all of the longitudinal extent PD<sub>K</sub> (FIG. 9B) of keel 130, as best shown in FIGS. 9A and 9B, such that fins 133 terminate at or near the distal tip of keel 133. In an exemplary

embodiment, longitudinal extent  $PD_K$  of tibial keel cylindrical core 131 may range from 27 mm to 48 mm, with smaller nominal sizes of baseplate 100 having relatively lesser extents  $PD_K$  and larger nominal sizes of baseplate 100 having relatively greater extents  $PD_K$ .

[0095] Keel fins 133 also define keel fin angle  $\gamma$  with respect to longitudinal axis  $A_K$  of cylindrical core 131 of keel 130. In an exemplary embodiment, keel angle  $\gamma$  is equal to between 22 degrees and 27 degrees. Keel fin angle  $\gamma$  and longitudinal extent longitudinal extent PD<sub>K</sub> of cylindrical core 131 cooperate to define a medial/lateral keel extent ML<sub>K</sub> (Fig. 9B) of between 38 mm and 54 mm, with smaller nominal sizes of baseplate 100 having relatively lesser extents ML<sub>K</sub> and larger nominal sizes of baseplate 100 having relatively greater extents ML<sub>K</sub>. Advantageously, this medial/lateral extent ML<sub>K</sub> defined by fins 133 of keel 130 present high resistance to rotation of tibial baseplate 100 in vivo, and enhance the overall strength of baseplate 100.

In an exemplary embodiment, keel 130 defines a substantially cylindrical outer [0096] profile as illustrated in Fig. 9A. Where such cylindrical outer profile is employed, an exemplary embodiment of core 131 of keel 130 may maintain an outer diameter between 14 mm and 16 mm, with such diameter remaining constant across the longitudinal extent. However, it is contemplated that core 131 of keel 130 may have a conical, tapered outer profile, particularly for small-stature baseplate sizes. The taper angle may be formed, for example, by tapering core 131 of keel 130 from a circular outer diameter of 17.1 mm at the proximal terminus of keel 130 (i.e., at the junction between keel 130 and distal surface 134 of tibial baseplate 100) to a circular diameter of 13.4 mm at the distal terminus of keel 130. An exemplary conical keel used in conjunction with a small-stature baseplate size is disclosed in U.S. Provisional Patent Application Serial No. 61/592,574 filed January 30, 2012 (Attorney Docket No. ZIM0919) and in U.S. Provisional Patent Application Serial No. 61/621,374 filed April 6, 2012 (Attorney Docket No. ZIM0919-01), both entitled ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS, the entire disclosures of which are hereby expressly incorporated herein by reference.

[0097] 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.

[0098] In FIG. 8, keel 130 is represented by a phantom oval to show the general location of keel 130, not necessarily the size or shape of keel 130. Rather than being cylindrical in shape, it is also within the scope of the present disclosure that core 131 of keel 130 may be conical in shape, with an outer diameter that tapers distally.

[0099] As discussed above, fixation pegs 30, 32 of baseplate 10 (FIGS. 1-3) may be designed to interact with cancellous bone surrounding the intramedullary canal of the patient's tibia T. To enhance this interaction with the cancellous bone, fixation pegs 30, 32 may be constructed of a highly porous biomaterial that accepts bone ingrowth. Keel 130 of baseplate 100 (FIGS. 8 and 9), by contrast, may be designed to fit into the intramedullary canal of the patient's tibia T. Like fixation pegs 30, 32, keel 130 may also be constructed of a highly porous biomaterial that accepts bone ingrowth. Alternatively, rather than achieving fixation via bone ingrowth, keel 130 may be constructed of a solid metal that achieves fixation via a tight interference fit with the patient's surrounding bone.

[00100] Although keel 130 may be the only fixation structure on baseplate 100, it is also within the scope of the present disclosure to combine keel 130 with additional fixation structures. In one embodiment, keel 130 may be combined with the above-described fixation pegs 30, 32 (FIGS. 1-3). On another embodiment, keel 130 may be combined with sharp spikes (not shown). Such spikes may be located in the same general areas discussed above with respect to fixation pegs 30, 32. However, unlike the blunt-tipped and porous fixation pegs 30, 32, the spikes may be sharp-tipped to pierce the patient's bone and may be solid in construction. The spikes may also have external ribs or barbs to enhance fixation with the patient's bone.

[00101] Keel 130 may also include a tapered bore (not shown) extending proximally into the distal tip of keel 130, designed to mate with a corresponding locking-taper surface of a tibial stem extension.

# 12. <u>Lateral/Medial Positioning of Fixation Keel</u>

[00102] As shown in FIG. 9A, keel 130 is asymmetrically disposed on distal surface 134 of baseplate 100 with respect to home axis  $A_H$ . More particularly, the longitudinal keel axis  $A_K$  of keel 130 is biased medially with respect to the vertical plane that contains home axis  $A_H$ , i.e.,

keel axis  $A_K$  is offset toward medial compartment 116 and away from lateral compartment 114 by offset distance 163. Throughout the following paragraphs, home axis  $A_H$  and the vertical plane that contains home axis  $A_H$  are used interchangeably.

[00103] According to an exemplary embodiment of the present disclosure, offset distance 163 is measured along distal surface 134 of baseplate 100. As a result, offset distance 163 is measured medially from the intersection of home axis  $A_H$  and distal surface 134 to the intersection of keel axis  $A_K$  and distal surface 134 (e.g., near the proximal end of keel 130). In embodiments where keel axis  $A_K$  is perpendicular to distal surface 134, offset distance 163 could also be measured away from distal surface 134 (e.g., near the distal end of keel 130) without impacting the measurement. In embodiments where keel axis  $A_K$  is canted relative to distal surface 134, however, the measurement could vary if taken away from distal surface 134 (e.g., near the distal end of the canted keel 130). Therefore, for consistency, the measurement is taken along distal surface 134 of baseplate 100.

