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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 August 2014 (14.08.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/124239 A1

(51) International Patent Classification:
A61B 17/56 (2006.01) *A61F 2/46* (2006.01)
A61B 17/70 (2006.01) *A61F 2/30* (2006.01)
A61B 19/00 (2006.01) *A61F 2/38* (2006.01)

(21) International Application Number:
PCT/US2014/015276

(22) International Filing Date:
7 February 2014 (07.02.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/762,492	8 February 2013 (08.02.2013)	US
61/904,083	14 November 2013 (14.11.2013)	US
61/904,086	14 November 2013 (14.11.2013)	US
61/904,099	14 November 2013 (14.11.2013)	US

(71) Applicant: **ORTHOPAEDIC INTERNATIONAL, INC.** [PH/PH]; #9 West Road, Light Industry and Science Park 1, Cabuyao, Laguna, 4025 (PH).

(72) Inventors; and
(71) Applicants : **LEW, William D.** [US/US]; 726 Decorah Lane, Mendota Heights, Minnesota 55120 (US). **CARTER, Robert D.** [US/US]; 14384 Excelsior Lane, Apple Valley, Minnesota 55124 (US). **GUSTILO, Ramon B.** [US/US]; 6541 Beach Road, Eden Prairie, Minnesota 55344 (US).

(74) Agents: **HAKAMAKI, Michaele, A.** et al.; Kagan Binder, PLLC, Suite 200, Maple Island Building, 221 Main Street North, Stillwater, Minnesota 55082 (US).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

[Continued on next page]

(54) Title: PROSTHETIC IMPLANTS FOR TOTAL KNEE ARTHROPLASTY

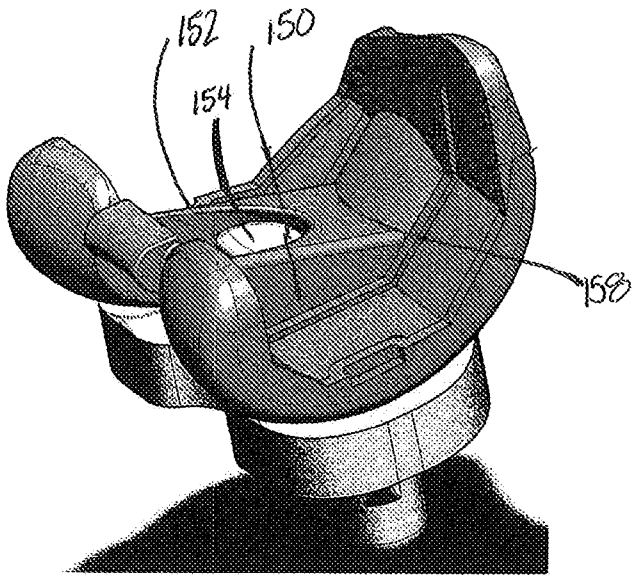

Fig. 21

(57) Abstract: A knee implant for use in total knee arthroplasty, the implant including a femoral component having a trochlear groove and an intercondylar notch, a tibial component engaged with the femoral component, and a patellar component having an upper domed surface, wherein the domed surface is configured for at least line contact articulation with the trochlear groove of the femoral component.

WO 2014/124239 A1

TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

PROSTHETIC IMPLANTS FOR TOTAL KNEE ARTHROPLASTY

Cross-Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/762,492, filed February 8, 2013 entitled "INSTRUMENT FOR LOCATING THE FEMORAL MECHANICAL AXIS", U.S. Provisional Patent Application No. 61/904,083, filed November 14, 2013 entitled "INSTRUMENTS AND METHODS FOR LOCATING A FEMORAL MECHANICAL AXIS", U.S. Provisional Patent Application No. 61/904,086, filed November 14, 2013 entitled "TOTAL KNEE ARTHROPLASTY METHODS, SYSTEMS, AND INSTRUMENTS", and U.S. Provisional Patent Application No. 61/904,099, filed November 14, 2013 entitled "TOTAL KNEE ARTHROPLASTY METHODS, SYSTEMS, AND INSTRUMENTS", which applications are incorporated herein by reference in their entireties.

Technical Field

[0002] The present invention relates to surgical devices for joint replacement, and particularly relates to prosthetic implants used for total knee arthroplasty.

Background

[0003] In the surgical field of total knee arthroplasty, providing properly sized and shaped implant components is one factor in the level of success that can be achieved by the procedure. The general size of the patient and his/her femur and tibia can be one determining factor in choosing implant components; however, a number of studies reveal that even with similarly sized people, other anatomical differences in segments of the population can result in different implant requirements. For example, many Western implants do not correspond to the geometries of Asian knees, and in addition, the shapes of Western implants, as represented by an aspect ratio, do not necessarily match the targeted Asian populations. Such differences between other specific segments of the population can also exist, wherein the differences in Western and Asian anatomies are one example. Thus, there is a need to address these differences in order to provide more effective implants for total knee arthroplasty for no western populations.

SUMMARY

[0004] Certain aspects of the invention use morphology studies reported in the literature to determine the anterior-posterior (AP) and medial-lateral (ML) footprints of the proximal tibia and distal femur, accounting for both genders of certain representative populations (e.g., Asian populations, including people from India, Korea, Japan, China, Thailand and Singapore). This data is used for the design of certain components for total knee arthroplasty, in accordance with the invention.

[0005] In accordance with aspects of the invention, implants are provided for total knee arthroplasty, wherein the geometry of patellar components, together with the femoral trochlea and borders of the intercondylar notch, provide patellofemoral articulation with both native un-resurfaced patellae and resurfaced modified dome-shaped patellae with at least line contact throughout range of motion, and smooth patellar transition between the trochlea and intercondylar notch. In addition, hyperextension and extension are limited through: (1) a broad contact area with a high degree of anterior tibiofemoral conformity; (2) engagement of the anterior surface of the intercondylar box with the anterior aspect of the tibial post; and (3) a posterior tibial slope or ramp built into the articular surfaces. This also prevents component damage, and minimizes abnormal posterior femoral sag in extension and anterior femoral roll-forward in early flexion.

[0006] In accordance with an aspect of the invention, a knee implant is provided for use in total knee arthroplasty, wherein the implant includes a femoral component comprising a trochlear groove and an intercondylar notch, a tibial component engaged with the femoral component, and a patellar component having an upper domed surface, wherein the domed surface is configured for at least line contact articulation with the trochlear groove of the femoral component.

[0007] Further in accordance with the invention, a knee implant for use in total knee arthroplasty is provided, wherein the implant includes a femoral component comprising a trochlear groove and intercondylar notch, and a tibial component engaged with the femoral component, wherein at least one of the femoral and tibial components are sized and shaped to match selected geometries for a target population. In this aspect of the invention, the trochlear groove of the femoral component can be configured to articulate with both a native patella of a

patient and with a patellar component having an upper domed surface, wherein the domed surface is configured for at least line contact articulation with the trochlear groove of the femoral component. Further, the sizes of the femoral and tibial components can be determined using measured anterior-posterior and medial-lateral data of distal ends of multiple femurs and proximal ends of multiple tibias, respectively, for the target population, and the shapes of the femoral and tibial components can be determined using measured aspect ratios of distal ends of multiple femurs and proximal ends of multiple tibias, respectively, for the target population.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The present invention will be further explained with reference to the appended Figures, wherein like structure is referred to by like numerals throughout the several views, and wherein:

[0009] Figure 1 is a graph of anterior-posterior (AP) and medial-lateral (ML) footprints for distal femurs obtained from various studies for a target population;

[0010] Figure 2 is a graph of anterior-posterior (AP) and medial-lateral (ML) footprints for proximal tibias obtained from various studies for a target population;

[0011] Figure 3 is a table of a selected exemplary group of sizes for femoral and tibial components of a total knee arthroplasty systems of the invention;

[0012] Figure 4 is a graph representing aspect ratios against the AP dimensions for distal femurs of a target population;

[0013] Figure 5 is a is a graph representing aspect ratios against the AP dimensions for proximal tibias of a target population;

[0014] Figure 6 is an end view of a native patella;

[0015] Figure 7 is a perspective view of a native patella positioned relative to a femoral component of an implant;

[0016] Figure 8 is an end view of a patella having a modified dome shape, in accordance with the invention;

[0017] Figure 9 is another end view of the patella of Figure 8, illustrating an exemplary patellar facet angle used in the shaping of an embodiment of a modified dome shape;

[0018] Figure 10 is an end view of a patella as positioned relative to a native positioning, and illustrating a patellar facet angle;

[0019] Figure 11 is a front view of a knee implant component of the invention;

[0020] Figure 12 is a sagittal profile of the lateral femoral condyle for six sizes of a femoral component of the invention;

[0021] Figure 13 is a graphical representation of the sulcus angle for a trochlear surface;

[0022] Figure 14 is an end view of a patellar component as positioned relative to a femoral component;

[0023] Figure 15 is another end view of a patellar component as positioned relative to a femoral component;

[0024] Figure 16 is another end view of a patellar component as positioned relative to a femoral component;

[0025] Figure 17 is another end view of a patellar component as positioned relative to a femoral component;

[0026] Figure 18 is a bottom view of a femoral component of the invention;

[0027] Figure 19 is a bottom view of a femoral component of the invention;

[0028] Figure 20 is a cross-sectional side view of several sizes of a femoral component of the invention;

[0029] Figure 21 is a perspective view of knee components of the invention;

[0030] Figure 22 is a perspective view of knee components of the invention;

[0031] Figure 23 is a cross-sectional side view of knee components of the invention;

[0032] Figure 24 is a side view of an exemplary posterior tilt for a tibial component of the invention;

[0033] Figure 25 is a cross-sectional side view of a femoral component of the invention at various angles;

[0034] Figure 26 is a cross-sectional side view of a tibial post and femoral cam follower in a first position;

[0035] Figure 27 is a cross-sectional side view of a tibial post and femoral cam follower in a second position; and

[0036] Figure 28 is a cross-sectional side view of a tibial post and femoral cam follower in a third position.

Detailed Description

[0037] In general, total knee arthroplasty (TKA), or knee replacement, involves preparation (i.e., cutting) of the bones that comprise the knee and then securing implant components in place relative to the prepared or cut bones to improve functioning of the knee joint. In more particularity, a predetermined amount of damaged surfaces at the ends of the femur and tibia are cut using specialized cutting blocks or guides, such as those described in U.S. Patent Application Serial No. 61/904,086, 61/904,086, filed November 14, 2013 entitled "TOTAL KNEE ARTHROPLASTY METHODS, SYSTEMS, AND INSTRUMENTS", the entire contents of which is herein incorporated by reference in its entirety, and then the removed material is replaced with prosthetic components that recreate the surfaces of the joint. The prosthetic components include both femoral and tibial components, which are cemented or otherwise secured to their respective bone ends. The patella can also be resurfaced, with the patellar component being inserted relative to the femoral and tibial components to create a smooth gliding surface.

[0038] In accordance with the invention, total knee arthroplasty is accomplished using fixed-bearing implant designs that include a femoral component, a tibial component, and a patellar component, the features and relationships of which are discussed and illustrated herein. Embodiments of components of the invention can be based on a posterior cruciate ligament (PCL)-stabilized design including a cam or post, along with a cam follower, rather than a posterior cruciate ligament-retaining design. Embodiments of the invention may also be based on the use of symmetric tibial components (i.e., components that include symmetric tibiofemoral articular surfaces). In addition, embodiments of the invention may include femoral components with symmetric portions that mate with the tibia, and are naturally used for symmetric tibial components. On the other hand, embodiments of femoral components described herein can also have asymmetric patellar flanges that necessitate right and left femoral components. The trochlear groove can be located laterally from the center of the femoral component, oriented laterally, and have a raised lateral ridge to accept and guide the patella into the

trochlea in early flexion and maintain normal patellar tracking throughout later flexion.

[0039] The geometries provided for the knee implant components of the invention match the geometries of the knees of the populations in which they will be implanted. Although certain embodiments of the invention described herein relate to considerations for Asian populations, other targeted populations can additionally or alternatively be considered, wherein assessments can be made of the knee geometries of those populations relative to various knee implant variations and the methodology described herein can be applied also to those populations.

[0040] Referring now to Figures 1 and 2, in accordance with an embodiment of the invention, anterior-posterior (AP) and medial-lateral (ML) footprints of the distal femur and the proximal tibia were digitized from scatterplots obtained from various studies for a target population and re-plotted as scatterplots 10, 20 of raw AP and ML data for the femoral and tibial components, respectively. Means ± 2 standard deviations were computed for each of the AP and ML dimensions, and were added to the plots to form a box 12 for the femur and a box 22 for the tibia within which 95% of the population of the chosen group were located. A linear regression was also performed and the standard error was computed. The regression line and standard error band were also added to the scatterplots. The areas enclosed by the ± 2 standard deviations and standard error bounds represent the AP and ML dimensions for the majority of the target population for the tibia and femur. The AP and ML dimensions for the tibial and femoral components for knee implants were determined within these spaces, as is illustrated in Figures 1 and 2. The "plus signs" or crosses 14, 24 shown on these figures are representative sizes that were chosen for femoral components and tibial components, respectively. Similar data can be acquired, plotted, and utilized to select component sizes for other target populations, if desired.

