

PATIENT-ADAPTED POSTERIOR STABILIZED KNEE IMPLANTS, DESIGNS AND RELATED METHODS AND TOOLS

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/606,284 to Slamin et al., entitled "Patient-Adapted Posterior Stabilized Knee Implants, Designs And Related Methods And Tools," filed March 2, 2012, the entire contents of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present application relates to articular repair systems (e.g., resection cut strategy, guide tools, and implant components) as described in, for example, U.S. Patent Application Serial No. 13/397,457, entitled "Patient-Adapted and Improved Orthopedic Implants, Designs And Related Tools," filed February 15, 2012, and published as U.S. Patent Publication No. 2012-0209394, which is incorporated herein by reference in its entirety. In particular, various embodiments disclosed herein provide improved features for knee joint articular repair systems designed for posterior stabilization, including patient-adapted (e.g., patient-specific and/or patient-engineered) features.

BACKGROUND

[0003] Generally, a diseased, injured or defective joint, such as, for example, a joint exhibiting osteoarthritis, has been repaired using standard off-the-shelf implants and other surgical devices. Specific off-the-shelf implant designs have been altered over the years to address particular issues. For example, several existing designs include implant components having rotating parts to enhance joint motion. However, in altering a design to address a particular issue, historical design changes frequently have created one or more additional issues for future designs to address. Collectively, many of these issues have arisen from one or more differences between a patient's existing or healthy joint anatomy and the corresponding features of an implant component.

[0004] Historically, joint implants have employed a one-size-fits-all (or a few-sizes-fit-all) approach to implant design resulting in significant differences

between a patient's existing or healthy biological structures and the resulting implant component features in the patient's joint. Accordingly, advanced implant designs and related devices and methods addressing needs of individual patient's are needed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] The foregoing and other objects, aspects, features, and advantages of embodiments will become apparent and may be better understood by referring to the following description, taken in conjunction with the accompanying drawings, in which:

[0006] **FIGS. 1A** and **1B** show schematic representations in a coronal plane of a patient's distal femur (**FIG. 1A**) and a femoral implant component (**FIG. 1B**);

[0007] **FIG. 2** is a flow chart illustrating a process that includes selecting and/or designing an initial patient-adapted implant;

[0008] **FIGS. 5A-5C** schematically represent three illustrative embodiments of implants and/or implant components;

[0009] **FIGS. 6A- 6C** depict designs of implant components that have six bone cuts (**FIG. 6A**), seven bone cuts (**FIG. 6B**), and three bone cuts with one being a curvilinear bone cut (**FIG. 6C**);

[00010] **FIG. 16** illustrates a coronal plane of the knee with exemplary resection cuts that can be used to correct lower limb alignment in a knee replacement;

[00011] **FIG. 17** depicts a coronal plane of the knee shown with femoral implant medial/lateral condyles having different thicknesses to help to correct limb alignment;

[00012] **FIG. 19A** illustrates perimeters and areas of two bone surface areas for two different bone resection cut depths; **FIG. 19B** is a distal view of the femur in which two different resection cuts are applied;

[00013] **FIGS. 22A** and **22B** depict the posterior margin of an implant component selected and/or designed using the imaging data or shapes derived from the imaging data so that the implant component will not interfere with and stay clear of the patient's PCL;

[00014] **FIGS. 23A** and **23B** schematically show a traditional implant component that dislocates the joint-line; **FIG. 23C** schematically shows a patient-specific implant component in which the existing or natural joint-line is retained;

[00015] **FIG. 27** is an illustrative flow chart showing exemplary steps taken by a practitioner in assessing a joint and selecting and/or designing a suitable replacement implant component;

[00016] **FIGS. 28A** through **28K** show implant components with exemplary features that can be selected and/or designed, e.g., derived from patient-specific and adapted to a particular patient, as well as be included in a library;

[00017] **FIGS. 49A** and **49B** illustrate a femoral implant component comprising an intercondylar housing (sometimes referred to as a "box");

[00018] **FIGS. 50A** and **50B** illustrate a femoral implant component comprising an intercondylar box (**FIG. 50A**) or intercondylar bars (**FIG. 50B**) and an engaging tibial implant component;

[00019] **FIG. 51** illustrates a femoral implant component comprising modular intercondylar bars or a modular intercondylar box;

[00020] **FIGS. 52A** through **52K** show various embodiments and aspects of cruciate-sacrificing femoral implant components and **FIGS. 52L** through **52P** show lateral views of different internal surfaces of intercondylar boxes;

[00021] **FIG. 60A** and **60B** show exemplary unicompartmental medial and lateral tibial implant components without (**FIG. 60A**) and with (**FIG. 60B**) a polyethylene layer or insert;

[00022] **FIGS. 61A** to **61C** depict three different types of step cuts separating medial and lateral resection cut facets on a patient's proximal tibia;

[00023] **FIGS. 62A** and **62B** show exemplary flow charts for deriving medial and/or lateral tibial component slopes for a tibial implant component;

[00024] **FIGS. 63A - 63J** show exemplary combinations of tibial tray designs;

[00025] **FIGS. 64A** through **64F** include additional embodiments of tibial implant components that are cruciate retaining;

[00026] **FIG. 65** shows proximal tibial resection cut depths of 2, 3 and 4 mm;

[00027] **FIG. 66** shows exemplary small, medium and large blank tibial trays;

[00028] **FIG. 67** shows exemplary A-P and peg angles for tibial trays;

[00029] **FIG. 68A** shows six exemplary tool tips a polyethylene insert for a tibial implant component; **FIG. 68B** shows a sagittal view of two exemplary tools sweeping from different distances into the polyethylene insert;

[00030] **FIG. 69A** shows an embodiment in which the shape of the concave groove on the medial side of the joint-facing surface of the tibial insert is matched by a convex shape on the opposing surface of the insert and by a concavity on the engaging surface of the tibial tray; **FIG. 69B** illustrates two exemplary concavity dimensions for the bearing surface of a tibial implant component;

[00031] **FIG. 70** illustrates two embodiments of tibial implant components having sloped sagittal J-curves;

[00032] **FIGS. 71A** and **71B** depict exemplary cross-sections of tibial implant components having a post (or keel or projection) projecting from the bone-facing surface of the implant component;

[00033] **FIG. 72A** is a flow chart for adapting a blank implant component for a particular patient; **FIG. 72B** illustrates various tibial cuts and corresponding surface features;

[00034] **FIG. 73A** depicts a medial balancer chip insert from top view to show the superior surface of the chip; **FIG. 73B** depicts a side view of a set of four medial balancer chip inserts; **FIG. 73C** depicts a medial balancing chip being inserted in flexion between the femur and tibia; **FIG. 73D** depicts the medial balancing chip insert in place while the knee is brought into extension; **FIG. 73E** depicts a cutting guide attached to the medial balancing chip; **FIG. 73F** shows that the inferior surface of the medial balancing chip can act as cutting guide surface for resectioning the medial portion of the tibia;