[00104] In embodiments where baseplate 100 has a symmetric outer periphery 112, an anterior-posterior axis of symmetry through outer periphery 112 may be used as a "home axis"  $A_H$  for referencing medial face 160, lateral face 162, keel 130, and other components of baseplate 100. This home axis  $A_H$  would be substantially centered between medial face 160 and lateral face 162. With keel axis  $A_K$  being medially offset from the central home axis  $A_H$ , keel axis  $A_K$  would be positioned closer to medial face 160 than lateral face 162. Thus, medial distance 164 between keel axis  $A_K$  and the medial-most portion of medial face 160 would be less than lateral distance 166 between keel axis  $A_K$  and the lateral-most portion of lateral face 162.

In embodiments where baseplate 100 has an asymmetric outer periphery 112, as shown in FIGS. 8 and 9, home axis  $A_H$  would not constitute an axis of symmetry and would be positioned closer to lateral face 162 than medial face 160. Depending on the degree to which keel axis  $A_K$  is medially offset from home axis  $A_H$ , keel axis  $A_K$  may still be positioned closer to medial face 160 than lateral face 162. Thus, medial distance 164 between keel axis  $A_K$  and the medial-most portion of medial face 160 may be less than lateral distance 166 between keel axis  $A_K$  and the lateral-most portion of lateral face 162.

[00106] The degree of medialization of keel 130 may be expressed as a ratio or a percentage and may be calculated by dividing the offset distance 163 between keel axis  $A_K$  and

home axis  $A_H$  by the total medial/lateral width of distal surface 134 (i.e., medial distance 164 plus lateral distance 166). For baseplate 100 having the dimensions set forth in **Table 1** below, for example, the degree of medialization would be approximately 6% (calculated as 5 mm / 88 mm x 100%).

Table 1: Sample Dimensions of a Large-Size Baseplate 100

Dimension	Value (mm)	% of Total Width
Offset Distance 163 between Keel Axis A <sub>K</sub> and Home Axis A <sub>H</sub>	5	6
Medial Distance 164	41	47
Lateral Distance 166	47	53
Total Width (Medial Distance 164 + Lateral Distance 166)	88	N/A

[00107] Advantageously, the medial bias of keel 130 (i.e., the relatively short medial distance 164 and the relatively long lateral distance 166) more closely aligns keel 130 with the intramedullary canal of the patient's tibia T (FIG. 1). Thus, upon implantation of baseplate 100 onto the patient's tibia T, keel 130 may be centered or nearly centered within the intramedullary canal. In this manner, keel 130 may avoid impinging onto hard, cortical bone around the intramedullary canal, thereby promoting firm and stable long-term fixation of tibial baseplate 100 to tibia T. The medial bias of keel 130 may also be important if it becomes necessary to attach a distal stem extension (not shown) to keel 130, such as during a revision surgical procedure. In this manner, tibial baseplate 100 may achieve an optimum metaphyseal fit on tibia T in the region of keel 130 and diaphyseal fit on tibia T in the region of the distal stem extension.

#### 13. <u>Lateral/Medial Positioning of Fixation Keel for Set of Prostheses</u>

[00108] Baseplate 100 may be provided in a kit or set of different prosthesis sizes. In one embodiment, nine nominal sizes of baseplate 100 are provided in the set, with baseplates 100 growing progressively in size.

**[0100]** According to an exemplary embodiment of the present disclosure, the degree of medialization of keel 130 increases as the prostheses in the set grow in size. Thus, rather than maintaining a fixed relationship between medial distance 164 and lateral distance 166 as the prostheses grow in size, medial distance 164 makes up a smaller and smaller portion of the total width as the prostheses grow in size, and lateral distance 166 makes up a larger and larger

portion of the total width as the prostheses grow in size. Stated differently, the rate at which keel 130 moves toward medial face 160 exceeds that rate at which the prostheses grow in size.

[0101] The dimensions of another sample baseplate 100 are provided in **Table 2** below. Baseplate 100 of **Table 2**, which has a total width of 58 mm, is smaller than baseplate 100 of **Table 1** above, which has a total width of 88 mm.

Table 2: Sample Dimensions of a Small-Size Baseplate 100

Dimension	Value (mm)	% of Total Width
Offset Distance 163 between Keel Axis A <sub>K</sub> and Home Axis A <sub>H</sub>	1	2
Medial Distance 164	29	50
Lateral Distance 166	29	50
Total Width (Medial Distance 164 + Lateral Distance 166)	58	N/A

[0102] As baseplates 100 of the present set grow in size from **Table 2** to **Table 1** (i.e., from a small nominal size having a 58 mm total width to a large nominal size having an 88 mm total width), the degree of medialization of keel 130 increases relative to home axis A<sub>H</sub> (from 2% to 6%). Also, as keel 130 moves medially from the small size of **Table 2** to the large size of **Table 1**, medial distance 164 makes up a smaller portion of the total width (from 50% to 47%), and lateral distance 166 makes up a larger portion of the total width (from 50% to 53%).

[0103] Advantageously, increasing the degree of medialization of keel 130 as baseplate 100 grows in size may better track the position of the intramedullary canal as the patient's tibia T (FIG. 1) grows in size. Therefore, keel 130 may be positioned inside the intramedullary canal rather than in hard, cortical bone around the intramedullary canal.

[0104] The increasing medialization of keel 130 is presented graphically in FIG. 10, where exemplary offset distances 163 between keel axis  $A_K$  and home axis  $A_H$  are shown for a set of prostheses of different sizes. More specifically, exemplary offset distances 163 between keel axis  $A_K$  and home axis  $A_H$  are shown for a set of prostheses having different medial/lateral widths (i.e., medial distance 164 plus lateral distance 166). The data points located farther to the left represent smaller medial/lateral widths (and therefore smaller prosthesis sizes), and data points located farther to the right represent larger medial/lateral widths (and therefore larger prosthesis sizes). Although adjacent nominal prosthesis sizes may share the same offset distance 163 between keel axis  $A_K$  and home axis  $A_H$  (compare, for example, the corresponding offset distances 163 of the size 5 and size 6 implants, shown as the fifth- and

sixth-from left data points respectively), the overall trend in FIG. 10 is that offset distance 163 increases as total medial/lateral width increases.