[0041] Figure 3 is a table 30 that represents the overall AP and ML dimensions of the footprints of tibial and femoral components for this exemplary embodiment of a knee system of the invention. This table illustrates a system in which only a limited number of sizes of the tibial and femoral components have been selected for use in a particular total knee arthroplasty system, in order to

minimize inventory and the associated costs, although it is understood that more or less components can be selected. For this example, however, six sizes of femoral components span the AP space with 4 mm between adjacent sizes. Since the data points were normally distributed, narrow and wide versions of the middle two sizes were created to capture the densest portion of the population, as shown by the shaded boxes on the left side of table 30. Referring again to Figure 2, the tibial component sizes have the same general pattern as the femoral component sizes, and six sizes were chosen for the AP space such that there are 3 mm between adjacent sizes. Again, narrow and wide versions of the middle two sizes were created to capture the densest portion of the normally distributed population, as is shown by the shaded boxes on the right side of table 30. The tibial component sizes in the unshaded boxes represent optional component sizes that can be chosen, although additional sizes can also be considered.

[0042] Further in accordance with the invention, not only do the sizes of the tibial and femoral components match the geometry space of the targeted populations, but the shapes of the components were selected as reflected in the aspect ratios to closely parallel the aspect ratios of the targeted populations computed from the geometry space, as can be seen in plots 40, 50 of Figures 4 and 5. These figures represent the aspect ratios (ML dimension / AP dimension x 100) of the femoral components (Figure 4) and tibial components (Figure 5) plotted (as dots 42, 52, respectively) against the aspect ratios of the targeted populations, as indicated by the regression lines 44, 54.

[0043] It is noted that in the selection of appropriate components, an oversized femoral component in the ML direction may lead to impingement with surrounding soft tissues, which may be an issue medially where impingement with the medial collateral ligament complex would occur. An undersized femoral component in the ML direction is less problematic. In the AP direction, an undersized femoral component may lead to notching of the anterior femoral cortex with the potential for fracture of the distal femur, unstable patellar tracking with the possibility of patellar subluxation or dislocation, and a tibiofemoral joint that is too loose in flexion, potentially causing instability in loading conditions requiring higher amounts of flexion, such as getting in and out of a chair or ascending stairs. An

oversized femoral component in the AP direction may lead to overstuffing of the patellofemoral joint with excessively high patellofemoral loads and abnormal patellar tracking, and to a tibiofemoral joint that is overly tight in flexion, possibly leading to restricted range of motion and abnormally high tibiofemoral loads in flexion. These considerations are also taken into account when shaping the femoral and tibial components.

[0044] In order to provide for efficient transmission of loads through the knee, the tibial component will be in contact with the denser outer cortical rim of the proximal tibia. An oversized tibial component may impinge with surrounding soft tissues, possibly causing irritation, restricted motion and discomfort. An undersized tibial component may cause loads to be transmitted through the weaker trabecular tibial bone, possibly causing bony damage with component subsidence and loosening.

[0045] In order to minimize or avoid occurrence of the above complications caused by improperly sized components, a testing protocol can be used that confirms coverage by the proposed component sizes in an intraoperative setting. One exemplary testing protocol involves the use of plastic templates that represent the footprints of the geometries of all of the sizes of the femoral and tibial components presented above in Figure 3, and placing these templates against their respective resected bony surfaces in actual surgical procedures. The templates for the femoral component sizes can have lines scribed on them to indicate where the anterior and posterior cuts will be made and where the intercondylar notch will be positioned. This assessment is made on the proximal tibial resection and the distal femoral resection before anterior, posterior and chamfer cuts are made, and on a straight patellar resection. The template size that best fits a resected surface is based on a subjective visual assessment of the adequacy of coverage. A detailed description of the adequacy or inadequacy of the coverage is recorded, including documentation of specific areas where problems might be evident. Direct measurements of the AP and ML dimensions of the resected surfaces can also be made with intraoperative calipers and recorded. Using the distal femoral resection as a base, templates can also be employed to assess the dimensions of the resected surface of the anterior

femoral condyles that will interface with the femoral component's patellar flange, as will be described further below.

[0046] Figures 6 and 7 illustrate an exemplary step of determining the patellar geometry for a targeted population. This information can be used to help guide the design of the trochlea of the femoral component. In this embodiment of the invention, the trochlea will articulate with either or both of the native patella and any dome-shaped patellar implants, as discussed herein. Although there can be variations in the geometry of the patellae, some average dimensions of the native patella were used to guide the design of the trochlea and patellar components. In an exemplary embodiment, an average native patella 60 was constructed based largely on dimensions from the targeted population in the literature, as shown in Figure 6. Figure 7 illustrates this average patella 60 as it can be located relative to and articulates with a corresponding femoral component 62 of an exemplary implant.

[0047] In general, the patellar components of the invention are based on a modified-dome configuration so that any size patellar component can articulate with any size femoral component with at least line contact. The radii forming the modified-dome design insure that at least line contact will occur with the femoral component trochlea and intercondylar notch. The patellar components are based on an average patellar facet angle of native patellae from the targeted population, as illustrated in Figure 10, for example, which is discussed below.

[0048] It is understood that native patellae come in a variety of different shapes and sizes; however, the unresurfaced native patella will attempt to eventually conform to the geometry of the opposing femoral component's trochlear surface by a process of bedding-in or remodeling, producing a gradual adaptation of the retro-patellar surface and subchondral bone plate to the shape of the implant's trochlear articular surface. In addition, native patellae are covered with a layer of compressible articular cartilage, the thickness of which depends on the severity of the arthritic process (e.g., approximately 2 to 4 mm). In spite of the fact that the native patella can tolerate the trochlea in this manner, having the initial geometry of the two be as compatible as possible will minimize the sclerosis and subsequent further cartilage degradation that can occur as a result of this remodeling process. This average native patella can be used as a comparative model so that the design of

the femoral trochlea will accommodate this average geometry as closely as possible, while, articulating with a series of modified dome-shaped patellar implants with as large of a contact area as possible.

[0049] Referring now to Figures 8-10, an embodiment of a patellar component 70 and its associated design is shown and described. With this embodiment, the design of the articular surfaces of the patellar component 70 will be coordinated with the design of the femoral component's trochlea and intercondylar notch to insure proper patellofemoral tracking with maximum contact throughout flexion, wherein the patellar articular surfaces will drive the trochlear articulation design. Although a patellar component with a spherical, dome-shaped geometry may be considered to be the most 'forgiving' design with respect to accommodating minor degrees of malpositioning, purely spherical components may result in point contact with subsequent polyethylene wear and eventual deformation when articulating with the trochlear surface, as well as with the extension of the trochlear groove concavity onto the inner portion of the femoral condyles adjacent to the intercondylar notch with later flexion. Because of the desire to provide a patellar component with increased metal-to-plastic contact, as well as the desire to provide a patellofemoral articular surface that articulates with native patellae, the modified dome shape for the patella 70 is used in accordance with the invention. This design is intended to ensure at least line contact with the trochlear surface and its extension into the intercondylar notch throughout flexion. The articular surface of the modified dome of the patella 70 will be achieved by a combination of a central convex radius that blends with a larger outer concave radius that will be extended so that different widths of patellar components can be obtained with the same articular surface design, as is shown in Figures 8 and 9. This design recognizes that larger patellofemoral contact areas can be more advantageous. All sizes of patellar components will preferably be able to interchangeably articulate with all sizes of femoral components in this embodiment.

[0050] Referring also to Figure 10, the mean ± standard deviation of the angle 74 of the native patellae for a targeted population is 133° ± 6°. The equivalent patellar facet angle of a patellar component needs to approximate this, as well as interact with the sulcus angle (see Figure 13) of the trochlea of the femoral

component to achieve at least line contact with the trochlear articular surface and its extension onto the intercondylar notch during patellofemoral tracking. As mentioned above, this target patellar facet angle 74 for the patellar component will encompass a central convex radius that blends with a larger outer concave radius that will be extended so that different widths of patellar components can be obtained with the same articular surface, as is shown in Figures 8 and 9. Coordinating the design of the femoral trochlear articular surface and its extension into the intercondylar notch with a patellar component design based on an anatomical patellar facet angle ensures that the patellofemoral articulation will accommodate both resurfaced and unresurfaced patellae.

[0051] With continued reference to Figures 8 and 9, in determining the widths of the patellar component, an undersized width may cause impingement between the periphery of the patellar bone remaining after resection and the facets of the trochlear articulating surface, possibly leading to abnormal patellofemoral tracking and patellar fracture. A patellar component with an oversized width may result in the component riding high with point contact on the ridges of the trochlear facets, and in possible overstuffing of the patellofemoral joint, again, leading to abnormal patellofemoral loading and tracking, and quadriceps function. With regard to the height of the patellar articular surface, the same thickness of the articulation of a patellar component of the invention can be used on all component sizes for a targeted population so that any patellar component can be interchangeably used on any femoral component trochlea.

[0052] In accordance with the invention, the trochlear surface is configured to articulate with both a native patella and a resurfaced patella. In particular, the trochlear articulating surface is configured to accommodate both an average-sized native patella for the targeted population, along with the modified dome-shaped patellar implants described herein (e.g., patella 70), with at least line contact and stable patellofemoral tracking. The geometry of the trochlear articular surface can be "carved into" the patellar flange by passing the articulation of the patellar component through the patellar flange within the constraints of the following: lateral offset and angulation of the trochlear groove; anterior radius of the lateral femoral condyle in the sagittal plane; trochlear groove based on a segment of a circle; a

sulcus angle that is deep and limited to less than 145°; and a lateral ridge that is more prominent than the medial ridge. Further, the trochlear articulation is extended onto the intercondylar notch area with a smooth transition and continued (at least) line contact throughout the range of motion.

[0053] With continued reference to the femoral component, the medial and lateral posterior condylar widths of an average-sized femoral component can be referenced to the means of these measurements from a targeted population, wherein the medial and lateral posterior condylar widths will be generally equal in each femoral component. Similarly, the medial and lateral posterior condylar heights of an average-sized femoral component can be referenced to the means of these measurements from a targeted population, wherein the medial and lateral posterior condylar heights will be generally equal in each femoral component. In addition, the width and anteromedial and anterolateral heights of the patellar flange of an average-sized femoral component can be referenced to the means of corresponding measures from resected surfaces for the targeted population, and anteroposterior lengths of the lateral femoral condyle in the sagittal plane of an average-sized femoral component can be referenced to the mean of this measure for the targeted population.

[0054] A number of additional relationships can be considered relative to the configuration of the femoral components of the invention. The peak-to-peak spacing between the anteromedial and anterolateral condyles of the patellar flange of an average-sized femoral component can be referenced to the mean of the corresponding measure from resected surfaces for the targeted population. The spacing between the posterior-most points of the posteromedial and posterolateral condyles of an average-sized femoral component can be referenced to the mean of the corresponding measure for the targeted population. The sagittal profiles of the medial and lateral posterior femoral condyles of an averaged-sized femoral component can be represented by a single radius of curvature referenced to the mean of corresponding measures for the targeted population, wherein the medial and lateral posterior condylar radii can be equal in each femoral component.

[0055] In the sizing of components, representative dimensions can be used for a tibial post (cam), intercondylar box, and coronal radius of curvature for

multiple selected component sizes. Such dimensions can be based on a configuration in which the coronal curvature of the posterior and distal femoral condyles are provided with a single radius for all sizes of femoral components, and can be further based on a configuration in which the curvature of the posterior and distal femoral condyles in the coronal plane: (1) provide for at least line contact when articulating with the mating tibial condyles; and (2) allow for interchangeability when mating with different-sized tibial components. To accomplish this, the same single radius of curvature (e.g., 30 mm) can carry around the profile of the posterior and distal sagittal radii for all femoral component sizes. In the coronal plane, the center for this radius will be a fixed distance from the center of the intercondylar box (and tibial post (cam)) for all of the femoral component sizes. The only difference between sizes will be the extent to which this radius will be extended toward the medial and lateral sides of the component to obtain the desired component medial-lateral width. The same concept can be applied to the larger coronal radii of the tibial component so that there is partial conformity to allow for component 'laxity' in flexion. In addition, this partial conformity will accommodate the occurrence of abduction/adduction and condylar lift-off without edge loading or damage to the post, which may be made of polyethylene, for example. Thus, the intercondylar box width, height and wall thicknesses, tibial post width and height, and relative clearance allow some degree of interchangeability between adjacent sized components.