[00035] **FIG. 74A** depicts a set of three medial spacer block inserts having incrementally increasing thicknesses; **FIGS. 74B** depicts a set of two medial femoral trials having incrementally increasing thicknesses; **FIGS. 74C** depicts a medial femoral trial in place and a spacer block being inserted to evaluate the balance of the knee in flexion and extension;

[00036] **FIGS. 75A** depicts a set of three medial tibial component insert trials having incrementally increasing thicknesses; **FIG. 75B** depicts the process of placing and adding various tibial component insert trials; **FIG. 75C** depicts the process of placing the selected tibial component insert;

[00037] **FIG. 87** is a flow chart illustrating an exemplary process for selecting and/or designing a patient-adapted total knee implant;

[00038] **FIG. 143A** illustrates a tibial proximal resection cut that can be selected and/or designed to be a certain distance below a particular location on the patient's tibial plateau; **FIG. 143B** illustrates anatomic sketches (e.g., using a CAD program to manipulate a model of the patient's biological structure) overlaid with the patient's tibial plateau; **FIG. 143C** illustrates sketched overlays used to identify the centers of tubercles and the centers of one or both of the lateral and medial plateaus;

[00039] **FIGS. 144A to 144C** illustrate one or more axes that can be derived from anatomic sketches;

[00040] **FIG. 145A** depicts a proximal tibial resection made at 2 mm below the lowest point of the patient's medial tibial plateau with a an A-P slope cut that matched the A-P slope; **FIGS. 145B** and **145C** illustrate an implant selected and/or designed to have 90% coverage of the patient's cut tibial surface;

[00041] **FIGS. 146A to 156C** describe exemplary steps for performing resection cuts to the tibia using the anatomical references identified above;

[00042] **FIGS. 157A to 157E** illustrate various aspects of an embodiment of a tibial implant component, including a view of the tibial tray bottom (**FIG. 157A**), a view of the tibial tray top (**FIG. 157B**), a view of the tibial insert bottom (**FIG. 157C**), a top-front (i.e., proximal-anterior) perspective view of the tibial tray (**FIG. 157D**), and a bottom front (i.e., distal anterior) perspective view of the tibial insert (**FIG. 157E**);

[00043] **FIGS. 158A to 158C** show aspects of an embodiment of a tibial implant component that includes a tibial tray and a one-piece insert;

[00044] **FIGS. 159A to 159C** show aspects of an embodiment of a tibial implant component that includes a tibial tray and a two-piece insert;

[00045] **FIGS. 160A to 160C** show exemplary steps for altering a blank tibial tray and a blank tibial insert to each include a patient-adapted profile, for example, to substantially match the profile of the patient's resected tibial surface;

[00046] **FIGS. 161A and 161B** show exemplary strategies for establishing proper tibial rotation for a patient;

[00047] **FIG. 162** illustrates exemplary stem design options for a tibial tray;

[00048] **FIGS. 163A and 163B** show an approach in certain embodiments for identifying a tibial implant perimeter profile based on the depth and angle of the proximal tibial resection, which can be applied in the selection and/or design of the tibial tray perimeter profile and/or the tibial insert perimeter profile;

[00049] **FIGS. 164A and 164B** show the same approach as described for **FIGS. 163A and 163B**, but applied to a different patient having a smaller tibia (e.g., smaller diameter and perimeter length);

[00050] **FIGS. 165A to 165D** show four different exemplary tibial implant profiles, for example, having different medial and lateral condyle perimeter shapes;

[00051] **FIG. 176A** depicts a patient's native tibial plateau in an uncut condition;

[00052] **FIG. 176B** depicts one embodiment of an intended position of a metal backed component and insert for treating the tibia of **FIG. 176A**;

[00053] **FIG. 176C** depicts an alternate embodiment of an intended position of a metal backed component and insert for treating the tibia of **FIG. 176A**;

[00054] **FIG. 176D** depicts an alternate embodiment of an intended position of a metal backed component and insert for treating the tibia of **FIG. 176A**;

[00055] **FIG. 191** depicts a condylar J-curve offset that desirably achieves a similar kinematic motion; and

[00056] **FIGS. 192 through 198** depict sagittal cross-section views of patient-specific/patient-adapted deep-dish tibial implants and corresponding femoral components/anatomy.

[00057] Additional figure descriptions are included in the text below. Unless otherwise denoted in the description for each figure, “M” and “L” in certain figures indicate medial and lateral sides of the view, respectively; “A” and “P” in certain figures indicate anterior and posterior sides of the view, respectively, and “S” and “I” in certain figures indicate superior and inferior sides of the view.

DETAILED DESCRIPTION

Introduction

[00058] Various embodiments described herein include one or more patient-adapted features. Patient-adapted features can include patient-specific and/or patient-engineered features. Patient-specific (or patient-matched) implant component or guide tool features can include features adapted to match one or more of the patient's biological features, for example, one or more biological/anatomical structures, alignments, kinematics, and/or soft tissue features. Patient-engineered (or patient-derived) features of an implant component can be designed and/or manufactured (e.g., preoperatively designed and manufactured) based on patient-specific data to substantially enhance or improve one or more of the patient's anatomical and/or biological features.

[00059] The patient-adapted (e.g., patient-specific and/or patient-engineered) implant components and guide tools described herein can be selected (e.g., from a library), designed (e.g., preoperatively designed including, optionally, manufacturing the components or tools), and/or selected and designed (e.g., by selecting a blank component or tool having certain blank features and then altering the blank features to be patient-adapted). Moreover, related methods, such as designs and strategies for resectioning a patient's biological structure also can be selected and/or designed. For example, an implant component bone-facing surface and a resectioning strategy for the corresponding bone-facing surface can be selected and/or designed together so that an implant component's bone-facing surface matches the resected surface. In addition, one or more guide tools optionally can be selected and/or designed to facilitate the resection cuts that are predetermined in accordance with resectioning strategy and implant component selection and/or design.

[00060] In certain embodiments, patient-adapted features of an implant component, guide tool or related method can be achieved by analyzing imaging test data and selecting and/or designing (e.g., preoperatively selecting from a library and/or designing) an implant component, a guide tool, and/or a procedure having a feature that is matched and/or optimized for the particular patient's biology. The imaging test data can include data from the patient's joint, for example, data generated from an image of the joint such as x-ray imaging, cone beam CT, digital tomosynthesis, and ultrasound, a MRI or CT scan or a PET or SPECT scan, is processed to generate a varied or corrected version of the joint or of portions of the joint or of surfaces within the joint. Certain embodiments provide method and devices to create a desired model of a joint or of portions or surfaces of a joint based on data derived from the existing joint. For example, the data can also be used to create a model that can be used to analyze the patient's joint and to devise and evaluate a course of corrective action. The data and/or model also can be used to design an implant component having one or more patient-specific features, such as a surface or curvature.