In a smaller bone, the metaphyseal region of tibia T is more closely aligned with the diaphyseal region of tibia T. Therefore, keel 130 may achieve an optimum metaphyseal and diaphyseal fit with a relatively small offset distance 163 (e.g., 1 mm, 2 mm). In a larger bone, by contrast, the metaphyseal region of tibia T is more offset from the diaphyseal region of tibia T. Therefore, keel 130 may require a relatively large offset distance 163 (e.g., 4 mm, 5 mm) to achieve an optimum metaphyseal and diaphyseal fit. FIG. 10 presents exemplary offset distances 163, but for any given size, offset distance 163 may vary by +/- 0.5 mm, +/- 1.0 mm, +/- 1.5 mm, or +/- 2.0 mm, for example.

[0106] As discussed above, the degree of medialization of keel 130 may be expressed as a percentage by dividing the offset distance 163 between keel axis  $A_K$  and home axis  $A_H$  by the total medial/lateral width. In FIG. 11, the offset distances 163 from FIG. 10 are shown as percentages of the total medial/lateral width. The overall trend in FIG. 11 is that the degree of medialization of keel 130 increases as medial/lateral width increases. With respect to a relatively small nominal size 3 implant, for example, the medial offset of keel 130 from home axis  $A_H$  is 3% of the total medial/lateral implant width. With respect to a relatively large nominal size 7 implant, the medial offset of keel 130 from home axis  $A_H$  is 5% of the total medial/lateral implant width.

# 14. Anterior/Posterior Positioning of Fixation Keel for Set of Prostheses

[0107] As shown in FIG. 8, the anterior/posterior keel distance 147 may be measured posteriorly from flat portion 118a of anterior face 118 to keel axis  $A_K$ , for example. The lateral depth 144 of lateral compartment 114 is also shown being measured posteriorly from flat portion 118a of anterior face 118 to posterior/lateral face 120 of baseplate 100 in FIG. 8, and this lateral depth 144 exceeds keel distance 147.

[0108] According to an exemplary embodiment of the present disclosure, keel distance 147 is measured along distal surface 134 of baseplate 100. As a result, keel distance 147 is measured posteriorly from the intersection of flat portion 118a of anterior face 118 and distal surface 134 to the intersection of keel axis  $A_K$  and distal surface 134 (e.g., near the proximal end of keel 130). In embodiments where keel axis  $A_K$  is perpendicular to distal surface 134, keel distance 147 could also be measured away from distal surface 134 (e.g., near the distal end

of keel 130) without impacting the measurement. In embodiments where keel axis  $A_K$  is canted relative to distal surface 134, however, the measurement could vary if taken away from distal surface 134 (e.g., near the distal end of the canted keel 130). Therefore, for consistency, the measurement is taken along distal surface 134 of baseplate 100.

[0109] Across a set of different tibial baseplates 100 having varying nominal sizes, the anterior/posterior positioning of keel 130 may vary. In FIG. 12, for example, exemplary anterior/posterior keel distances 147 are shown for a set of prostheses of different sizes. The overall trend in FIG. 12 is that keel distance 147 increases as lateral depth 144 increases. Moving keel 130 further and further from anterior face 118 as baseplate 100 increases in size may avoid anterior cortical bone impingement by keel 130, especially if keel 130 also increases in size (e.g., diameter, length) along with baseplate 100. FIG. 12 depicts exemplary keel distances 147, but for any given size, keel distance 147 may vary by +/- 0.5 mm, +/- 1.0 mm, +/- 1.5 mm, or +/- 2.0 mm, for example.

# 15. <u>Proximal Keel Expansion</u>

[0110] As shown in FIG. 9A, the illustrative keel 130 includes a blind proximal bore 180 therein that is sized to receive a fixation structure, such as a set screw (not shown), from proximal surface 111 of baseplate 100. The fixation structure may be used to attach a tibial bearing component onto proximal surface 111 of baseplate 100, for example.

[0111] The illustrative bore 180 of FIG. 9A is centered along home axis  $A_H$ . However, because keel axis  $A_K$  is offset from home axis  $A_H$ , bore 180 becomes offset in keel 130. To ensure that the walls of keel 130 surrounding bore 180 are adequately thick along the axial extent of bore 180 (e.g., 1.5 mm), keel 130 may expand radially outwardly around bore 180 to form bulge 182.

[0112] As keel 130 becomes more and more offset from home axis  $A_H$  and bore 180, bulge 182 may become larger and larger in size. For example, for medium nominal prosthesis sizes (e.g., sizes 5 and 6) having medium offset distances 163 between keel axis  $A_K$  and home axis  $A_H$  (e.g., 3 mm), bulge 182 may increase the diameter of keel 130 by 0.5 mm. For large nominal prosthesis sizes (e.g., sizes 7-9) having large offset distances 163 between keel axis  $A_K$  and home axis  $A_H$  (e.g., 4 mm, 5 mm), bulge 182 may increase the diameter of keel 130 by

1.4 mm. For small nominal prosthesis sizes (e.g., sizes 1-4) having small offset distances 163 between keel axis  $A_K$  and home axis  $A_H$  (e.g., 1 mm, 2 mm), bulge 182 may be excluded.

[0113] While this invention has been described as having exemplary designs, 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.

# WHAT IS CLAIMED IS:

- 1. A tibial prosthesis system comprising:
  - a first tibial baseplate comprising:
    - a first proximal surface;
- a first distal surface opposite the first proximal surface, the first distal surface sized and shaped to substantially cover a proximal resected surface of a tibia;
  - a first medial face;
  - a first lateral face opposite the first medial face;
  - a first total width measured from the first medial face to the first lateral face; and
- a first keel extending distally from the first distal surface, the first keel spaced from the first medial face by a first medial distance and spaced apart from the first lateral face by a first lateral distance; and
  - a second tibial baseplate comprising:
    - a second proximal surface;
- a second distal surface opposite the second proximal surface, the second distal surface sized and shaped to substantially cover a proximal resected surface of a tibia;
  - a second medial face;
  - a second lateral face opposite the second medial face;
- a second total width measured between the second medial face and the second lateral face, the second total width differing from the first total width whereby the first and second tibial baseplates comprise unique nominal sizes; and
- a second keel extending distally from the second distal surface, the second keel spaced apart from the second medial face by a second medial distance and spaced apart from the second lateral face by a second lateral distance,
- a first ratio of the first medial distance to the first total width differing from a second ratio of the second medial distance to the second total width.
- 2. The tibial prosthesis system of claim 1, wherein the first total width is greater than the second total width, and the first ratio is less than the second ratio.
- 3. The tibial prosthesis system of claim 1, wherein:
- the first keel is medially biased toward the first medial face, such that the first lateral distance exceeds the first medial distance; and

the second keel is medially biased toward the second medial face, such that the second lateral distance exceeds the second medial distance.