[0056] Figure 11 illustrates a configuration of an implant component 80 of the invention in which the proximal trochlear groove is asymmetric and angulated laterally. An asymmetric patellar flange increases the probability that the patella will become centered in the trochlear groove 82 without subluxing or dislocating during patellofemoral tracking from extension to early flexion, while subjecting it to a normal level of contact force. An asymmetric patellar flange of the invention can extend and lateralize the patellar groove in the supracondylar region (e.g., the position the patella occupies is from 0° to approximately 30° flexion) in order to more easily and smoothly guide the patella, which normally rides high laterally in extension, into the trochlear groove 82 without subjecting it to high contact forces or to a discontinuity in its motion by riding over an edge. The trochlear groove 82 can

be angled at approximately 7° laterally, for example, wherein this lateral tilt will begin at the entrance of the intercondylar notch and extend proximally to the top of the patellar flange.

[0057] The distal portion of the trochlear groove 82 (or sulcus) is positioned lateral to the midline of the femur in the frontal plane in normal anatomy, as also shown in the femoral component of Figure 11. A lateral offset (e.g., 3 mm) of the distal groove from the center of the component 80 will be built into the patellar trochlea in the proposed design, which is the average of the values that can be found in the art. This, together with positioning the femoral component in approximately 3° of external rotation, will sufficiently lateralize the sulcus to more closely match the normal anatomy and provide for proper patellofemoral tracking.

[0058] Figure 12 is a representative example of a sagittal profile of the lateral femoral condyle for six sizes of a femoral component 88 of the invention. As shown, the anterior, distal and posterior femoral condylar radii form the sagittal profile of the component, along with the slanted geometry of the intercondylar box and anterior tilt of the patellar flange (e.g., 3°). The anterior profile of the lateral femoral condyle in the sagittal plane will form the boundary condition from which all other trochlear design features will be defined. The anterolateral radius will be defined while considering the overall anteroposterior dimension of the lateral femoral condyle, and the curvatures of the posterior and distal femoral condyles in the sagittal plane. The anterolateral radius will also play a role in the tibiofemoral conformity limiting hyperextension and limiting 'laxity' in and near extension. The anterior tilt of the patellar flange allows for easier installation of the femoral component on the distal femur, and reduces the chance of notching the anterior femoral cortex with subsequent fracture.

[0059] The geometry of the trochlear groove used in an embodiment of the invention can be based on a segment of a circle so that the center of the patella will move in a circular pattern when engaged in the trochlea during flexion. A best-fit circular surface can be determined, and the mean value for the radii of such a circle as determined from the literature, plus or minus 2 standard deviations, will serve as a reference for the build-out of femoral component sizes of the invention, wherein the trochlear groove will be offset from the center of the trochlea and angulated

approximately 7 degrees laterally, rather than being perpendicular to the distal femoral resection and parallel to the mechanical axis of the knee. As such, this circular profile of the trochlear groove will not have a clear radius, but will be offset and tilted, and thus, described in cross sections through the trochlea.

[0060] Figure 13 illustrates an exemplary difference in heights between medial and lateral trochlear facets, in accordance with the invention. That is, the lateral ridge of the trochlear articulation will be more prominent than the medial ridge, wherein a high lateral ridge is better able to guide the patellar component into the trochlea in early flexion, and, together with a deepened trochlear groove, is better able to contain the patellar component within the groove with more normal patellofemoral tracking with less patellar tilt and rotation, and decrease the chances for patellar subluxation or dislocation. The anterolateral sagittal femoral radius provides a border for the trochlear surface. As is also shown in Figure 13, the sulcus angle is the angle between lines CB and CD (i.e., angle BCD), as points B and D are determined as the high points of the trochlear facets, and point C is at the bottom of the trough (i.e., the trochlear groove) between these high points. The trochlear surface is based on an average sulcus angle determined from a target population, and the geometry of the trochlear groove is based on a segment of a circle, also determined from a target population.

[0061] The actual geometry of the trochlear articulation will be the same for all femoral component sizes, but the periphery of the patellar flange will be extended to satisfy the size condition of the anterior femoral resection. The patellar component's articulation will be designed in the same way, such that the articulation will be the same on all components, but will be extended out to the sides to generate different component sizes. In this way, any patellar component size will be able to mate with any femoral component size with complete interchangeability and at least line contact.

[0062] Figures 14-17 are images showing patellofemoral contact from extension to increasing flexion. In an embodiment of the invention, the relative geometries of the patellar and trochlear articulations will be such that there will be lower patellofemoral conformity in extension to 20°-30° flexion so that a patella 90 will be guided into a trochlea 92, as is illustrated in Figure 14. With further flexion,

there will then be greater conformity and contact between the patellar and trochlear articulations, as is illustrated in Figure 15. The trochlear articulation will then smoothly transition into the intercondylar notch, as is shown in Figure 16, and continue onto the intercondylar region, as is shown in Figure 17, so there will be at least line contact between the patellar and femoral component surfaces. The trochlear groove will be of sufficient depth and tailored to the geometry of the patellar component so that there will be as large of a contact area as possible with the patellar component (at least line contact and no point contact), less total and shear loads on the patellar component, and more normal patellofemoral tracking.

[0063] In accordance with the invention, since the articulation of the patellar components will be based on an average patellar facet angle for a target population, and since the trochlear articulation will be based on an average sulcus angle for a target population, the femoral component trochlear surface will subsequently also be able to articulate with an average-sized unresurfaced patella with a high degree of conformity, as is illustrated in Figure 7.

[0064] The following testing protocol provides an exemplary manner of measuring both patellofemoral and tibiofemoral contact areas and relative motion, which uses a three-dimensional coordinate device to measure the coordinates of grids on all articular surfaces of interest on all implant components (patellar, femoral and tibial articulations, including the cam surfaces), as well as reference points on each component. Grids are transformed to local coordinate systems on each component. Tibial, femoral and patellar components are then implanted in synthetic knee joints that are, in turn, mounted in a "bench-top" knee testing rig. Knees are extended from a flexed position by pulling on the synthetic knee's quadriceps mechanism. At each flexion angle, positions of reference points on each component are re-measured in an unloaded state, with a compressive load applied, and with a compressive load with a superimposed anterior/posterior shear load, internal/external rotation moment and abduction/adduction moment. After each load condition is applied, the relative tibiofemoral and patellofemoral motions are computed, as well as the relative distances between the respective grid points on the surfaces of interest. Contact is considered to have occurred when these distances are less than a predetermined cut-off distance. This process provides a neutral path of

motion over the range of flexion-extension (with and without compressive forces), as well as the laxities about this neutral path (as a result of superimposed shear loads and moments). The following points to be evaluated below are then addressed through the data generated with this protocol. This process is repeated for each pair of matched tibial and femoral component sizes, as well as tibial and femoral components that are interchanged with one size up and one size down. All patellar component sizes are also tested with all femoral component sizes.

[0065] As set out above, for the patellofemoral articulation, the measurements made are intended to confirm the following configurations and/or relationships: at least line contact between the modified dome-shaped patellar component and trochlear articulation of the femoral component (i.e., no point contact); at least line contact between the patellar component and extension of the trochlear articulation along the edges of the intercondylar notch of the femoral component (i.e., no point contact); contact between the patellar component and trochlear articulation will be down the center of the trochlear groove during flexion (i.e., not along the sides or edge of the trochlea); contact between the patellar component and extension of the trochlear articulation along the intercondylar notch will be balanced on both sides of the notch (i.e., not along one side or the other); the patella rides high in the suprapatellar region in extension, and is guided into the trochlea in early flexion (e.g., extension to 20°-30° flexion); the patella rides at the bottom of the trochlear groove during flexion from 20°-30° to 90°-100°, such that there is no medial/lateral tilt or rotation due to poor tracking; the patella rides in the middle of the extension of the trochlear articulation along the intercondylar notch through maximal flexion; and a smooth transition of the patella exists between the articulation with the trochlea and the articulation with the notch.

[0066] The protocol above can be modified by using miniature pressure sensors, instrumented components or pressure-measuring films applied to the surfaces of interest to directly measure contact area, rather than predicting contact areas by the above grid/kinematics approach. The protocol can also be modified by implanting components in cadaveric knee specimens.

[0067] Referring now to Figure 18, an image of an example of the continuation of the trochlear articulation surface 100 onto the intercondylar region

102 is illustrated. Improper patellofemoral articulation in the intercondylar region may result in 2-point contact with possible wear and deformation of the polyethylene patellar component, abnormal patellofemoral loads and tracking in extreme flexion, or catching or locking of the patellar component in the intercondylar notch. In order to avoid this situation, the trochlear articulation surface 100 described above will be continued onto the inner portion of the femoral condyles that border the intercondylar notch 102 so as to provide increased patellofemoral congruency in flexion, thereby allowing at least line contact and minimizing the chance for 2-point contact, as is shown in Figure 16. This will be achieved in the femoral component through the coordinated design of the trochlear articular surface, the blending of this surface with the coronal and sagittal profiles of the distal femoral condyles, and the modified-dome articular surface of the patellar component, all of which are described above.

[0068] Additional optional features can be incorporated into the design and selection of the femoral component. For example, the components can be designed to provide for a smooth transition area 104 in patellar tracking between the trochlear articular surface 100 and the extension of that surface onto the borders of the intercondylar notch 102. This can be achieved through the coordinated design of the trochlear articular surface, the blending of this surface with the coronal and sagittal profiles of the distal femoral condyles, the extension of the trochlear surface onto the edges of the intercondylar notch, and the modified-dome articular surface of the patellar component, all of which are illustrated with respect to Figure 18.

[0069] The distal femoral radius in the sagittal plane is used to connect the trochlea with the posterior femoral condylar radius while maintaining the overall AP depth of the femoral condyle. This radius will allow the anterior and posterior contours of the features of the femoral component in the sagittal plane to blend while still preserving the prescribed anteroposterior dimension of the component. When building out the femoral component sizes, the magnitudes of the distal femoral radii will be such that they preferably allow the anterior trochlear profiles to blend with the posterior femoral radii within the confines of the overall AP dimension of the femoral component. In addition, the design of the trochlear

articulation can be coordinated with the anterior tibial condyle so that there is maximum tibiofemoral conformity in hyperextension and extension.

[0070] In an embodiment of the invention that is illustrated in Figure 19, an intercondylar box ratio that is less than 0.7 will minimize patellar clunk and crepitus, and an intercondylar box ratio of greater than 0.8 will run the risk of increased incidence of patellar clunk and symptomatic or asymptomatic crepitus. Clunk and crepitus can be further minimized by rounding the edges 106 of the transition between the trochlea and entrance into the intercondylar notch, as shown in Figure 18. These relationships are described in further detail with regard to Figure 19, which illustrates the intercondylar box ratio as the AP depth 112 of the intercondylar box 110 / AP depth 114 of the femoral component. In particular, a fibrous nodule sometimes forms next to the patella when the quadriceps tendon impinges with the intercondylar notch of a posterior-stabilized femoral component in flexion. Patellar clunk occurs when the nodule becomes entrapped in the notch in deep flexion, with an audible clunk resulting as the nodule escapes with extension. Painful or painless crepitus occurs when a smaller tissue mass grates against the notch with flexion/extension. The low intercondylar box ratio illustrated in Figure 18 moves the entrance into the notch (and box) 106 posteriorly so that the quadriceps tendon contacts the notch later in flexion, thereby reducing clunk and crepitus.

[0071] Referring now to Figure 20, an exemplary embodiment is illustrated of the position of a cam follower 146 of a femoral component 140, and the height of the tibial post 142 and intercondylar box 144 for multiple sizes of femoral components. In accordance with this aspect of the invention, the height of the intercondylar box 144 can accommodate the cam mechanism and allow for some degree of interchangeability among sizes, while minimizing the amount of femoral bone removal. In particular, for each of the femoral component sizes that have been chosen to cover the geometry of the targeted population discussed above, the (1) height and curvature of the posterior femoral condyles, (2) curvature of the posterior tibial articulation, (3) height and position of the tibial post (cam) 142, and (4) position of the femoral cam (cam follower) 146 as related to the height of the femoral intercondylar box 144, will all be designed and balanced in such a way so as to (1) produce cam engagement at 50-55° flexion, (2) provide approximately 12 mm

of femoral rollback so as to allow 130° of flexion and a proper quadriceps moment arm, (3) prevent the femoral component 140 from rolling off the end of the tibial component in extreme flexion, (4) prevent femoral component roll-forward in early flexion, (5) have the contact between the cam follower and post progress down the post with increasing flexion, and (6) provide an additional stop at extension and hyperextension without polyethylene deformation. With the larger components the cam and cam follower need to change position and shape in order for all of this to occur. The intercondylar box 144 will have a different height on each size since the cam location varies due to the growth of the condyles, creating longer articulations as the component size increases. The heights of the intercondylar boxes 144 for the femoral component sizes are defined such that minimal amounts of femoral bone will need to be removed while still maintaining the desired function of the cam mechanism.