[00061] As described herein, an implant (also referred to as an "implant system") can include one or more implant components, which, can each include one or more patient-specific features, one or more patient-engineered features, and one or more standard (e.g., off-the-shelf) features. Moreover, an implant system can include one or more patient-adapted (e.g., patient-specific and/or patient-engineered) implant components and one or more standard implant components.

[00062] For example, a knee implant can include a femoral implant component having one or more patient-adapted and standard features, and an off-the-shelf tibial implant component having only standard features. In this example, the entire tibial implant component can be off-the-shelf. Alternatively, a metal-backed implant component (or portion of an implant component) can be patient-specific, e.g., matched in the A-P dimension or the M-L dimension to the patient's tibial cortical bone, while the corresponding plastic insert implant component (or corresponding portion of the implant component) can include a standard off-the-shelf configuration.

[00063] Off-the-shelf configuration can mean that the tibial insert has fixed, standard dimensions to fit, for example, into a standard tibial tray. Off-the-shelf configuration also can mean that the tibial insert has a fixed, standard dimension or distance between two tibial dishes or curvatures to accommodate the femoral bearing surface. The latter configuration is particularly applicable in an implant system that uses a femoral implant component that is patient-specifically matched in the M-L dimension to the distal femur of the patient's bone, but uses a standardized intercondylar notch width on the femoral component to achieve optimal mating with a corresponding tibial insert. For example, **FIGS. 1A** and **1B** show schematic representations in a coronal plane of a patient's distal femur (**FIG. 1A**) and a femoral implant component (**FIG. 1B**). As shown in the figures, the implant component M-L dimension **100** (e.g. epicondylar M-L dimension) patient-specifically matches the corresponding M-L dimension of the patient's femur **102**. However, the intercondylar M-L dimension (i.e., notch width) of the implant component, **104**, can be standard, which in this figure is shorter than the patient's intercondylar M-L dimension **106**. In this way, the epicondylar M-L dimension of the implant component is patient-specific, while the intercondylar M-L dimension (i.e., notch width) is designed to be a standard length, for example, so that it can properly engage during joint motion a tibial insert having a standard distance between its dishes or curvatures that engage the condyles of the femoral implant component.

IMPROVED IMPLANTS, GUIDE TOOLS AND RELATED METHODS

[00064] Certain embodiments are directed to implants, guide tools, and/or related methods that can be used to provide to a patient a primary procedure and/or a primary implant such that a subsequent, replacement implant can be performed with a second (and, optionally, a third, and optionally, a fourth) patient-adapted pre-primary implant or with a traditional primary implant. In certain embodiments, the pre-primary implant procedure can include 3, 4, 5, 6, 7, or more resection or surgical cuts to the patient's bone and the pre-primary implant can include on its corresponding bone-facing surface a matching number and orientation of bone-cut facets or surfaces.

[00065] **FIG. 2** is a flow chart illustrating a process that includes selecting and/or designing a first patient-adapted implant, for example, a primary implant.

First, using the techniques described herein or those suitable and known in the art, measurements of the target joint are obtained **210**. This step can be repeated multiple times, as desired. Optionally, a virtual model of the joint can be generated, for example, to determine proper joint alignment and the corresponding resection cuts and implant component features based on the determined proper alignment. This information can be collected and stored **212** in a database **213**. Once measurements of the target joint are obtained and analyzed to determine resection cuts and patient-adapted implant features, the patient-adapted implant components can be selected **214** (e.g., selected from a virtual library and optionally manufactured without further design alteration **215**, or selected from a physical library of implant components). Alternatively, or in addition, one or more implant components with best-fitting and/or optimized features can be selected **214** (e.g., from a library) and then further designed (e.g., designed and manufactured) **216**. Alternatively or in addition, one or more implant components with best-fitting and/or optimized features can be designed (e.g., designed and manufactured) **218**, **216** without an initial selection from a library. Using a virtual model to assess the selected or designed implant component(s), this process also can be repeated as desired (e.g., before one or more physical components are selected and/or generated). The information regarding the selected and/or designed implant component(s) can be collected and stored **220**, **222** in a database **213**. Once a desired first patient-adapted implant component or set of implant components is obtained, a surgeon can prepare the implantation site and install the first implant **224**. The information regarding preparation of the implantation site and implant installation can be collected and stored **226** in a database **213**. In this way, the information associated with the first pre-primary implant component is available for use by a surgeon for subsequent implantation of a second pre-primary or a primary implant.

[00066] Accordingly, certain embodiments described herein are directed to implants, implant components, guide tools, and related methods that address many of the problems associated with traditional implants, such as mismatches between an implant component and a patient's biological features (e.g., a feature of a biological structure, a distance or space between two biological structures,

and/or a feature associated with anatomical function) and substantial bone removal that limits subsequent revisions following a traditional primary implant.

Exemplary implant systems and patient-adapted features

[00067] In certain embodiments described herein, an implant or implant system can include one, two, three, four or more components having one or more patient-specific features that substantially match one or more of the patient's biological features, for example, one or more dimensions and/or measurements of an anatomical/biological structure, such as bone, cartilage, tendon, or muscle; a distance or space between two or more aspects of a biological structure and/or between two or more different biological structures; and a biomechanical or kinematic quality or measurement of the patient's biology. In addition or alternatively, an implant component can include one or more features that are engineered to optimize or enhance one or more of the patient's biological features, for example, (1) deformity correction and limb alignment (2) preserving bone, cartilage, and/or ligaments, (3) preserving and/or optimizing other features of the patient's anatomy, such as trochlea and trochlear shape, (4) restoring and/or optimizing joint kinematics or biomechanics, and/or (5) restoring and/or optimizing joint-line location and/or joint gap width. In addition, an implant component can be designed and/or manufactured to include one or more standard (i.e., non-patient-adapted) features.

[00068] Exemplary patient-adapted (i.e., patient-specific and/or patient-engineered) features of the implant components described herein are identified in **Table 1**. One or more of these implant component features can be selected and/or designed based on patient-specific data, such as image data.

Table 1: Exemplary implant features that can be patient-adapted based on patient-specific measurements

Category	Exemplary feature
Implant or implant or component (applies knee, shoulder, hip, ankle, or other implant or implant component)	- One or more portions of, or all of, an external implant component curvature
	- One or more portions of, or all of, an internal implant dimension
	- One or more portions of, or all of, an internal or external implant angle

Category	Exemplary feature
	- Portions or all of one or more of the ML, AP, SI dimension of the internal and external component and component features - An locking mechanism dimension between a plastic or non-metallic insert and a metal backing component in one or more dimensions - Component height - Component profile - Component 2D or 3D shape - Component volume - Composite implant height - Insert width - Insert shape - Insert length - Insert height - Insert profile - Insert curvature - Insert angle - Distance between two curvatures or concavities - Polyethylene or plastic width - Polyethylene or plastic shape - Polyethylene or plastic length - Polyethylene or plastic height - Polyethylene or plastic profile - Polyethylene or plastic curvature - Polyethylene or plastic angle - Component stem width - Component stem shape - Component stem length - Component stem height - Component stem profile - Component stem curvature - Component stem position - Component stem thickness - Component stem angle - Component peg width - Component peg shape - Component peg length - Component peg height - Component peg profile - Component peg curvature - Component peg position - Component peg thickness - Component peg angle - Slope of an implant surface

Category	Exemplary feature
	- Number of sections, facets, or cuts on an implant surface
Femoral implant or implant component	- Condylar distance of a femoral component, e.g., between femoral condyles - A condylar coronal radius of a femoral component A condylar sagittal radius of a femoral component
Tibial implant or implant component	- Slope of an implant surface - Condylar distance, e.g., between tibial joint-facing surface concavities that engage femoral condyles - Coronal curvature (e.g., one or more radii of curvature in the coronal plane) of one or both joint-facing surface concavities that engage each femoral condyle - Sagittal curvature (e.g., one or more radii of curvature in the sagittal plane) of one or both joint-facing surface concavities that engage each femoral condyle

[00069] The patient-adapted features described in **Table 1** also can be applied to patient-adapted guide tools described herein.