4. The tibial prosthesis system of claim 1, wherein:

the first tibial baseplate includes:

- a first medial compartment;
- a first lateral compartment opposite the first medial compartment; and
- a first, anterior-posterior axis extending centrally between the first medial and lateral compartments throughout its length, the first keel being medially offset from the first axis by a first offset distance; and

the second tibial baseplate includes:

- a second medial compartment;
- a second lateral compartment opposite the second medial compartment; and
- a second, anterior-posterior axis extending centrally between the second medial and lateral compartments throughout its length, the second keel being medially offset from the second axis by a second offset distance less than the first offset distance.
- 5. The tibial prosthesis system of claim 4, wherein the first total width is greater than the second total width, and wherein the first offset distance constitutes a greater portion of the first total width than the second offset distance constitutes of the second total width.
- 6. The tibial prosthesis system of claim 4, wherein the first axis and the second axis are positioned to correspond to a home axis of a patient's proximal tibia when one of the first and second tibial baseplates, respectively, is implanted onto the patient's proximal tibia, the home axis defined as a line extending from:
- a posterior point disposed at a geometric center of an attachment area between a posterior cruciate ligament and the patient's proximal tibia, to
- an anterior point disposed on an anterior tubercle of the patient's proximal tibia and bordering a medial third of the anterior tubercle.
- 7. The tibial prosthesis system of claim 4, wherein the first and second tibial baseplates are symmetric about the first axis and second axis, respectively.

8. The tibial prosthesis system of claim 4, wherein the first and second tibial baseplates are asymmetric about the first axis and second axis, respectively.

- 9. The tibial prosthesis system of claim 4, wherein the first total width is greater than the second total width, the first keel having a first bulge around a first proximal bore formed in the first tibial baseplate, and the second keel having a second bulge around a second proximal bore formed in the second tibial baseplate, wherein the first bulge is larger than the second bulge.
- 10. The tibial prosthesis system of claim 4, wherein the first tibial baseplate is larger than the second tibial baseplate, and wherein:

the first tibial baseplate includes a first anterior face joining the first lateral face to the first medial face, the first keel being posteriorly spaced from the first anterior face by a first distance; and

the second tibial baseplate includes a second anterior face joining the second lateral face to the second medial face, the second keel being posteriorly spaced from the second anterior face by a second distance less than the first distance.

- 11. The tibial prosthesis system of claim 1, wherein at least one of the first keel and the second keel defines a longitudinal extent equal to between 27 mm and 48 mm.
- 12. The tibial prosthesis system of claim 1, further comprising a tibial bearing component configured to be received on at least one of the first proximal surface and the second proximal surface in one of a fixed relationship and a sliding relationship, the tibial bearing component comprising:
- a lateral articular surface positioned to align with a lateral compartment of one of the first tibial baseplate and the second tibial baseplate; and
- a medial articular surface positioned to align with a medial compartment of one of the first tibial baseplate and the second tibial baseplate.
- 13. The tibial prosthesis system of claim 12, wherein the medial and lateral articular surfaces of the tibial bearing component are shaped to articulate with medial and lateral femoral condyles respectively.

14. The tibial prosthesis system of claim 1, wherein each of the first keel and the second keel comprises a cylindrical core defining a longitudinal keel axis.

- 15. The tibial prosthesis system of claim 14, wherein the cylindrical core of each of the first keel and the second keel defines a diameter of at least 14 mm.
- 16. The tibial prosthesis system of claim 14, wherein the cylindrical core defines a longitudinal extent of between 27 mm and 48 mm.
- 17. The tibial prosthesis system of claim 1, wherein each of the first tibial baseplate and the second tibial baseplate comprises at least two fins extending radially outwardly from a core of the first or second keel respectively, the fins arranged symmetrically with respect to the core of the first or second keel respectively.
- 18. The tibial prosthesis system of claim 17, wherein each of the fins extend along substantially of a longitudinal extent of the keel.
- 19. A tibial baseplate configured for implantation upon a patient's proximal tibia, the tibial baseplate comprising:
  - a medial compartment;
  - a lateral compartment opposite the medial compartment;
  - a proximal surface;
- a distal surface opposite the proximal surface, the distal surface sized and shaped to substantially cover the patient's proximal tibia;
- an outer periphery cooperatively defined by an anterior face, a medial face, a lateral face, and at least one posterior face;
- a first, anterior-posterior axis located between the medial face and the lateral face and intersecting the anterior face, the first axis extending centrally between the medial and lateral compartments throughout its length;
- a plurality of fixation pegs extending distally from the distal surface, each of the plurality of fixation pegs being positioned inward of the outer periphery for implantation into the patient's proximal tibia, the plurality of fixation pegs comprising:
  - a medial fixation peg located at the medial compartment; and

a lateral fixation peg located at the lateral compartment, the lateral fixation peg being positioned more anteriorly than each other fixation peg among the plurality of fixation pegs.