[0072] An intercondylar box that is too large would require removal of too much femoral bone that could weaken the anterior femoral cortex or the medial and lateral femoral condyles, possibly resulting in an intraoperative or postoperative periprosthetic fracture. Thus, one desired feature related to the design of an intercondylar box 150 of a posterior-stabilized knee implant of the invention is to conserve as much femoral bone as possible by making the box 150 with a low profile while still maintaining the desired function of the cam mechanism. In order to achieve this outcome and conserve bone, the intercondylar box 150 will be angulated downward from a back end 156 to a front end 158 and have an open top area 152, as shown in Figures 21 and 22. The intercondylar box 150 will be grown out over the femoral component sizes while maintaining the function of the cam mechanism. The preparation of the femoral bone to accommodate the intercondylar box can be made with simple bone cuts using a saw or osteotome. In addition, the intercondylar box 150 can have an open section on its top surface 152 to prevent the extreme top of the polyethylene post 154 of the tibial component from impinging with the inner surface of the top of the intercondylar box during range of motion with functional activities.

[0073] Figure 23 illustrates an embodiment showing the limit of hyperextension by contact of the inner face of an intercondylar box 162 with the

anterior face of a post 164 of a tibial component 160. In particular, the angulated intercondylar box design with its partially opened top 168 (discussed above) can include a sufficiently sized anterior inner surface 162 that will be oriented and positioned to contact the anterior face of the post 164 of tibial component 160 so as to provide a secondary stop to hyperextension. The primary stop to hyperextension is provided by a high degree of conformity between the tibiofemoral articular surfaces anteriorly, including a build-up of material in an anterior intercondylar region 174.

[0074] Additional or extra material 176 can be added to the backside of the patellar flange to strengthen the flange under the trochlear groove. This may be done so that the patellar flange can structurally support the details of the patellofemoral articulation, particularly in the region of the trochlear groove. In order to do this, extra material 176 will be added to strengthen the backside of the patellar flange in the region of the trochlear groove as is illustrated in Figure 23. This material will be provided with a radius so that it can be accommodated by easy removal of a minimal amount of femoral bone using a rasp.

[0075] In order to achieve particular amounts of femoral component rollback with flexion, the femoral component is located on the tibial component with prescribed amounts of femoral rollback as a function of flexion angle, and then the locations of the contact between the tibial cam (post) and femoral cam follower surfaces needed to achieve that rollback are plotted. In this way, the anteroposterior and superoinferior position of the cam follower and the geometry of the posterior articulating face of the post are determined for each of the component sizes. This will be done so that the contact between the cam follower and post progresses down the post with increasing rollback and flexion, and at extreme flexion, the contact with the femoral component will be at least 5 mm from the posterior edge of the tibial component.

[0076] The intercondylar box growth over femoral component sizes described above will allow some degree of interchangeability between adjacently sized tibial and femoral components. That is, when performing total knee arthroplasty, a surgeon may achieve proper coverage of the resected distal femur with a suitably sized femoral component, but may find that the equivalent sized

tibial component does not similarly achieve adequate coverage of the proximal tibia. Thus, the devices and methods of the invention advantageously match the femoral component with a tibial component that is one size smaller or one size larger. Component interchangeability can be assessed by creating plastic prototypes of the different component sizes, and qualitatively determining cam function and relative tibiofemoral motion when adjacent sizes of tibial and femoral components are interchanged.

[0077] It is recognized that given the constraints of the AP and ML dimensions of the tibial component sizes described herein (e.g., the sizes in the table 30 of Figure 3), the shapes of the components are scaled, based on geometry data from a targeted population, so that they maximize the coverage of the corresponding resected tibial surfaces. That is, in order to provide for efficient transmission of loads through the knee, the tibial component needs to be in contact with the denser outer cortical rim of the resected proximal tibia. An oversized tibial component may impinge with surrounding soft tissues, which can possibly cause tissue irritation, restricted motion and general discomfort. An undersized tibial component may cause loads to be transmitted through the weaker trabecular tibial bone, possibly causing bony damage with component subsidence and loosening. Thus, close approximation between the tibial component profile and the resected tibial surface is important.

[0078] Another consideration for the tibial components is that the anterior radius in the sagittal plane can be designed in combination with the anterior curvature of the corresponding femoral component so as to produce a high degree of conformity in hyperextension, extension and early flexion. That is, the anterior radius of the tibial component in the sagittal plane will have a suitable magnitude that, when combined with the corresponding radius of the femoral component (defined primarily to provide a boundary condition for the design of the trochlear articulating surface), will produce this high level of conformity and stability with corresponding low levels of rotational 'laxity'. These considerations help to produce a broad contact area to limit motion and polyethylene damage in hyperextension, as will be discussed in further detail below. The femoral components' anterior radii and the need for stability in and near extension and early flexion will drive the magnitude of the anterior tibial radii. Anterior tibial radii will be similar in

magnitude (or perhaps slightly larger) when compared to the corresponding anterior femoral radii, and can range from approximately 24 mm to 38 mm over a series of tibial and femoral component sizes, for example.

[0079] Implant components that are provided with improper tibiofemoral conformity in flexion will lead to compromised cam function with either too much or too little posterior femoral rollback and tibiofemoral laxity. Excessive laxity and rollback may cause the femoral component to roll off the back of the tibial component, possibly leading to tibial loosening or polyethylene damage. To avoid these issues, in accordance with the invention, the posterior radius of tibial components in the sagittal plane will be selected in combination with the posterior condylar curvature of the corresponding femoral component so as to allow desired levels of posterior femoral roll-back and rotational laxity in flexion.

[0080] It is also desirable in total knee arthroplasty to have low conformity in the posterior tibiofemoral articulation so that the components are able to respond to the posterior rollback generated by the cam mechanism with increasing flexion beyond cam engagement, and are able to accommodate transverse rotational laxity, as well as abduction/adduction and medial/lateral lift-off. The posterior radius of the tibial component in the sagittal plane will have a suitable magnitude so that, when combined with the corresponding height and radius of the posterior femoral condyles and the details of the cam mechanism, will accommodate posterior femoral rollback, transverse rotation, abduction/adduction and condylar lift-off in flexion. This is important for attaining a desired range of flexion and proper muscle function (particularly the quadriceps). The magnitude of the femoral components' posterior radii and the need for posterior rollback and the accommodation of transverse rotation in flexion will drive the tibial sagittal radii. Posterior tibial radii can range in the neighborhood from 20 mm to 26 mm, for example, and will be significantly larger than the respective femoral component radii (16 mm to 24 mm) in order to achieve low conformity.

[0081] Figure 24 illustrates a posterior tilt provided for the tibial component 180 in the sagittal plane incorporated into the component's articulating surface. In other words, the illustrated posterior slope is incorporated into the blend 182 between the anterior and distal tibial sagittal radii. Proper selection of the posterior

tilt is important to avoid posterior tibiofemoral subluxation caused by too large of a posterior tilt of the tibial component 180, to minimize or avoid increased polyethylene wear of the posterior portion of the tibial condylar surface, and also to minimize or avoid a reduction in femoral rollback with flexion. On the other hand, an insufficient amount of posterior tilt of the tibial component 180 will also negatively affect range of motion by increasing the chance that the posterior femoral bone would contact the posterior lips of the tibial component 180 before a suitable amount of flexion is obtained.

[0082] In accordance with the invention, the posterior slope of the tibial condyles can be reproduced in TKA through either a posterior-tilted proximal tibial resection or through building a posterior tilt into the component itself, thus allowing the proximal tibial resection to be perpendicular to the mechanical axis. Although posterior tibial slopes in un-operated knees are often greater than 8 degrees, a posterior tilt of the tibial component of greater than 7-8 degrees is considered to be unfavorable since it may lead to posterior tibiofemoral subluxation, increased polyethylene wear of the posterior portion of the tibial condylar surface, and a reduction in femoral rollback with flexion. Considering all of these factors, the posterior tilt in an exemplary embodiment of the invention will be approximately 5-7 degrees, and will be built into the tibial component articulation and not obtained from a posterior-tilted proximal tibial resection. In the posterior-stabilized situation, this approach is important for greater range of motion before impingement of the posterior femoral bone with the posterior lip of the tibial component, for proper cam engagement at a desired target flexion angle, and for providing a backward sloping tibial articulation that will counteract anterior femoral roll-forward. Posterior tilting of the tibial component on the bone bed tends to result in the femoral component needing to move through a larger range of flexion before its cam follower contacts the tibial cam (post), thereby reducing rollback by postponing post engagement until higher flexion angles. Thus, the intended flexion angle at which cam engagement should take place would be compromised. Because of this, the posterior tilt will be built into the articulation of the component where cam engagement occurs at the intended flexion angle.

[0083] In the coronal plane, the curvature of tibial articular surfaces of the invention will consist of a single radius for all sizes of tibial components. In designing this curvature in the coronal plane, it is desirable to have at least line contact when articulating with the mating femoral condyles and to allow for interchangeability when mating with different-sized femoral components. To accomplish this, the same single radius of curvature (e.g., approximately 31 mm), will carry along the entire sagittal profile of the articulation of all tibial component sizes. The only difference between sizes will be the extent to which this radius will be extended toward the medial and lateral sides of the component to obtain the desired component mediolateral width. The same concept can be applied to the slightly smaller coronal radii of the femoral component so that there will be partial conformity to allow for some component laxity in flexion. This partial conformity and the extension of the coronal curvature a short distance up the walls of the post will accommodate the occurrence of abduction/adduction and condylar lift-off without edge loading or damage to the polyethylene post.

[0084] Additional optional considerations can be incorporated into a configuration of the tibial component of the invention. One consideration is to provide post widths that are just large enough to be structurally sound, to insure proper cam function, and to minimize the amount of femoral bone removed. Another consideration is to provide an implant in which the AP location of the tibial post will be coordinated with other design features such that it will provide a stop to hyperextension, limit posterior femoral sag and anterior femoral roll-forward in early flexion, generate posterior femoral rollback beyond cam engagement, and accommodate transverse rotation without rolling off the back of the tibial condyles. Another consideration is that the tibial component can have an anterior recess to accommodate the patellar tendon in flexion. In addition, the tibial component can have a posterior recess to accommodate posterior soft tissues.

[0085] The components and systems of the invention recognize that failure to allow for sufficient hyperextension in posterior-stabilized TKA systems will increase the probability for generating damage to the anterior aspect of the polyethylene tibial post from impingement with the notch of the femoral component, which can possibly result in polyethylene wear debris and fracture of the post. Thus,

designs of the invention accommodate up to 10° of hyperextension. Hyperextension is limited to 10° through a broad contact area with a high degree of tibiofemoral conformity and through engagement of the anterior surface of the intercondylar box with the anterior surface of the post, and in doing so, minimizes polyethylene damage of the post and posterior femoral sagging in extension, both of which commonly occur in posterior-stabilized designs. However, an inadequate limit to hyperextension may lead to increased contact stresses on the anterior aspect of the tibial post, with potential accelerated wear and macroscopic damage and possible failure of the tibial post. Thus, hyperextension can be mechanically limited by anteriorly conforming tibiofemoral surfaces and contact between the anterior surface of the intercondylar box and anterior surface of the tibial post. In an embodiment of the invention, hyperextension is limited by broad contact between the anterior surface of the tibial post and the anterior inner wall of the intercondylar box. The contact area between the post and box is sufficiently large so as to generate low contact stresses and prevent damage to the polyethylene post. This intercondylar box/post interface works in tandem with the broad tibiofemoral contact area with a high degree of conformity under compressive loading in the sagittal and coronal planes. This interface and conformity, in essence, behave like the anterior cruciate ligament in hyperextension, if it were present.

[0086] Embodiments of the invention, as described herein, can advantageously provide for a high degree of conformity and a relatively large contact area in extension due to the integrated design of the femoral coronal, anterior sagittal and distal sagittal radii, the tibial coronal and anterior sagittal radii, and the incorporation of the posterior tibial slope into the sagittal articular contour, as discussed herein. Similarly, embodiments of the invention further help to minimize component "laxity" in the tibiofemoral articulation between extension and cam engagement, due to the integrated design of the femoral coronal, anterior sagittal and distal sagittal radii, the tibial coronal and anterior sagittal radii, and the incorporation of the posterior tibial slope into the sagittal articular contour.