[00070] The patient-adapted implant components and guide tools described herein can include any number of patient-specific features, patient-engineered features, and/or standard features. Illustrative combinations of patient-specific, patient-engineered, and standard features of an implant component are provided in **Table 2**. Specifically, the table illustrates an implant or implant component having at least thirteen different features. Each feature can be patient-specific (P), patient-engineered (PE), or standard (St). As shown, there are 105 unique combinations in which each of thirteen is either patient-specific, patient-engineered, or standard features.

Table 2: Exemplary combinations of patient-specific (P), patient-engineered (PE), and standard (St) features¹ in an implant

Implant system number	Implant feature number ²												
	1	2	3	4	5	6	7	8	9	10	11	12	13
1	P	P	P	P	P	P	P	P	P	P	P	P	P
2	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE
3	St	St	St	St	St	St	St	St	St	St	St	St	St
4	P	St	St	St	St	St	St	St	St	St	St	St	St

Implant system number	Implant feature number ²												
	1	2	3	4	5	6	7	8	9	10	11	12	13
5	P	P	St	St	St	St	St	St	St	St	St	St	St
6	P	P	P	St	St	St	St	St	St	St	St	St	St
7	P	P	P	P	St	St	St	St	St	St	St	St	St
8	P	P	P	P	P	St	St	St	St	St	St	St	St
9	P	P	P	P	P	P	St	St	St	St	St	St	St
10	P	P	P	P	P	P	P	St	St	St	St	St	St
11	P	P	P	P	P	P	P	P	St	St	St	St	St
12	P	P	P	P	P	P	P	P	P	St	St	St	St
13	P	P	P	P	P	P	P	P	P	P	St	St	St
14	P	P	P	P	P	P	P	P	P	P	P	St	St
15	P	P	P	P	P	P	P	P	P	P	P	P	St
16	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE
17	P	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE
18	P	P	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE
19	P	P	P	P	PE	PE	PE	PE	PE	PE	PE	PE	PE
20	P	P	P	P	P	PE	PE	PE	PE	PE	PE	PE	PE
21	P	P	P	P	P	P	PE	PE	PE	PE	PE	PE	PE
22	P	P	P	P	P	P	P	PE	PE	PE	PE	PE	PE
23	P	P	P	P	P	P	P	P	PE	PE	PE	PE	PE
24	P	P	P	P	P	P	P	P	P	PE	PE	PE	PE
25	P	P	P	P	P	P	P	P	P	P	PE	PE	PE
26	P	P	P	P	P	P	P	P	P	P	P	PE	PE
27	P	P	P	P	P	P	P	P	P	P	P	P	PE
28	PE	St	St	St	St	St	St	St	St	St	St	St	St
29	PE	PE	St	St	St	St	St	St	St	St	St	St	St
30	PE	PE	PE	St	St	St	St	St	St	St	St	St	St
31	PE	PE	PE	PE	St	St	St	St	St	St	St	St	St
32	PE	PE	PE	PE	PE	St	St	St	St	St	St	St	St
33	PE	PE	PE	PE	PE	PE	St	St	St	St	St	St	St
34	PE	PE	PE	PE	PE	PE	PE	St	St	St	St	St	St
35	PE	PE	PE	PE	PE	PE	PE	PE	St	St	St	St	St
36	PE	PE	PE	PE	PE	PE	PE	PE	PE	St	St	St	St
37	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	St	St	St
38	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	St	St
39	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	St
40	P	PE	St	St	St	St	St	St	St	St	St	St	St
41	P	PE	PE	St	St	St	St	St	St	St	St	St	St
42	P	PE	PE	PE	St	St	St	St	St	St	St	St	St
43	P	PE	PE	PE	PE	St	St	St	St	St	St	St	St
44	P	PE	PE	PE	PE	PE	St	St	St	St	St	St	St
45	P	PE	PE	PE	PE	PE	PE	St	St	St	St	St	St
46	P	PE	PE	PE	PE	PE	PE	PE	St	St	St	St	St

Implant system number	Implant feature number ²												
	1	2	3	4	5	6	7	8	9	10	11	12	13
47	P	PE	PE	PE	PE	PE	PE	PE	PE	St	St	St	St
48	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	St	St	St
49	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	St	St
50	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	St
51	P	P	PE	St	St	St	St	St	St	St	St	St	St
52	P	P	PE	PE	St	St	St	St	St	St	St	St	St
53	P	P	PE	PE	PE	St	St	St	St	St	St	St	St
54	P	P	PE	PE	PE	PE	St	St	St	St	St	St	St
55	P	P	PE	PE	PE	PE	PE	St	St	St	St	St	St
56	P	P	PE	PE	PE	PE	PE	PE	St	St	St	St	St
57	P	P	PE	PE	PE	PE	PE	PE	PE	St	St	St	St
58	P	P	PE	PE	PE	PE	PE	PE	PE	PE	St	St	St
59	P	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	St	St
60	P	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	PE	St
61	P	P	P	PE	St	St	St	St	St	St	St	St	St
62	P	P	P	PE	PE	St	St	St	St	St	St	St	St
63	P	P	P	PE	PE	PE	St	St	St	St	St	St	St
64	P	P	P	PE	PE	PE	PE	St	St	St	St	St	St
65	P	P	P	PE	PE	PE	PE	PE	St	St	St	St	St
66	P	P	P	PE	PE	PE	PE	PE	PE	St	St	St	St
67	P	P	P	PE	PE	PE	PE	PE	PE	PE	St	St	St
68	P	P	P	PE	PE	PE	PE	PE	PE	PE	PE	St	St
69	P	P	P	PE	PE	PE	PE	PE	PE	PE	PE	PE	St
70	P	P	P	P	PE	St	St	St	St	St	St	St	St
71	P	P	P	P	PE	PE	St	St	St	St	St	St	St
72	P	P	P	P	PE	PE	PE	St	St	St	St	St	St
73	P	P	P	P	PE	PE	PE	PE	St	St	St	St	St
74	P	P	P	P	PE	PE	PE	PE	PE	St	St	St	St
75	P	P	P	P	PE	PE	PE	PE	PE	PE	St	St	St
76	P	P	P	P	PE	PE	PE	PE	PE	PE	PE	St	St
77	P	P	P	P	PE	PE	PE	PE	PE	PE	PE	PE	St
78	P	P	P	P	P	PE	St	St	St	St	St	St	St
79	P	P	P	P	P	PE	PE	St	St	St	St	St	St
80	P	P	P	P	P	PE	PE	PE	St	St	St	St	St
81	P	P	P	P	P	PE	PE	PE	PE	St	St	St	St
82	P	P	P	P	P	PE	PE	PE	PE	PE	St	St	St
83	P	P	P	P	P	PE	PE	PE	PE	PE	PE	St	St
84	P	P	P	P	P	PE	PE	PE	PE	PE	PE	PE	St
85	P	P	P	P	P	P	PE	St	St	St	St	St	St
86	P	P	P	P	P	P	PE	PE	St	St	St	St	St
87	P	P	P	P	P	P	PE	PE	PE	St	St	St	St
88	P	P	P	P	P	P	PE	PE	PE	PE	St	St	St