- 20. The tibial baseplate of claim 19, wherein the plurality of fixation pegs are medially biased from the first axis, such that the lateral fixation peg is closer to the first axis than the medial fixation peg.
- 21. The tibial baseplate of claim 20, wherein the plurality of fixation pegs are medially biased from the first axis by between 3 mm and 6 mm.
- 22. The tibial baseplate of claim 19, wherein the tibial baseplate further comprises a second, medial-lateral axis perpendicular to the first axis, the second axis intersecting the medial face and the lateral face, the medial fixation peg posteriorly offset from the second axis and the lateral fixation peg anteriorly offset from the second axis.
- 23. The tibial baseplate of claim 22, wherein the second axis intersects the first axis at a location posterior of the anterior face and anterior of a posterior cutout formed in the at least one posterior face of the tibial baseplate, the first and second axes intersecting within the outer periphery of the tibial baseplate.
- 24. The tibial baseplate of claim 19, wherein:

the first and second axes divide the tibial baseplate into an anterior/medial quadrant, a posterior/medial quadrant, an anterior/lateral quadrant, and a posterior/lateral quadrant,

the medial fixation peg is arranged more in the posterior/medial quadrant than the anterior/medial quadrant, and

the lateral fixation peg is arranged more in the anterior/lateral quadrant than the posterior/lateral quadrant.

25. The tibial baseplate of claim 19, wherein:

the first and second axes divide the tibial baseplate into an anterior/medial quadrant, a posterior/medial quadrant, an anterior/lateral quadrant, and a posterior/lateral quadrant, and

the plurality of fixation pegs are generally arranged along a third axis that diagonally intersects both the first and second axes, the third axis traveling from the anterior/lateral quadrant to the posterior/medial quadrant.

26. The tibial baseplate of claim 19, wherein the first axis is positioned to correspond to a home axis of the patient's proximal tibia when the tibial baseplate is implanted onto the patient's proximal tibia, the home axis defined as a line extending from:

a posterior point disposed at a geometric center of an attachment area between a posterior cruciate ligament and the patient's proximal tibia, to

an anterior point disposed on an anterior tubercle of the patient's proximal tibia and bordering a medial third of the anterior tubercle.

- 27. The tibial baseplate of claim 19, wherein the first axis bisects a flat portion of the anterior face in a perpendicular manner.
- 28. The tibial baseplate of claim 19, wherein the first axis bisects a posterior cutout formed in the at least one posterior face of the tibial baseplate.
- 29. The tibial baseplate of claim 19, wherein the outer periphery of the tibial baseplate is symmetric about the first axis.
- 30. The tibial baseplate of claim 19, wherein the outer periphery of the tibial baseplate is asymmetric about the first axis.
- 31. The tibial baseplate of claim 30, wherein the medial compartment has a medial anterior/posterior depth measured posteriorly from the anterior face and the lateral compartment has a lateral anterior/posterior depth measured posteriorly from the anterior face, the medial depth exceeding the lateral depth.
- 32. The tibial baseplate of claim 30, wherein the first axis is closer to a lateral-most point on the lateral face than to a medial-most point on the medial face.

33. The tibial baseplate of claim 19, in combination with a tibial bearing component configured to be received on the proximal surface of the tibial baseplate in one of a fixed relationship and a sliding relationship, the tibial bearing component comprising:

- a lateral articular surface positioned to align with a lateral compartment of the tibial baseplate; and
- a medial articular surface positioned to align with a medial compartment of the tibial baseplate.
- 34. The tibial prosthesis system of claim 33, wherein the medial and lateral articular surfaces of the tibial bearing component are shaped to articulate with medial and lateral femoral condyles respectively.
- 35. A tibial baseplate configured for implantation upon a patient's proximal tibia, the tibial baseplate comprising:
  - a medial compartment;
  - a lateral compartment opposite the medial compartment;
  - a proximal surface;
- a distal surface opposite the proximal surface, the distal surface sized and shaped to substantially cover the patient's proximal tibia;
- an outer periphery cooperatively defined by an anterior face, a medial face, a lateral face, and at least one posterior face;
- at most one medial fixation peg associated with the medial compartment, the medial fixation peg extending distally from the distal surface and positioned for implantation into the patient's proximal tibia; and
- at most one lateral fixation peg associated with the lateral compartment, the lateral fixation peg extending distally from the distal surface and positioned for implantation into the patient's proximal tibia, the lateral fixation peg being located closer to the anterior face than the medial fixation peg.
- 36. The tibial baseplate of claim 35, wherein the anterior face has a flat portion disposed between the medial and lateral compartments, the lateral fixation peg being located closer to the flat portion of the anterior face than the medial fixation peg.

37. The tibial baseplate of claim 36, further comprising an anterior-posterior axis that bisects the flat portion of the anterior face and bisects a posterior cutout formed in the at least one posterior face of the tibial baseplate.

- 38. The tibial baseplate of claim 37, wherein the medial and lateral fixation pegs are medially biased from the anterior-posterior axis, such that the lateral fixation peg is closer to the anterior-posterior axis than the medial fixation peg.
- 39. The tibial baseplate of claim 38, wherein the medial and lateral fixation pegs are medially biased from the anterior-posterior axis by between 3 mm and 6 mm.
- 40. The tibial baseplate of claim 35, wherein the medial and lateral fixation pegs define an anterior-posterior gap therebetween.
- 41. The tibial baseplate of claim 40, wherein the anterior-posterior gap is between 5 mm and 11 mm, as measured on center between the medial and lateral fixation pegs.
- 42. The tibial baseplate of claim 35, in combination with a tibial bearing component configured to be received on the proximal surface of the tibial baseplate in one of a fixed relationship and a sliding relationship, the tibial bearing component comprising:
- a lateral articular surface positioned to align with the lateral compartment of the tibial baseplate when the tibial bearing component is received on the proximal surface of the tibial baseplate; and
- a medial articular surface positioned to align with the medial compartment of the tibial baseplate when the tibial bearing component is received on the proximal surface of the tibial baseplate.
- 43. The tibial prosthesis system of claim 42, wherein the medial and lateral articular surfaces of the tibial bearing component are shaped to articulate with medial and lateral femoral condyles respectively.
- 44. A tibial baseplate configured for implantation upon a patient's proximal tibia, the tibial baseplate comprising:
  - a medial compartment;

- a lateral compartment opposite the medial compartment;
- a proximal surface;
- a distal surface opposite the proximal surface, the distal surface sized and shaped to substantially cover the patient's proximal tibia;

an outer periphery cooperatively defined by an anterior face, a medial face, a lateral face, and at least one posterior face;

a first, anterior-posterior axis located between the medial face and the lateral face and intersecting the anterior face, the first axis extending centrally between the medial and lateral compartments throughout its length;

a first fixation peg extending distally from the distal surface, the first fixation peg being inset from the outer periphery for implantation into the patient's proximal tibia, the first fixation peg being medially spaced from the first axis by a first distance; and

a second fixation peg extending distally from the distal surface, the second fixation peg being inset from the outer periphery for implantation into the patient's proximal tibia, the second fixation peg being laterally spaced from the first axis by a second distance, the second distance less than the first distance.