[0087] In a healthy knee, the anterior cruciate ligament (ACL) restrains the tibia from moving anteriorly on the femur near extension, or with opposite reference, the femur from moving posteriorly on the tibia. As a result, the ACL helps

maintain the proper tibiofemoral contact anteriorly in extension. The ACL cannot fulfill this particular role in a posterior-stabilized knee where both cruciates are excised. Because of this, the femur can sag posteriorly near extension, which abnormally biases the contact posteriorly rather than anteriorly and may prove to be symptomatic in some cases. Posterior femoral sag causes the tibiofemoral contact to be in an abnormally posterior position near extension, which may generate a feeling of instability on the part of the patient during weight-bearing activities near extension, as well as abnormal patellofemoral tracking as the patella attempts to initially engage the trochlear articular surface near extension. In accordance with configurations of the invention disclosed herein, however, the potential for posterior femoral sag near extension due to the absent ACL can be reduced. This is accomplished through contact between the anterior surface of the tibial post and the anterior inner wall of the intercondylar box in near extension (hyperextension to approximately 10-15 degrees flexion), which will limit the femur from sagging posteriorly over the tibia. The contact area between the post and box will be sufficiently large so as to prevent damage to the polyethylene post. To a lesser extent, posterior sag will be limited near extension through a broad tibiofemoral contact area with a high degree of conformity with compressive loading. This interface and conformity can essentially function in place of the missing ACL.

[0088] Configurations of the invention minimize "paradoxical" anterior femoral roll-forward in early flexion, wherein Figure 25 illustrates this situation with superimposed images of tibiofemoral contact from extension to cam engagement near 50 degrees, demonstrating posterior movement of tibiofemoral contact over that range of flexion, instead of anterior roll-forward. That is, rather than posterior rollback of the femoral component 200 that normally accompanies flexion, this paradoxical motion means that the femoral component instead rolls forward in early flexion. This abnormal motion is primarily attributed to the absence of the cruciates with TKA. Anterior femoral roll-forward in early flexion limits range of motion, compromises the efficiency of the quadriceps musculature, accelerates polyethylene wear, and creates in the patient an unwanted feeling of instability and abnormalcy. Embodiments of the implants of the invention minimize this abnormal motion by building in an anteriorly directed ramp 202 through incorporating a posterior tilt

built into the tibial articular surface, and through highly conforming tibiofemoral articular surfaces in extension and early flexion. In this way, the femoral component needs to move 'up-hill' in early flexion, making it harder to roll forward. The anterior roll-forward can also be neutralized by engaging the cam at an earlier flexion angle so that rollback will be forced.

[0089] In accordance with the invention, contact between the tibial post and femoral cam follower will be at least line contact with or without transverse rotation, and will progress down the post with flexion. Wear of the polyethylene post due to articulation of the cam mechanism, dislocation or subluxation at the cam mechanism, or deformation or fracture of the polyethylene post, sometimes occur in posterior-stabilized designs. The implants of the invention include a somewhat curved interface between the post and cam follower that provides line contact to minimize wear, wherein the contact between the post and cam follower will move down the post with increasing flexion. Distal movement of the cam follower will provide greater resistance to the anteriorly directed shear loads experienced by the tibial post in high degrees of flexion, and will insure that dislocation will not occur. That is, the components are provided with as broad of a contact area as possible at this interface, even when transverse rotation about the neutral track occurs. The slight curvature of the interface between the post and cam follower provide for line contact that can be built into the cam mechanism without decreasing the size of the post or cam follower.

[0090] As set out above, contact between the tibial post (cam) and femoral cam follower will progress down the post with flexion, which is illustrated in Figures 26-28. In particular, these figures show the contact between the cam follower and the post with flexion of 55 degrees (Figure 26), 75 degrees (Figure 27), and 105 degrees (Figure 28). Distal movement of the cam follower also provides greater resistance to the anteriorly directed shear loads experienced by the tibial post in high degrees of flexion.

[0091] In accordance with an embodiment of the invention, the tibiofemoral articulation and cam mechanism will produce at least 12 mm of posterior femoral rollback from cam engagement to 130 degrees of flexion. Tibiofemoral contact at maximum flexion will be at least 5 mm from the posterior edge of the tibial

component. The main reason for this rollback is that it allows the posterior femur to clear the posterior edge of the tibial component without impingement with posterior femoral bone in maximal flexion. Rollback and an accommodation for transverse rotation are also important for maintaining a proper moment arm for quadriceps function so that one can efficiently perform activities such as getting out of a chair and going up stairs. If designed improperly, the femoral component may articulate with the posterior edges of the polyethylene tibial component in extreme flexion, or, even roll off the back of the tibial component. Damage to the polyethylene occurs in either case, not to mention the potential for compromised function with activities requiring maximal flexion, as well as the possibility of component loosening. Embodiments of the invention address the above issues by providing at least 12 mm of rollback that stops 5 mm from the posterior edge of the tibia.

[0092] In accordance with particular configurations of the invention, a number of tibiofemoral matters are addressed, which can be confirmed through the same testing protocol summarized earlier and applied to the patellofemoral articulation. In particular, the contact area between the cam follower on the metal femoral component and the cam (post) on the polyethylene tibial component is measured to confirm the following: Cam engagement at 50-55° flexion; contact of the cam follower with the cam progresses down the cam with increasing flexion; contact of the cam follower with the cam occurs in the lower third of the cam beyond 90° flexion; contact of the cam follower with the cam is at least line contact throughout the range of flexion; contact of the cam follower with the cam is at least line contact throughout the range of flexion with addition of internal and external rotation; absence of contact between the cam and inner wall of the intercondylar box with up to 4 mm of medial and lateral liftoff and 4° abduction/adduction; and contact between the anterior face of the cam with the anterior inner wall of the intercondylar box is at least area contact in hyperextension (i.e., no line contact between the femoral notch and base of the cam).

[0093] The contact area of the articulation between the metal femoral component and polyethylene tibial component (tibiofemoral articulation) can also be measured using the same previously described testing protocol to confirm the following: tibiofemoral contact in hyperextension occurs in the anterior half of the

tibial articulation, and is at least area contact in both medial and lateral condyles (high degree of conformity without posterior sagging of the femoral component that occurs because the ACL is absent); anterior tibiofemoral contact at extension and early flexion is in the anterior half of the tibial articulation, and is at least area contact in both medial and lateral condyles (high degree of conformity without posterior sagging of the femoral component that occurs because the ACL is absent); tibiofemoral contact throughout the range of flexion is at least line contact; at least 12 mm of posterior femoral rollback between cam engagement at 50-55° flexion and maximum flexion (130° flexion); tibiofemoral contact at maximum flexion at least 5 mm from the posterior edge of the tibial component; tibiofemoral contact from extension to cam engagement at 50-55° flexion will remain stationary or progress, to some degree, posteriorly (there will be no paradoxical 'roll-forward' motion of the femur in early flexion).

[0094] Finally, the tibiofemoral kinematics can be measured using the same previously described testing protocol to confirm the following: attainment of 10° hyperextension; attainment of 130° flexion; minimal transverse rotational 'laxity' between hyperextension and cam engagement at 50-55° flexion; accommodate at least 10° to 12° rotational laxity in both internal and external directions from cam engagement to just before 120°-130° flexion; reduction in transverse rotational laxity from 120°-130° flexion so that the posterior femoral condyles don't run off the back of the tibial articular surface at maximal flexion; accommodate up to 4° adduction/abduction throughout the flexion range; accommodate up to 3-4 mm of medial and/or lateral lift-off throughout the flexion range; absence of posterior sagging of the femoral component from hyperextension to cam engagement; and absence of rolling-forward of the femoral component in early flexion before cam engagement.

[0095] In accordance with the invention, the tibiofemoral articulation will accommodate in the neighborhood of 15° transverse rotation, 4° of abduction/adduction and up to 4 mm of condylar lift-off in later flexion after cam engagement. In particular, rollback and an accommodation for transverse rotation are also important for maintaining a proper moment arm for quadriceps function so that one can efficiently perform activities such as getting out of a chair and going up

stairs. Adequate transverse rotation is made possible in the designs of the present invention by the clearance between the tibial post and walls of the femoral intercondylar box, the partial conformity of the tibiofemoral articulation in the sagittal and coronal planes, and the curved articulation between the femoral cam follower and tibial post, wherein up to 4° of adduction can occur during gait. In addition, condylar lift-off occurs in a large percentage of patients where there is a separation of the tibiofemoral contact surfaces during weight-bearing conditions due to absence of the cruciate ligaments. The designs of the present invention also accommodate this abduction/adduction and lift-off while minimizing polyethylene wear and damage.

[0096] As discussed above, interaction of articular conformity and cam mechanics will limit transverse rotation so that the femoral condyles do not roll off the back of the tibial condyles in extreme flexion. That is, as is set out above, tibiofemoral contact at maximum flexion will be at least 5 mm from the posterior edge of the tibial component. If large amounts of transverse rotation are superimposed on that constraint, the femoral condyles may still roll off the back of the tibial component. An embodiment of the invention will include further constraints to limit the amount of transverse rotation that can occur in late flexion. Rotation in extreme flexion can be limited to levels less than rotations occurring earlier in the flexion range, which can be accomplished with the implants of the invention through the coordinated design of the height and width of the posterior femoral condyles, the relative curvatures of the posterior tibial and femoral components that come in contact at extreme flexion, and the details of the cam mechanism.

[0097] The present invention has now been described with reference to several embodiments thereof. The entire disclosure of any patent or patent application identified herein is hereby incorporated by reference. The foregoing detailed description and examples have been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom. It will be apparent to those skilled in the art that many changes can be made in the embodiments described without departing from the scope of the invention. Thus, the scope of the present

invention should not be limited to the structures described herein, but only by the structures described herein and the equivalents of those structures.

Claims

1. A knee implant for use in total knee arthroplasty, the implant comprising:

a femoral component comprising a trochlear groove and an intercondylar notch;

a tibial component engaged with the femoral component; and

a patellar component having an upper domed surface, wherein the domed surface is configured for at least line contact articulation with the trochlear groove of the femoral component.

2. The knee implant of claim 1, wherein the femoral component comprises a base portion from which a plurality of asymmetric patellar flanges extend.

3. The knee implant of claim 1, wherein the femoral component comprises a body having a central plane, wherein the trochlear groove is located laterally from the central plane and is angulated laterally, and wherein the trochlear groove comprises a raised lateral ridge configured for accepting and guiding the patellar component into the trochlear groove at an initial flexion between the patellar and femoral components and then maintain normal tracking throughout continued flexion between the patellar and femoral components.

4. The knee implant of claim 3, wherein the trochlear groove is angled at approximately 7 degrees laterally from an entrance of the intercondylar notch to a top of a patellar flange.

5. The knee implant of claim 1, wherein the upper domed surface of the patellar component comprises a non-spherical shape.

6. The knee implant of claim 5, wherein the shape of the upper domed surface of the patellar component comprises a central convex radius that blends with an outer concave radius that is larger than the central convex radius.

7. The knee implant of claim 1, wherein the femoral component further comprises a cam follower and an intercondylar box, wherein the intercondylar box comprises an open top area and is angulated downwardly from a back end to a front end.

8. The knee implant of claim 7, wherein the tibial component comprises a tibial post having an anterior surface that is engageable with an anterior inner face of the intercondylar box.

9. The knee implant of claim 8, wherein engagement between the tibial post and the cam follower of the femoral component provides for at least line contact with or without transverse rotation.

10. The knee implant of claim 8, wherein initial engagement between the cam follower and the tibial post occurs in the range of about 50 to 55 degrees flexion.

11. A knee implant for use in total knee arthroplasty, the implant comprising:

a femoral component comprising a trochlear groove and intercondylar notch; and

a tibial component engaged with the femoral component;

wherein at least one of the femoral and tibial components are sized and shaped to match selected geometries for a target population.

12. The knee implant of claim 11, wherein the trochlear groove of the femoral component is configured to articulate with both a native patella of a patient and a patellar component having an upper domed surface, wherein the domed surface is configured for at least line contact articulation with the trochlear groove of the femoral component.

13. The knee implant of claim 12, wherein the trochlear groove comprises at least a portion that is a segment of a circle.

14. The knee implant of claim 11, wherein sizes of the femoral and tibial components are determined using measured anterior-posterior and medial-lateral data of distal ends of multiple representative femurs and proximal ends of multiple representative tibias, respectively, for the target population.

15. The knee implant of claim 11, wherein shapes of the femoral and tibial components are determined using measured aspect ratios of distal ends of multiple femurs and proximal ends of multiple tibias, respectively, for the target population.