Implant system number	Implant feature number ²												
	1	2	3	4	5	6	7	8	9	10	11	12	13
89	P	P	P	P	P	P	PE	PE	PE	PE	PE	St	St
90	P	P	P	P	P	P	PE	PE	PE	PE	PE	PE	St
91	P	P	P	P	P	P	P	PE	St	St	St	St	St
92	P	P	P	P	P	P	P	PE	PE	St	St	St	St
93	P	P	P	P	P	P	P	PE	PE	PE	St	St	St
94	P	P	P	P	P	P	P	PE	PE	PE	PE	St	St
95	P	P	P	P	P	P	P	PE	PE	PE	PE	PE	St
96	P	P	P	P	P	P	P	P	PE	St	St	St	St
97	P	P	P	P	P	P	P	P	PE	PE	St	St	St
98	P	P	P	P	P	P	P	P	PE	PE	PE	St	St
99	P	P	P	P	P	P	P	P	PE	PE	PE	PE	St
100	P	P	P	P	P	P	P	P	P	PE	St	St	St
101	P	P	P	P	P	P	P	P	P	PE	PE	St	St
102	P	P	P	P	P	P	P	P	P	PE	PE	PE	St
103	P	P	P	P	P	P	P	P	P	P	PE	St	St
104	P	P	P	P	P	P	P	P	P	P	PE	PE	St
105	P	P	P	P	P	P	P	P	P	P	P	PE	St

1: S = standard, off-the-shelf, P = patient-specific, PE = patient-engineered (e.g., constant coronal curvature, derived from the patient's coronal curvatures along articular surface)

2: Each of the thirteen numbered implant features represents a different exemplary implant feature, for example, for a knee implant the thirteen features can include: (1) femoral implant component M-L dimension, (2) femoral implant component A-P dimension, (3) femoral implant component bone cut, (4) femoral implant component sagittal curvature, (5) femoral implant component coronal curvature, (6) femoral implant component inter-condylar distance, (7) femoral implant component notch location / geometry, (8) tibial implant component M-L dimension, (9) tibial implant component A-P dimension, (10) tibial implant component insert inter-condylar distance, (11) tibial implant component insert lock, (12) tibial implant component metal backing lock, and (13) tibial implant component metal backing perimeter.

[00071] The term “implant component” as used herein can include: (i) one of two or more devices that work together in an implant or implant system, or (ii) a complete implant or implant system, for example, in embodiments in which an implant is a single, unitary device. The term “match” as used herein is envisioned to include one or both of a negative-match, as a convex surface fits a concave surface, and a positive-match, as one surface is identical to another surface.

[00072] Three illustrative embodiments of implants and/or implant components are schematically represented in **FIGS. 5A-5C**. In **FIG. 5A**, the illustrative implant component **500** includes an inner, bone-facing surface **502** and an outer, joint-facing surface **504**. The inner bone-facing surface **502** engages a first articular surface **510** of a first biological structure **512**, such as bone or

cartilage, at a first interface **514**. The articular surface **510** can be a native surface, a resected surface, or a combination of the two. The outer, joint-facing surface **504** opposes a second articular surface **520** of a second biological structure **522** at a joint interface **524**. The dashed line across each figure illustrates a patient's joint-line. In certain embodiments, one or more features of the implant component, for example, an M-L, A-P, or S-I dimension, a feature of the inner, bone-facing surface **502**, and/or a feature of the outer, joint-facing surface **504**, are patient-adapted (i.e., include one or more patient-specific and/or patient-engineered features).

[00073] The illustrative embodiment shown in **FIG. 5B** includes two implant components **500**, **500'**. Each implant component **500**, **500'** includes an inner, bone-facing surface **502**, **502'** and an outer, joint-facing surface **504**, **504'**. The first inner, bone-facing surface **502** engages a first articular surface **510** of a first biological structure **512** (e.g., bone or cartilage) at a first interface **514**. The first articular surface **510** can be a native surface, a cut surface, or a combination of the two. The second bone-facing surface **502'** engages a second articular surface **520** of a second biological structure **522** at a second interface **514'**. The second articular surface **520** can be a native surface, a resected surface, or a combination of the two. In addition, an outer, joint-facing surface **504** on the first component **500** opposes a second, outer joint-facing surface **504'** on the second component **500'** at the joint interface **524**. In certain embodiments, one or more features of the implant component, for example, one or both of the inner, bone-facing surfaces **502**, **502'** and/or one or both of the outer, joint-facing surfaces **504**, **504'**, are patient-adapted (i.e., include one or more patient-specific and/or patient-engineered features).

[00074] The illustrative embodiment represented in **FIG. 5C** includes the two implant components **500**, **500'**, the two biological structures **512**, **522**, the two interfaces **514**, **514'**, and the joint interface **524**, as well as the corresponding surfaces, as described for the embodiment illustrated in **FIG. 5B**. However, **FIG. 5C** also includes structure **550**, which can be an implant component in certain embodiments or a biological structure in certain embodiments. Accordingly, the presence of a third structural **550** surface in the joint creates a second joint interface **524'**, and possibly a third **524''**, in addition to joint interface **524**.

Alternatively or in addition to the patient-adapted features described above for components **500** and **500'**, the components **500**, **500'** can include one or more features, such as surface features at the additional joint interface(s) **524**, **524''**, as well as other dimensions (e.g., height, width, depth, contours, and other dimensions) that are patient-adapted, in whole or in part. Moreover, structure **550**, when it is an implant component, also can have one or more patient-adapted features, such as one or more patient-adapted surfaces and dimensions.

[00075] Traditional implants and implant components can have surfaces and dimensions that are a poor match to a particular patient's biological feature(s). The patient-adapted implants, guide tools, and related methods described herein improve upon these deficiencies. The following two subsections describe two particular improvements, with respect to the bone-facing surface and the joint-facing surface of an implant component; however, the principles described herein are applicable to any aspect of an implant component.