- 45. The tibial baseplate of claim 44, wherein the first fixation peg is the only fixation peg associated with the medial compartment and the second fixation peg is the only fixation peg associated with the lateral compartment.
- 46. The tibial baseplate of claim 44, wherein the first and second fixation pegs are the same shape.
- 47. The tibial baseplate of claim 44, wherein:

the tibial baseplate further comprises a second, medial-lateral axis perpendicular to the first axis, the second axis intersecting the medial face and the lateral face, and

the second axis extends through an anterior-posterior gap formed between the first and second fixation pegs, such that the first fixation peg is located posteriorly of the second axis and the second fixation peg is located anteriorly of the second axis.

48. The tibial baseplate of claim 47, wherein the anterior-posterior gap is between 5 mm and 11 mm, as measured on center between the first and second fixation pegs.

49. The tibial baseplate of claim 47, wherein the tibial baseplate comprises a first tibial baseplate in combination with a second tibial baseplate larger in size than the first tibial baseplate, the second tibial baseplate having a first fixation peg and a second fixation peg that define a larger anterior-posterior gap therebetween as compared to the anterior-posterior gap formed between the first and second fixation pegs of the first tibial baseplate.

- 50. The tibial baseplate of claim 44, wherein the first axis is positioned to correspond to a home axis of the patient's proximal tibia when the tibial baseplate is implanted onto the patient's proximal tibia, the home axis defined as a line extending from:
- a posterior point disposed at a geometric center of an attachment area between a posterior cruciate ligament and the patient's proximal tibia, to

an anterior point disposed on an anterior tubercle of the patient's proximal tibia and bordering a medial third of the anterior tubercle.

- 51. The tibial baseplate of claim 44, wherein the first axis bisects a flat portion of the anterior face in a perpendicular manner.
- 52. The tibial baseplate of claim 44, wherein the first axis bisects a posterior cutout formed in the at least one posterior face of the tibial baseplate.
- 53. The tibial baseplate of claim 44, wherein the outer periphery of the tibial baseplate is symmetric about the first axis.
- 54. The tibial baseplate of claim 44, wherein the outer periphery of the tibial baseplate is asymmetric about the first axis.
- 55. The tibial baseplate of claim 44, in combination with a tibial bearing component configured to be received on the proximal surface of the tibial baseplate in one of a fixed relationship and a sliding relationship, the tibial bearing component comprising:

a lateral articular surface positioned to align with the lateral compartment of the tibial baseplate when the tibial bearing component is received on the proximal surface of the tibial baseplate; and

a medial articular surface positioned to align with the medial compartment of the tibial baseplate when the tibial bearing component is received on the proximal surface of the tibial baseplate.

56. The tibial prosthesis system of claim 55, wherein the medial and lateral articular surfaces of the tibial bearing component are shaped to articulate with medial and lateral femoral condyles respectively.

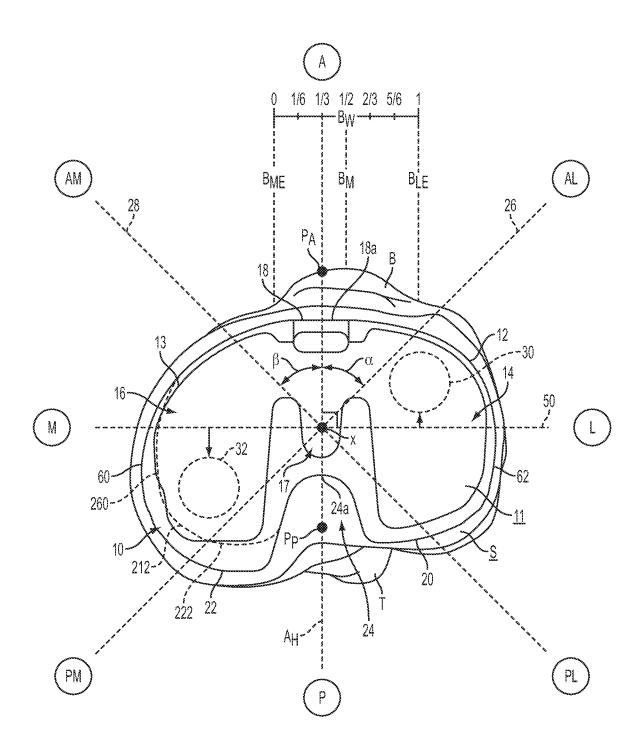
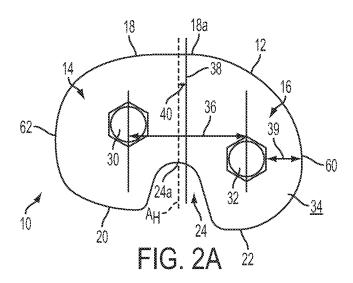
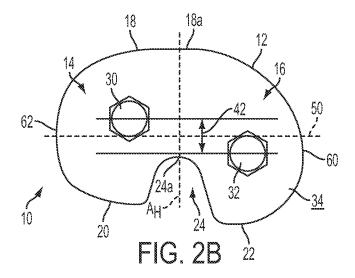
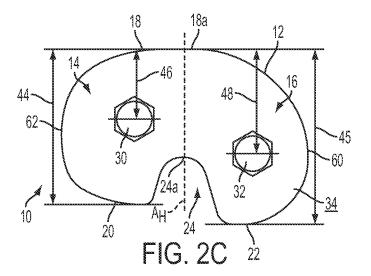