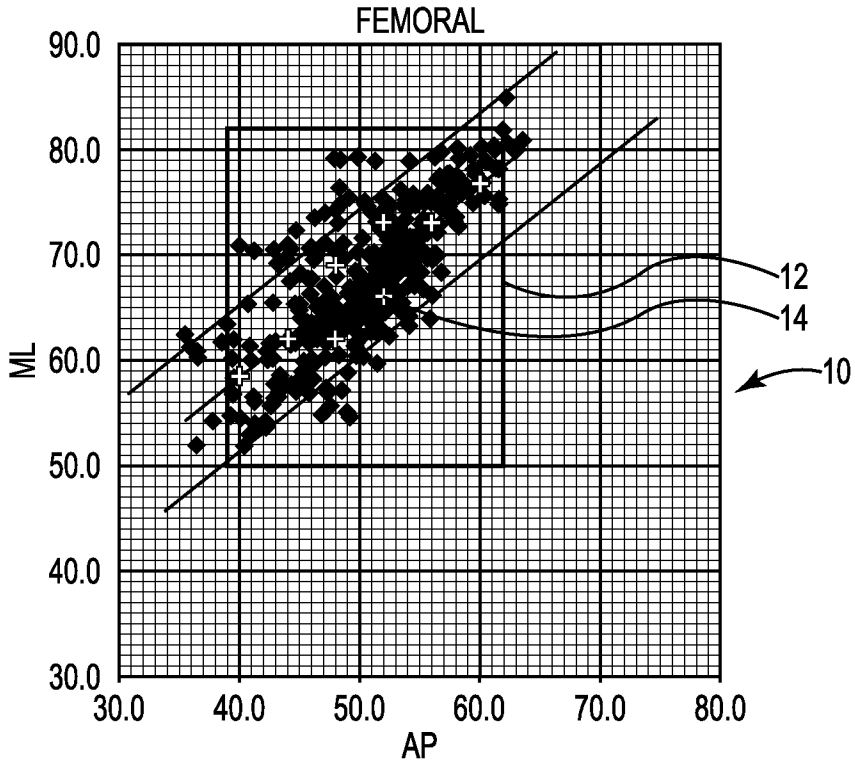
FEMORAL
90.0
80.0
70.0
60.0
50.0
40.0
30.0
ML
30.0
40.0
50.0
60.0
70.0
80.0
AP
12
14
10

Fig. 1

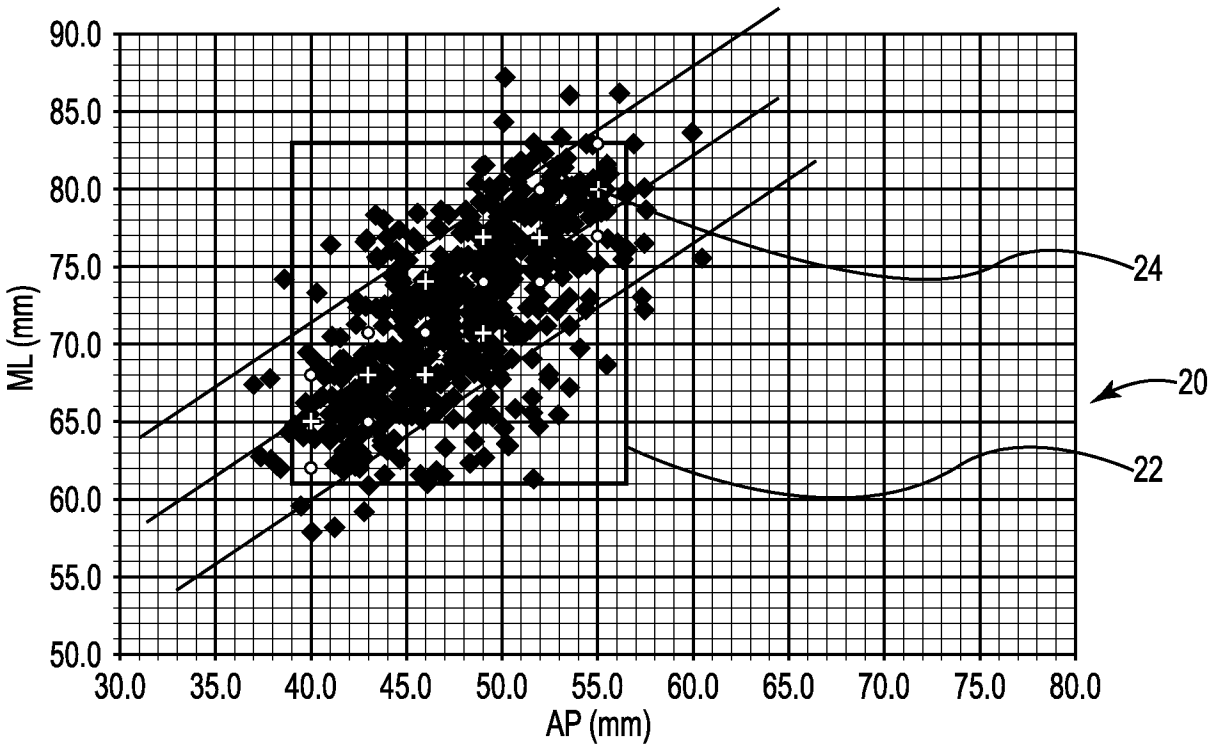
90.0
85.0
80.0
75.0
70.0
65.0
60.0
55.0
50.0
ML (mm)
30.0
35.0
40.0
45.0
50.0
55.0
60.0
65.0
70.0
75.0
80.0
AP (mm)
24
20
22

Fig. 2

SIZE	FEMORAL COMPONENT				TIBIAL COMPONENT			
	AP	ML			AP	ML		
		WIDE	MID	NARROW		WIDE	MID	NARROW
1	40	-	58	-	40	68	65	62
2	44	-	62	-	43	71	68	65
3	48	69	-	62	46	74	71	68
4	52	73	-	66	49	77	74	71
5	56	-	73	-	52	80	77	74
6	60	-	77	-	55	83	80	77

30

Fig. 3

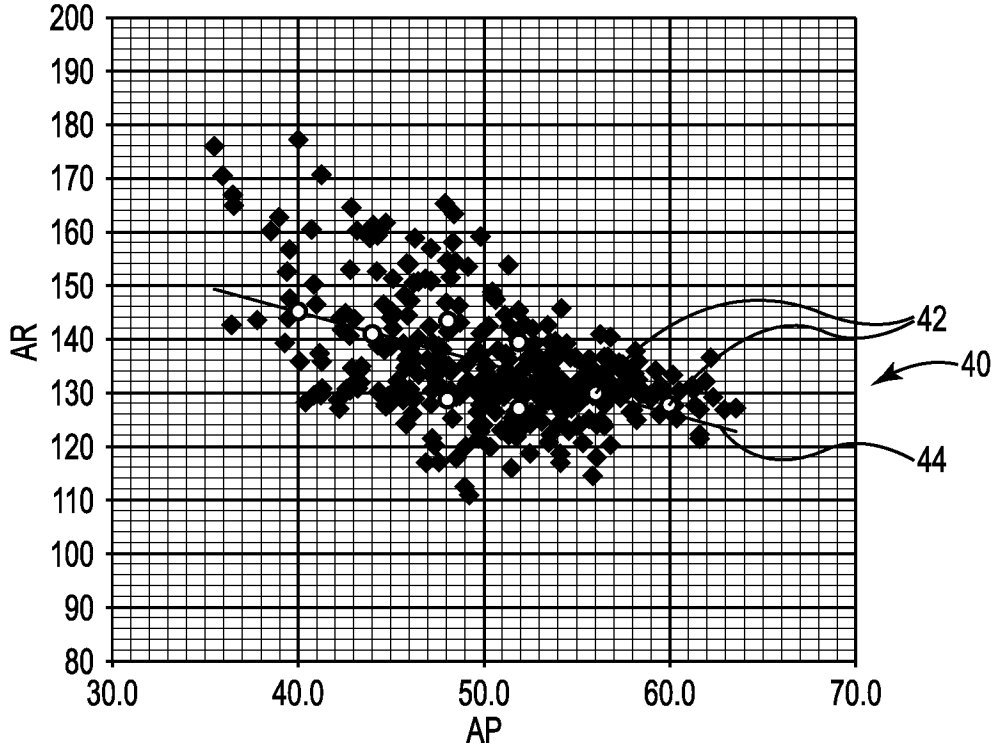
200
190
180
170
160
150
140
130
120
110
100
90
80
AR
30.0
40.0
50.0
60.0
70.0
AP
42
40
44

Fig. 4

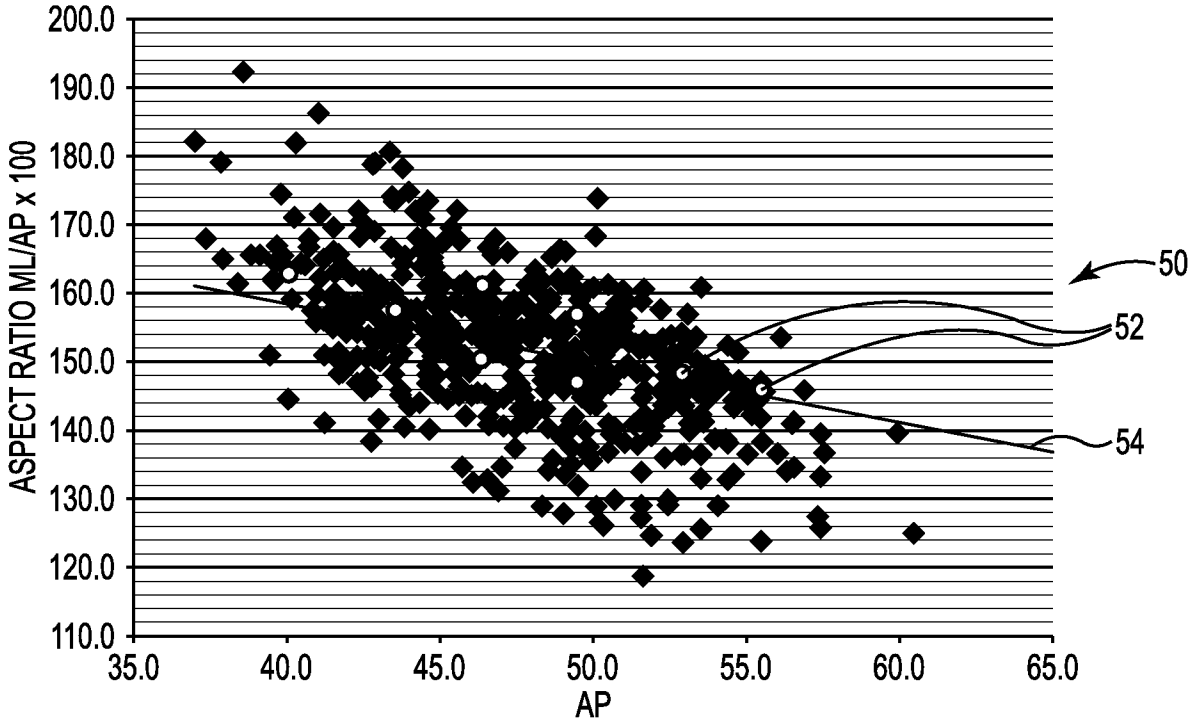
200.0
190.0
180.0
170.0
160.0
150.0
140.0
130.0
120.0
110.0
ASPECT RATIO ML/AP x 100
35.0
40.0
45.0
50.0
55.0
60.0
65.0
AP
50
52
54