BONE-FACING SURFACE OF AN IMPLANT COMPONENT

[00076] In certain embodiments, the bone-facing surface of an implant can be designed to substantially negatively-match one more bone surfaces. For example, in certain embodiments at least a portion of the bone-facing surface of a patient-adapted implant component can be designed to substantially negatively-match the shape of subchondral bone, cortical bone, endosteal bone, and/or bone marrow. A portion of the implant also can be designed for resurfacing, for example, by negatively-matching portions of a bone-facing surface of the implant component to the subchondral bone or cartilage. Accordingly, in certain embodiments, the bone-facing surface of an implant component can include one or more portions designed to engage resurfaced bone, for example, by having a surface that negatively-matches uncut subchondral bone or cartilage, and one or more portions designed to engage cut bone, for example, by having a surface that negatively-matches a cut subchondral bone.

[00077] In certain embodiments, the bone-facing surface of an implant component includes multiple surfaces, also referred to herein as bone cuts. One or more of the bone cuts on the bone-facing surface of the implant component can be selected and/or designed to substantially negatively-match one or more

surfaces of the patient's bone. The surface(s) of the patient's bone can include bone, cartilage, or other biological surfaces. For example, in certain embodiments, one or more of the bone cuts on the bone-facing surface of the implant component can be designed to substantially negatively-match (e.g., the number, depth, and/or angles of cut) one or more resected surfaces of the patient's bone. The bone-facing surface of the implant component can include any number of bone cuts, for example, two, three, four, less than five, five, more than five, six, seven, eight, nine or more bone cuts. In certain embodiments, the bone cuts of the implant component and/or the resection cuts to the patient's bone can include one or more facets on corresponding portions of an implant component. For example, the facets can be separated by a space or by a step cut connecting two corresponding facets that reside on parallel or non-parallel planes. These bone-facing surface features can be applied to various joint implants, including knee, hip, spine, and shoulder joint implants.

[00078] In certain embodiments, it can be advantageous to maintain certain features across different portions of an implant component, while varying certain other features. For example, two or more corresponding sections of an implant component can include the same implant thickness(es). As a specific example, with a femoral implant component, corresponding medial and lateral sections of the implant's condyles (e.g., distal medial and lateral condyle and/or posterior medial and lateral condyles) can be designed to include the same thickness or at least a threshold thickness, particularly the bone cut intersections. Alternatively or in addition, every section on the medial and lateral condyles can be designed to include the same thickness or at least a threshold thickness. This approach is particularly useful when the corresponding implant sections are exposed to similar stress forces and therefore require similar minimum thicknesses in response to those stresses. Alternatively or in addition, an implant design can include a rule, such that a quantifiable feature of one section is always greater than, greater than or equal to, less than, or less than or equal to the same feature of another section of the implant component. For example, in certain embodiments, an implant design can include a lateral distal and/or posterior condylar portion that is thicker than or equal in thickness to the corresponding medial distal and/or posterior condylar portion. Similarly, in certain embodiments, an implant design can include

a lateral distal posterior condyle height that is higher than or equal to the corresponding medial posterior condylar height.

JOINT-FACING SURFACE OF AN IMPLANT COMPONENT

[00079] In various embodiments described herein, the outer, joint-facing surface of an implant component includes one or more patient-adapted (e.g., patient-specific and/or patient-engineered features). For example, in certain embodiments, the joint-facing surface of an implant component can be designed to match the shape of the patient's biological structure. The joint-facing surface can include, for example, the bearing surface portion of the implant component that engages an opposing biological structure or implant component in the joint to facilitate typical movement of the joint. The patient's biological structure can include, for example, cartilage, bone, and/or one or more other biological structures.

[00080] For example, in certain embodiments, the joint-facing surface of an implant component is designed to match the shape of the patient's articular cartilage. For example, the joint-facing surface can substantially positively-match one or more features of the patient's existing cartilage surface and/or healthy cartilage surface and/or a calculated cartilage surface, on the articular surface that the component replaces. Alternatively, it can substantially negatively-match one or more features of the patient's existing cartilage surface and/or healthy cartilage surface and/or a calculated cartilage surface, on the opposing articular surface in the joint. As described below, corrections can be performed to the shape of diseased cartilage by designing surgical steps (and, optionally, patient-adapted surgical tools) to re-establish a normal or near normal cartilage shape that can then be incorporated into the shape of the joint-facing surface of the component. These corrections can be implemented and, optionally, tested in virtual two-dimensional and three-dimensional models. The corrections and testing can include kinematic analysis and/or surgical steps.

[00081] In certain embodiments, the joint-facing surface of an implant component can be designed to positively-match the shape of subchondral bone. For example, the joint-facing surface of an implant component can substantially positively-match one or more features of the patient's existing subchondral bone

surface and/or healthy subchondral bone surface and/or a calculated subchondral bone surface, on the articular surface that the component attaches to on its bone-facing surface. Alternatively, it can substantially negatively-match one or more features of the patient's existing subchondral bone surface and/or healthy subchondral bone surface and/or a calculated subchondral bone surface, on the opposing articular surface in the joint. Corrections can be performed to the shape of subchondral bone to re-establish a normal or near normal articular shape that can be incorporated into the shape of the component's joint-facing surface. A standard thickness can be added to the joint-facing surface, for example, to reflect an average cartilage thickness. Alternatively, a variable thickness can be applied to the component. The variable thickness can be selected to reflect a patient's actual or healthy cartilage thickness, for example, as measured in the individual patient or selected from a standard reference database.

[00082] In certain embodiments, the joint-facing surface of an implant component can include one or more standard features. The standard shape of the joint-facing surface of the component can reflect, at least in part, the shape of typical healthy subchondral bone or cartilage. For example, the joint-facing surface of an implant component can include a curvature having standard radii or curvature of in one or more directions. Alternatively or in addition, an implant component can have a standard thickness or a standard minimum thickness in select areas. Standard thickness(es) can be added to one or more sections of the joint-facing surface of the component or, alternatively, a variable thickness can be applied to the implant component.

[00083] Certain embodiments, such as those illustrated by **FIG. 5B** and **5C**, include, in addition to a first implant component, a second implant component having an opposing joint-facing surface. The second implant component's bone-facing surface and/or joint-facing surface can be designed as described above. Moreover, in certain embodiments, the joint-facing surface of the second component can be designed, at least in part, to match (e.g., substantially negatively-match) the joint-facing surface of the first component. Designing the joint-facing surface of the second component to complement the joint-facing surface of the first component can help reduce implant wear and optimize kinematics. Thus, in certain embodiments, the joint-facing surfaces of the first and

second implant components can include features that do not match the patient's existing anatomy, but instead negatively-match or nearly negatively-match the joint-facing surface of the opposing implant component.