FIG. 1







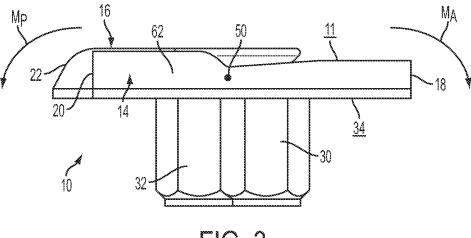
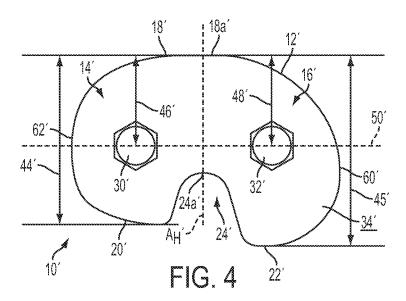
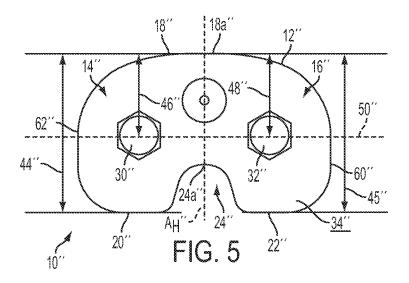
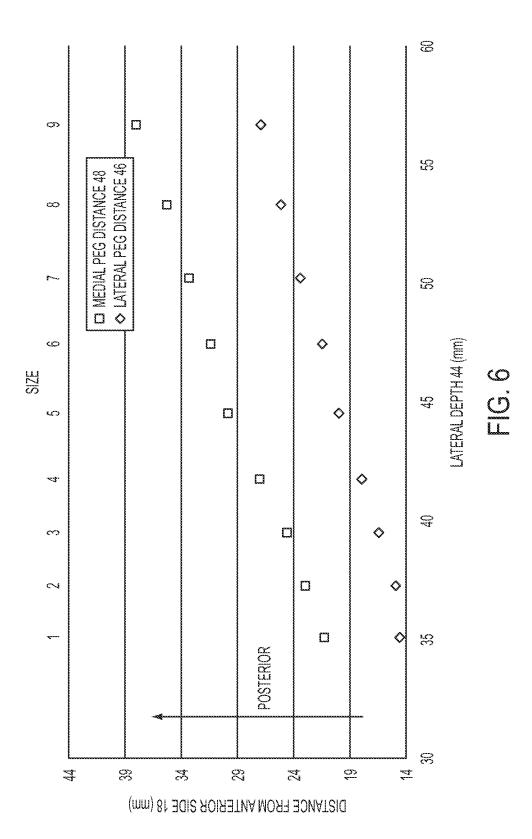


FIG. 3







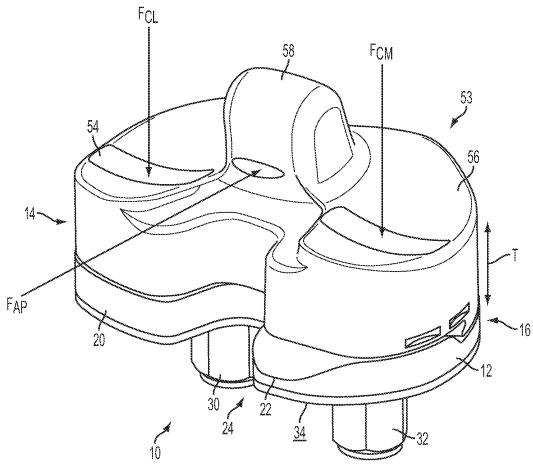
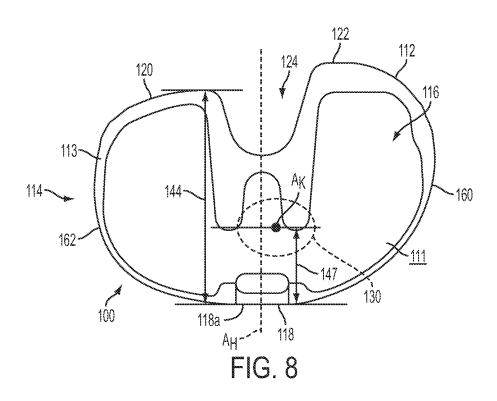
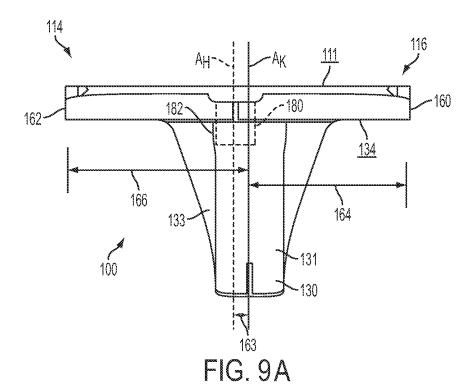