Fig. 5

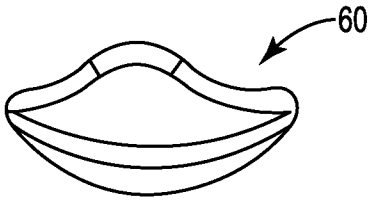

Fig. 6

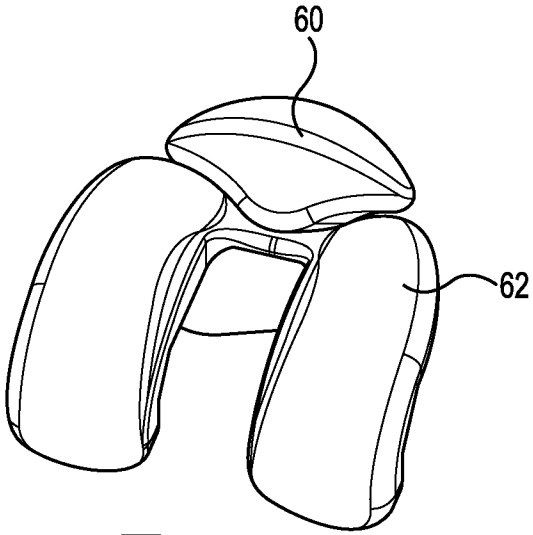

Fig. 7

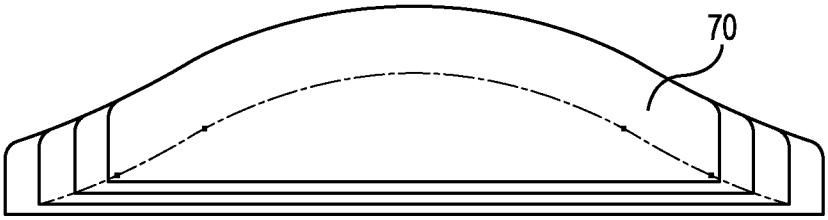

Fig. 8

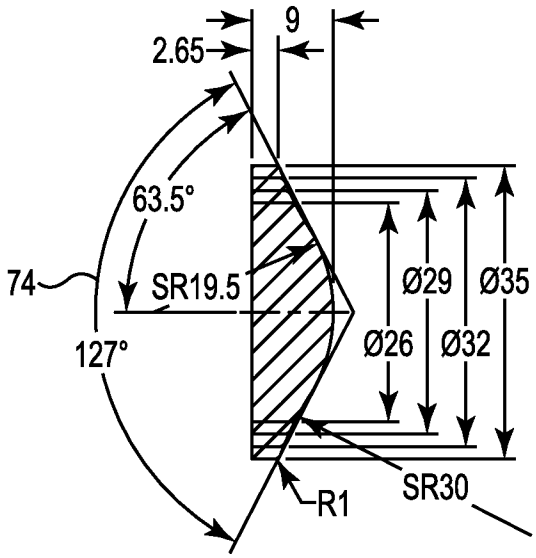

Fig. 9

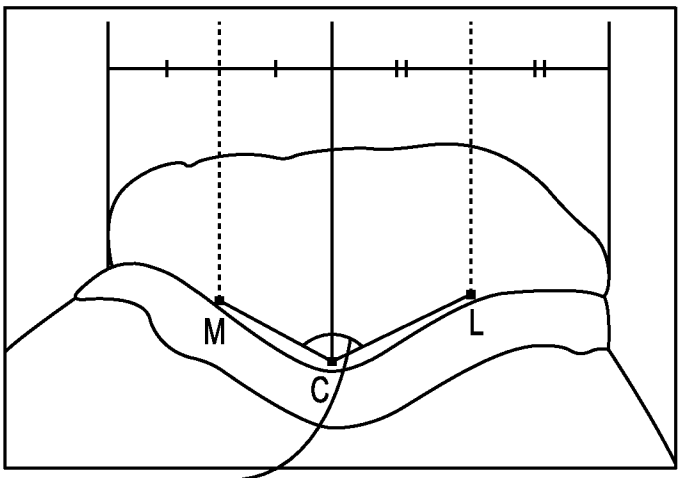

Fig. 10

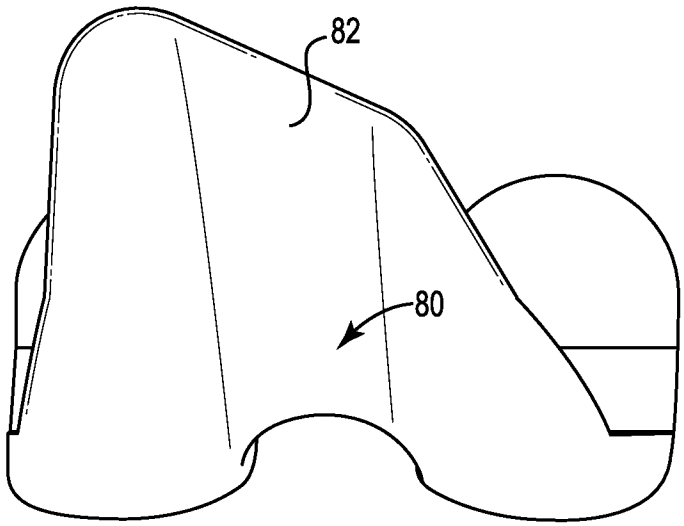

Fig. 11

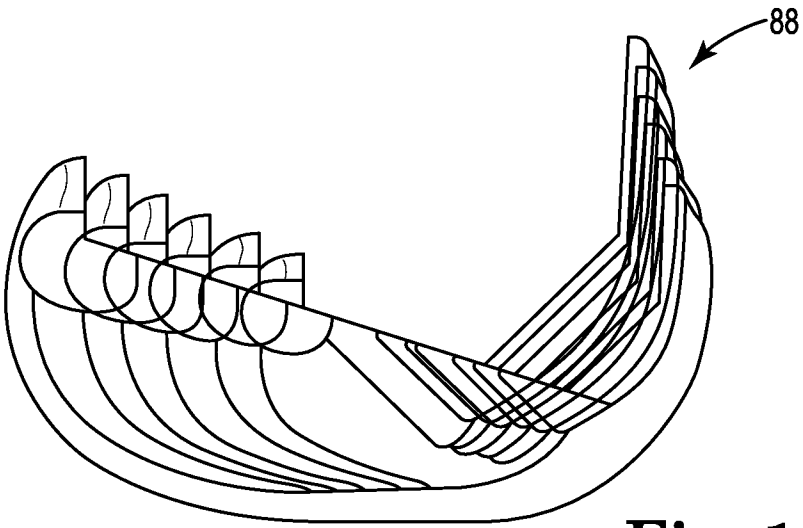

Fig. 12

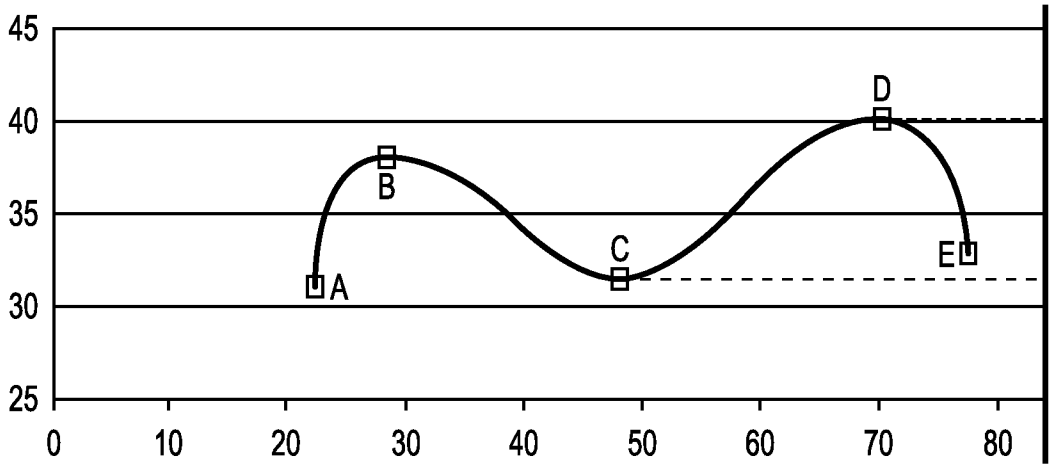

Fig. 13

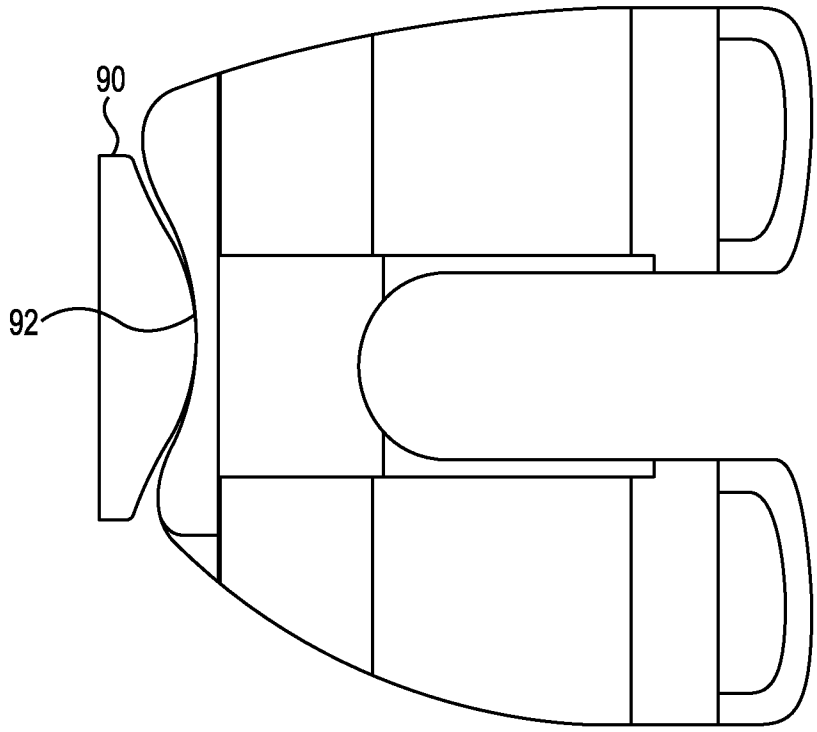

Fig. 14

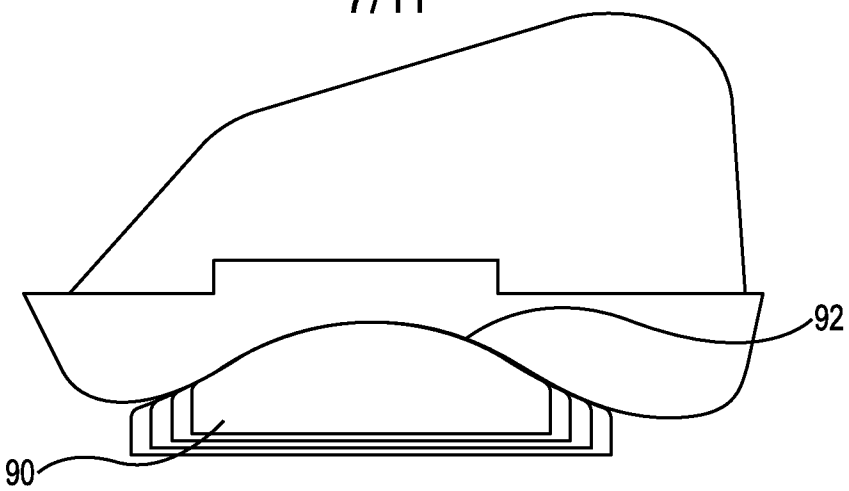

Fig. 15

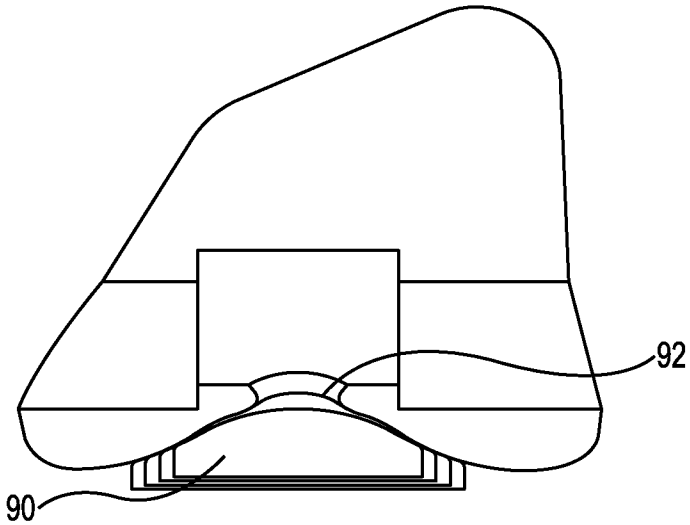

Fig. 16

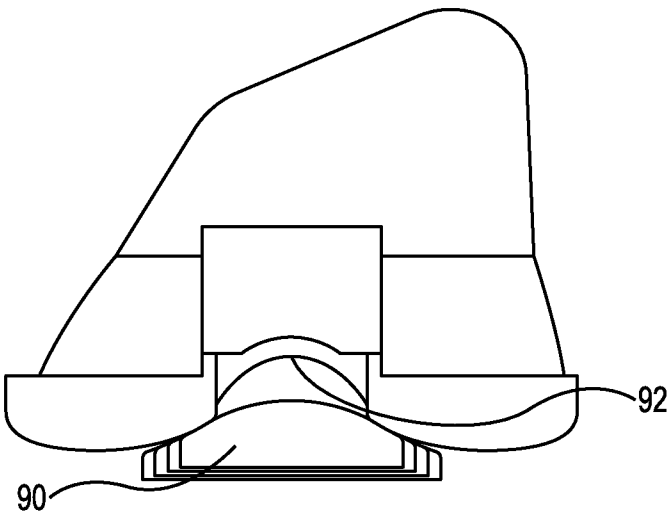

Fig. 17

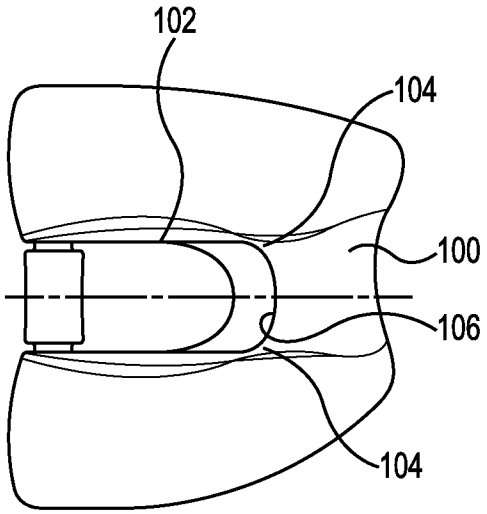

Fig. 18

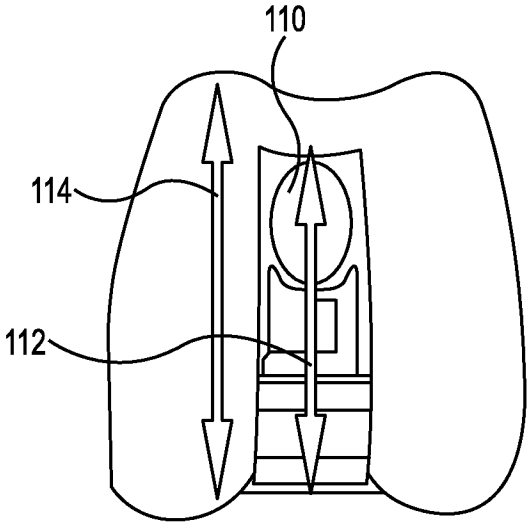

Fig. 19

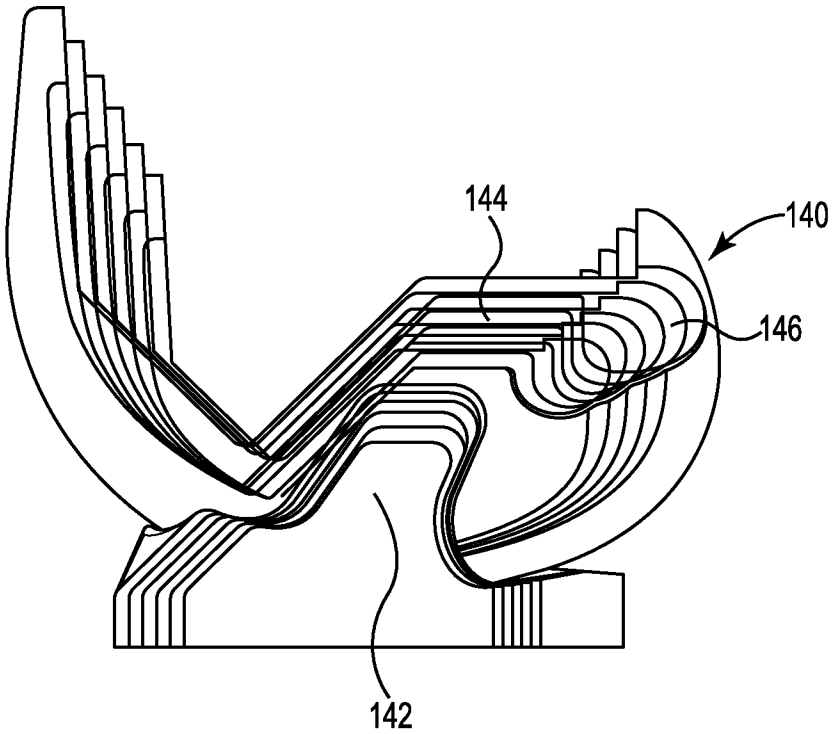

Fig. 20

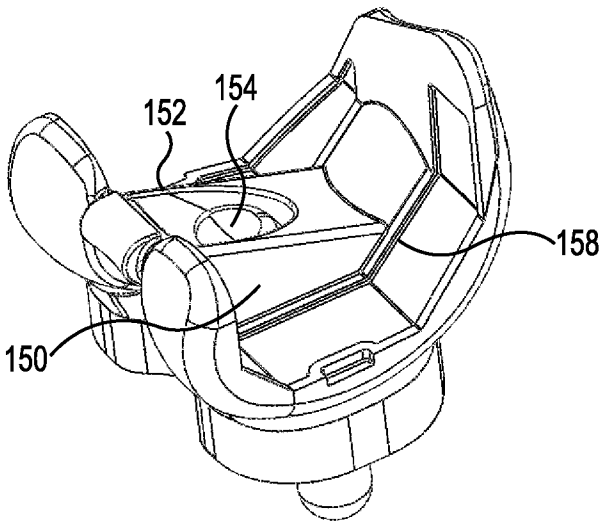

Fig. 21

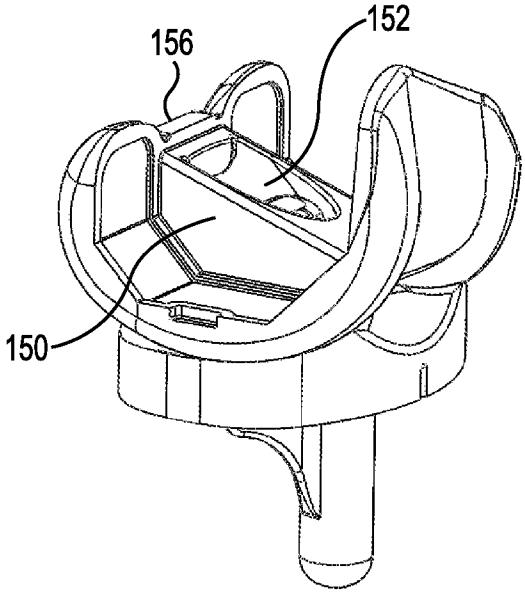

Fig. 22

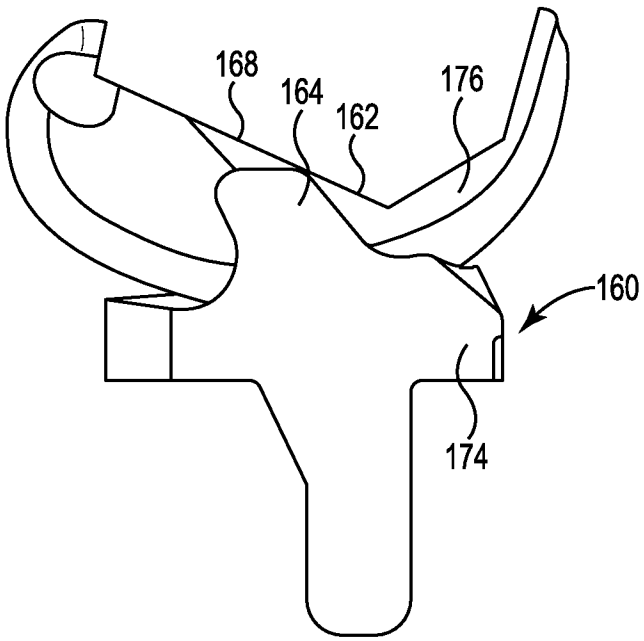

Fig. 23

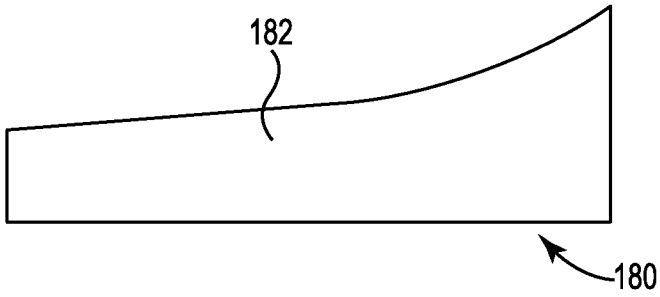

Fig. 24

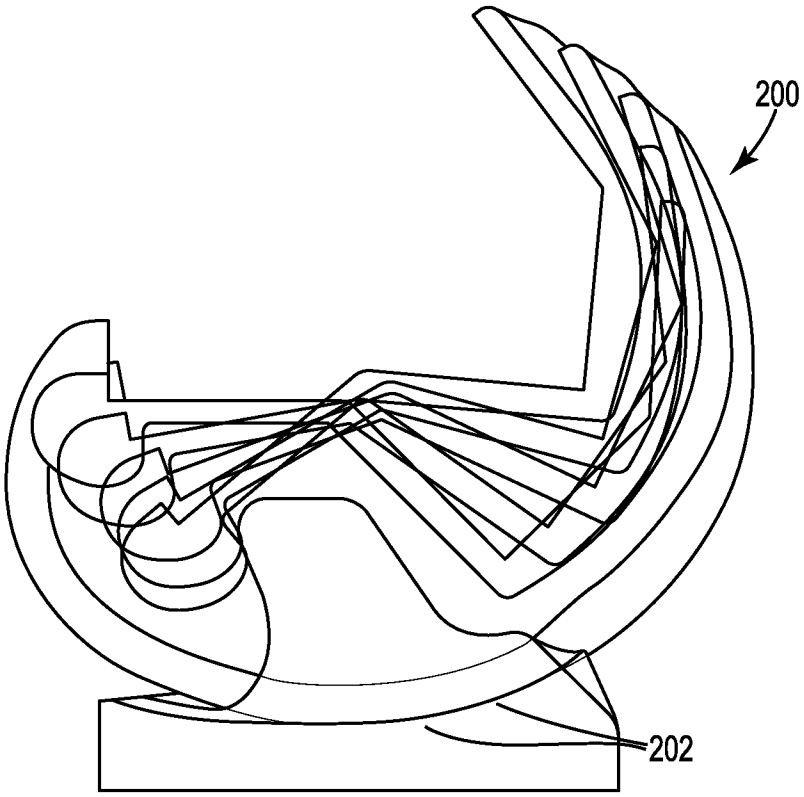

Fig. 25

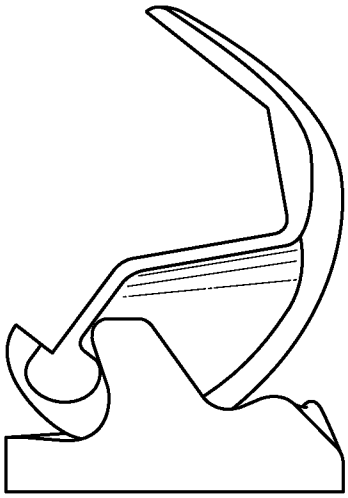

Fig. 26

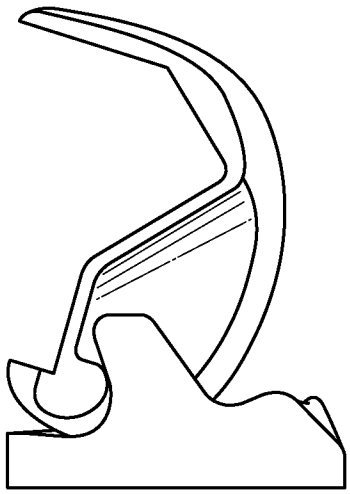

Fig. 27

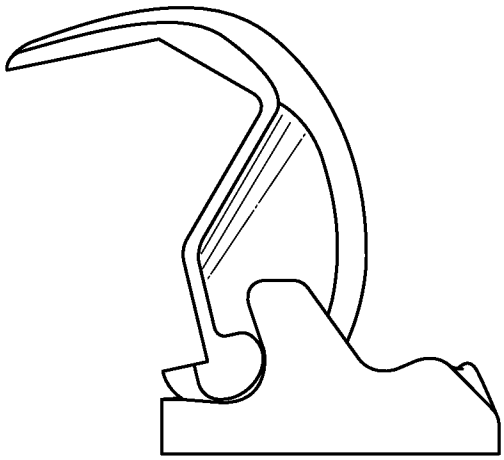

Fig. 28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/15276

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/56, 17/70, 19/00; A61F 2/46, 2/30, 2/38 (2014.01)
USPC - 606/130; 128/898
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)
IPC(8): A61B 17/56, 17/70, 19/00; A61F 2/46, 2/30, 2/38 (2014.01)
USPC: 606/130; 128/898

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)
MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Science.org; Google/Google Scholar; Medline/PubMed; Search terms used: knee, implant, degree*, cam, follower, line, contact, tibi*, post, stem, concave, convex, flange, notch, patella*, femur, femoral, orthopedic, international, Lew, arthroplasty, trochlear, groove, intercondylar, replacement

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 8092546 B2 (COON, TM et al.) January 10, 2012; abstract; figures 5-7, 9, 12; column 1, lines 35-45; column 2, lines 29-34; column 4, lines 28-52; column 5, lines 43-48; column 12, lines 40-46	1-15
Y	US 2009/0228111 A1 (OTTO, JK) September 10, 2009; figures 2, 12a-c; paragraphs [0046], [0056], [0058], [0060]-[0061]	1-10, 12-13
Y	US 2011/0305379 A1 (MAHFOUZ, MR) December 15, 2011; abstract; figures 6-7, 33, 42-44, 46; paragraphs [0003], [0005], [0027], [0150]-[0163], [0174], [0176]	11-15
Y	US 2012/0232671 A1 (BOJARSKI, RA et al.) September 13, 2012; paragraph [0562]	4
Y	US 5358527 A (FORTE, MR) October 25, 1994; figures 15, 30a-e, 32; column 7, line 52; column 20, lines 50-65; column 24, lines 40-47; column 22, lines 7-28	8-10
A	US 7875081 B2 (LIPMAN, JD et al.) January 25, 2011; entire document	1-15
A	US 5871540 A (WEISSMAN, MG et al.) February 16, 1999; entire document	1-15

☐ Further documents are listed in the continuation of Box C. ☐

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

Date of the actual completion of the international search	Date of mailing of the international search report
15 April 2014 (15.04.2014)	29 APR 2014

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)