[00084] However, when a first implant component's joint-facing surface includes a feature adapted to a patient's biological feature, a second implant component having a feature designed to match that feature of the first implant component also is adapted to the patient's same biological feature. By way of illustration, when a joint-facing surface of a first component is adapted to a portion of the patient's cartilage shape, the opposing joint-facing surface of the second component designed to match that feature of the first implant component also is adapted to the patient's cartilage shape. When the joint-facing surface of the first component is adapted to a portion of a patient's subchondral bone shape, the opposing joint-facing surface of the second component designed to match that feature of the first implant component also is adapted to the patient's subchondral bone shape. When the joint-facing surface of the first component is adapted to a portion of a patient's cortical bone, the joint-facing surface of the second component designed to match that feature of the first implant component also is adapted to the patient's cortical bone shape. When the joint-facing surface of the first component is adapted to a portion of a patient's endosteal bone shape, the opposing joint-facing surface of the second component designed to match that feature of the first implant component also is adapted to the patient's endosteal bone shape. When the joint-facing surface of the first component is adapted to a portion of a patient's bone marrow shape, the opposing joint-facing surface of the second component designed to match that feature of the first implant component also is adapted to the patient's bone marrow shape.

[00085] The opposing joint-facing surface of a second component can substantially negatively-match the joint-facing surface of the first component in one plane or dimension, in two planes or dimensions, in three planes or dimensions, or in several planes or dimensions. For example, the opposing joint-facing surface of the second component can substantially negatively-match the joint-facing surface of the first component in the coronal plane only, in the sagittal plane only, or in both the coronal and sagittal planes.

[00086] In creating a substantially negatively-matching contour on an opposing joint-facing surface of a second component, geometric considerations can improve wear between the first and second components. For example, the radii of a concave curvature on the opposing joint-facing surface of the second component can be selected to match or to be slightly larger in one or more dimensions than the radii of a convex curvature on the joint-facing surface of the first component. Similarly, the radii of a convex curvature on the opposing joint-facing surface of the second component can be selected to match or to be slightly smaller in one or more dimensions than the radii of a concave curvature on the joint-facing surface of the first component. In this way, contact surface area can be maximized between articulating convex and concave curvatures on the respective surfaces of first and second implant components.

[00087] The bone-facing surface of the second component can be designed to negatively-match, at least in part, the shape of articular cartilage, subchondral bone, cortical bone, endosteal bone or bone marrow (e.g., surface contour, angle, or perimeter shape of a resected or native biological structure). It can have any of the features described above for the bone-facing surface of the first component, such as having one or more patient-adapted bone cuts to match one or more predetermined resection cuts.

[00088] Many combinations of first component and second component bone-facing surfaces and joint-facing surfaces are possible. **Table 3** provides illustrative combinations that may be employed.

Table 3: Illustrative Combinations of Implant Components

1 st component bone-facing surface	1 st component joint-facing surface	1 st component bone cut(s)	2 nd component joint facing surface	2 nd component bone facing surface	2 nd component bone cuts
Example: Femur	Example: Femur	Example: Femur	Example: Tibia	Example: Tibia	Example: Tibia
At least one bone cut	Cartilage	Yes	Negative-match of 1 st component joint-facing (opposing cartilage)	At least one bone cut	Yes
At least one bone cut	Cartilage	Yes	Negative-match of 1 st component joint-facing (opposing cartilage)	Subchondral bone	Optional

1st component bone-facing surface	1st component joint-facing surface	1st component bone cut(s)	2nd component joint facing surface	2nd component bone facing surface	2nd component bone cuts
At least one bone cut	Cartilage	Yes	Negative-match of 1 st component joint-facing (opposing cartilage)	Cartilage (same side, e.g. tibia)	Optional
At least one bone cut	Subchondral bone	Yes	Negative-match of 1 st component joint-facing (opposing subchondral bone)	At least one bone cut	Yes
At least one bone cut	Subchondral bone	Yes	Negative-match of 1 st component joint-facing (opposing subchondral bone)	Subchondral bone	Optional
At least one bone cut	Subchondral bone	Yes	Negative-match of 1 st component joint-facing (opposing subchondral bone)	Cartilage (same side, e.g. tibia)	Optional
Subchondral bone	Cartilage	Optional	Negative-match of 1 st component joint-facing (opposing cartilage)	At least one bone cut	Yes
Subchondral bone	Cartilage	Optional	Negative-match of 1 st component joint-facing (opposing cartilage)	Subchondral bone	Optional
Subchondral bone	Cartilage	Optional	Negative-match of 1 st component joint-facing (opposing cartilage)	Cartilage (same side, e.g. tibia)	Optional
Subchondral bone	Subchondral bone	Optional	Negative-match of 1 st component joint-facing (opposing subchondral bone)	At least one bone cut	Yes
Subchondral bone	Subchondral bone	Optional	Negative-match of 1 st component joint-facing (opposing subchondral bone)	Subchondral bone	Optional
Subchondral bone	Subchondral bone	Optional	Negative-match of 1 st component joint-facing (opposing subchondral bone)	Cartilage (same side, e.g. tibia)	Optional

1st component bone-facing surface	1st component joint-facing surface	1st component bone cut(s)	2nd component joint facing surface	2nd component bone facing surface	2nd component bone cuts
Subchondral bone	Standard / Model	Optional	Negative-match of 1 st component joint-facing standard	At least one bone cut	Yes
Subchondral bone	Standard / Model	Optional	Negative-match of 1 st component joint-facing standard	Subchondral bone	Optional
Subchondral bone	Standard / Model	Optional	Negative-match of 1 st component joint-facing standard	Cartilage (same side, e.g. tibia)	Optional
Subchondral bone	Subchondral bone	Optional	Non-matching standard surface	At least one bone cut	Yes
Subchondral bone	Cartilage	Optional	Non-matching standard surface	At least one bone cut	Yes

MULTI-COMPONENT IMPLANTS AND IMPLANT SYSTEMS

[00089] The implants and implant systems described herein include any number of patient-adapted implant components and any number of non-patient-adapted implant components. In certain embodiments, the implants and implant systems described herein can include a combination of implant components, such as a traditional unicompartamental device with a patient-specific bicompartamental device or a combination of a patient-specific unicompartamental device with standard bicompartamental device. Such implant combinations allow for a flexible design of an implant or implant system that includes both standard and patient-specific features and components. This flexibility and level of patient-specificity allows for various engineered optimizations, such as retention of alignments, maximization of bone preservation, and/or restoration of normal or near-normal patient kinematics.

[00090] Embodiments described herein can be applied to partial or total joint replacement systems. Bone cuts or changes to an implant component dimension described herein can be applied to a portion of the dimension, or to the entire dimension.

Collecting and modeling patient-specific data

[00091] As mentioned above, certain embodiments include implant components designed and made using patient-specific data that is collected preoperatively. The patient-specific data can include points, surfaces, and/or landmarks, collectively referred to herein as “reference points.” In certain embodiments, the reference points can be selected and used to derive a varied or altered surface, such as, without limitation, an ideal surface or structure. For example, the reference points can be used to create a model of the patient's relevant biological feature(s) and/or one or more patient-adapted surgical steps, tools, and implant components. For example the reference points can be used to design a patient-adapted implant component having at least one patient-specific or patient-engineered feature, such as a surface, dimension, or other feature.