FIG. 7





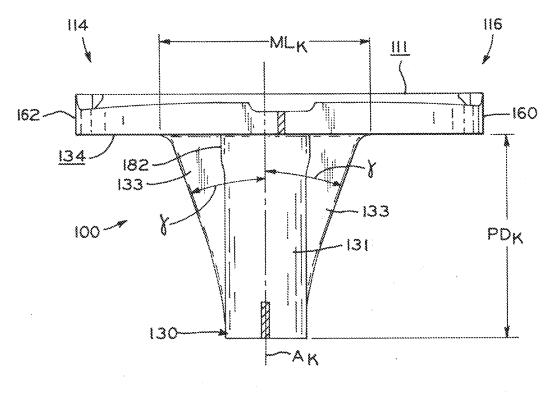
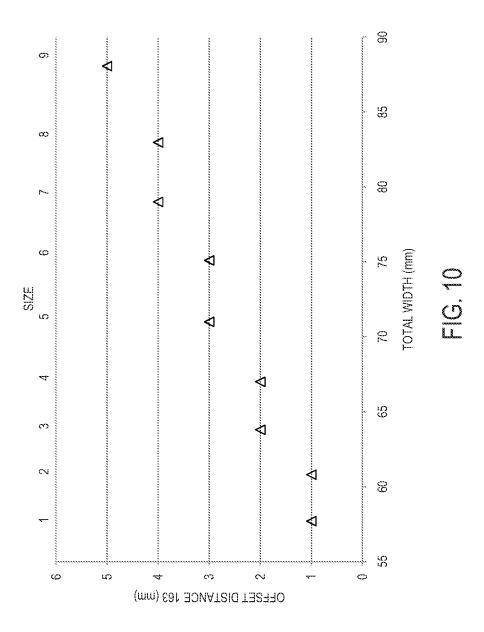
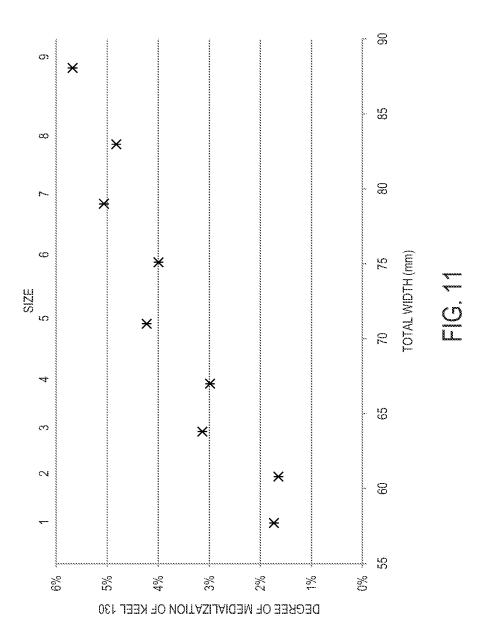
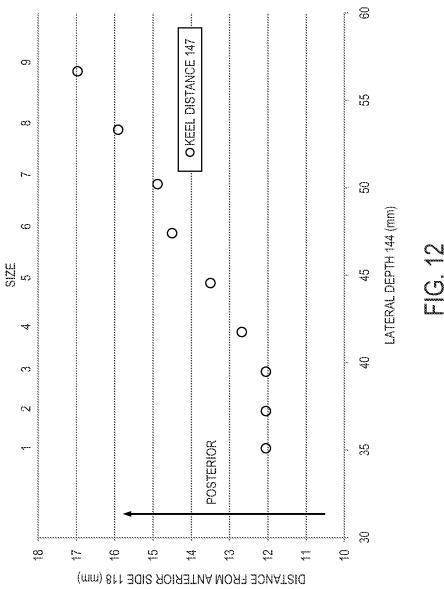


FIG.9B







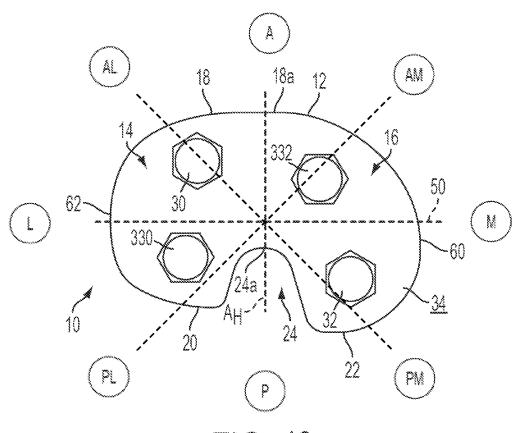


FIG. 13

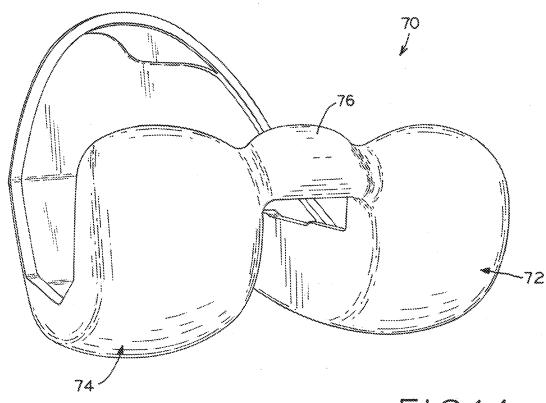


FIG.14

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/052132 A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/38 ADD. A61F2/46 A61F2/30 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) A61F Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Category' Citation of document, with indication, where appropriate, of the relevant passages US 2010/063594 A1 (HAZEBROUCK STEPHEN A 1,2 Χ [US] ET AL) 11 March 2010 (2010-03-11) paragraph [0050] - paragraph [0051]; 3-18 figure 14 paragraph [0062] - paragraph [0063] US 5 824 102 A (BUSCAYRET CHRISTIAN [FR]) 3 - 1820 October 1998 (1998-10-20) figures 3,6,7 US 2012/035735 A1 (SANFORD ADAM H [US] ET A,P 1-18 AL) 9 February 2012 (2012-02-09) cited in the application the whole document Α EP 0 956 836 A1 (JOHNSON & JOHNSON 1-18 PROFESSIONAL [US] DEPUY PRODUCTS INC [US]) 17 November 1999 (1999-11-17) the whole document Х Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be special reason (as specified) considered to involve an inventive step when the document is combined with one or more other such documents, such combination "O" document referring to an oral disclosure, use, exhibition or other being obvious to a person skilled in the art document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 7 November 2012 10/01/2013 Name and mailing address of the ISA Authorized officer

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European Patent Office, P.B. 5818 Patentlaan 2

## **INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No
PCT/US2012/052132

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International application No. PCT/US2012/052132

## **INTERNATIONAL SEARCH REPORT**

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)					
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:					
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:					
2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:					
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).					
Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)					
This International Searching Authority found multiple inventions in this international application, as follows:					
see additional sheet					
As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.					
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.					
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:					
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  1-18					
Remark on Protest  The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.  The additional search fees were accompanied by the applicant's protest but the applicable protest					
fee was not paid within the time limit specified in the invitation.					
No protest accompanied the payment of additional search fees.					

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-18

tibial prosthesis system comprising different baseplates having different sizes and one fixation keel each

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2. claims: 19-56

tibial baseplate system having a plurality of fixation pegs

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