MEASURING BIOLOGICAL FEATURES

[00092] Reference points and/or data for obtaining measurements of a patient's joint, for example, relative-position measurements, length or distance measurements, curvature measurements, surface contour measurements, thickness measurements (in one location or across a surface), volume measurements (filled or empty volume), density measurements, and other measurements, can be obtained using any suitable technique. For example, one dimensional, two-dimensional, and/or three-dimensional measurements can be obtained using data collected from mechanical means, laser devices, electromagnetic or optical tracking systems, molds, materials applied to the articular surface that harden as a negative match of the surface contour, and/or one or more imaging techniques described above and/or known in the art. Data and measurements can be obtained non-invasively and/or preoperatively. Alternatively, measurements can be obtained intraoperatively, for example, using a probe or other surgical device during surgery.

[00093] In certain embodiments, an imaging data collected from the patient, for example, imaging data from one or more of x-ray imaging, digital tomosynthesis, cone beam CT, non-spiral or spiral CT, non-isotropic or isotropic MRI, SPECT, PET, ultrasound, laser imaging, photo-acoustic imaging, is used to qualitatively and/or quantitatively measure one or more of a patient's biological

features, one or more of normal cartilage, diseased cartilage, a cartilage defect, an area of denuded cartilage, subchondral bone, cortical bone, endosteal bone, bone marrow, a ligament, a ligament attachment or origin, menisci, labrum, a joint capsule, articular structures, and/or voids or spaces between or within any of these structures. The qualitatively and/or quantitatively measured biological features can include, but are not limited to, one or more of length, width, height, depth and/or thickness; curvature, for example, curvature in two dimensions (e.g., curvature in or projected onto a plane), curvature in three dimensions, and/or a radius or radii of curvature; shape, for example, two-dimensional shape or three-dimensional shape; area, for example, surface area and/or surface contour; perimeter shape; and/or volume of, for example, the patient's cartilage, bone (subchondral bone, cortical bone, endosteal bone, and/or other bone), ligament, and/or voids or spaces between them.

[00094] In certain embodiments, measurements of biological features can include any one or more of the illustrative measurements identified in **Table 4**.

Table 4: Exemplary patient-specific measurements of biological features that can be used in the creation of a model and/or in the selection and/or design of an implant component

Anatomical feature	Exemplary measurement
Joint-line, joint gap	- Location relative to proximal reference point - Location relative to distal reference point - Angle - Gap distance between opposing surfaces in one or more locations - Location, angle, and/or distance relative to contralateral joint
Soft tissue tension and/or balance	- Joint gap distance - Joint gap differential, e.g., medial to lateral
Medullary cavity	- Shape in one or more dimensions - Shape in one or more locations - Diameter of cavity - Volume of cavity
Subchondral bone	- Shape in one or more dimensions - Shape in one or more locations - Thickness in one or more dimensions - Thickness in one or more locations - Angle, e.g., resection cut angle
Cortical bone	- Shape in one or more dimensions - Shape in one or more locations - Thickness in one or more dimensions

Anatomical feature	Exemplary measurement
	- Thickness in one or more locations - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level
Endosteal bone	- Shape in one or more dimensions - Shape in one or more locations - Thickness in one or more dimensions - Thickness in one or more locations - Angle, e.g., resection cut angle
Cartilage	- Shape in one or more dimensions - Shape in one or more locations - Thickness in one or more dimensions - Thickness in one or more locations - Angle, e.g., resection cut angle
Intercondylar notch	- Shape in one or more dimensions - Location - Height in one or more locations - Width in one or more locations - Depth in one or more locations - Angle, e.g., resection cut angle
Medial condyle	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Lateral condyle	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Trochlea	- 2D and/or 3D shape of a portion or all - Height in one or more locations

Anatomical feature	Exemplary measurement
	- Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Groove location in one or more locations - Trochlear angle, e.g. groove angle in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Medial trochlea	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Central trochlea	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Groove location in one or more locations - Trochlear angle, e.g. groove angle in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Lateral trochlea	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations

Anatomical feature	Exemplary measurement
	- Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Entire tibia	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions (e.g. medial and/or lateral) - Angle, e.g., resection cut angle - Axes, e.g., A-P and/or M-L axes - Osteophytes - Plateau slope(s), e.g., relative slopes medial and lateral - Plateau heights(s), e.g., relative heights medial and lateral - Bearing surface radii, e.g., e.g., relative radii medial and lateral - Perimeter profile - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Medial tibia	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness or height in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Perimeter profile - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Lateral tibia	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations

Anatomical feature	Exemplary measurement
	- Thickness/height in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Perimeter profile - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Entire patella	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Perimeter profile - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Medial patella	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Central patella	- 2D and/or 3D shape of a portion or all - Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level
Lateral patella	- 2D and/or 3D shape of a portion or all

Anatomical feature	Exemplary measurement
	- Height in one or more locations - Length in one or more locations - Width in one or more locations - Depth in one or more locations - Thickness in one or more locations - Curvature in one or more locations - Slope in one or more locations and/or directions - Angle, e.g., resection cut angle - Portions or all of cortical bone perimeter at an intended resection level - Resection surface at an intended resection level

[00095] Depending on the clinical application, a single or any combination or all of the measurements described in **Table 4** and/or known in the art can be used. Additional patient-specific measurements and information that be used in the evaluation can include, for example, joint kinematic measurements, bone density measurements, bone porosity measurements, identification of damaged or deformed tissues or structures, and patient information, such as patient age, weight, gender, ethnicity, activity level, and overall health status. Moreover, the patient-specific measurements may be compared, analyzed of otherwise modified based on one or more “normalized” patient model or models, or by reference to a desired database of anatomical features of interest. For example, a series of patient-specific femoral measurements may be compiled and compared to one or more exemplary femoral or tibial measurements from a library or other database of “normal” femur measurements. Comparisons and analysis thereof may concern, but is not limited to one, more or any combination of the following dimensions: femoral shape, length, width, height, of one or both condyles, intercondylar shapes and dimensions, trochlea shape and dimensions, coronal curvature, sagittal curvature, cortical/cancellous bone volume and/or quality, etc., and a series of recommendations and/or modifications may be accomplished. Any parameter mentioned in the specification and in the various Tables throughout the specification including anatomic, biomechanical and kinematic parameters can be utilized, not only in the knee, but also in the hip, shoulder, ankle, elbow, wrist, spine and other joints. Such analysis may include modification of one or more patient-specific features and/or design criteria for the implant to account for any underlying deformity reflected in the patient-specific

measurements. If desired, the modified data may then be utilized to choose or design an appropriate implant to match the modified features, and a final verification operation may be accomplished to ensure the chosen implant is acceptable and appropriate to the original unmodified patient-specific measurements (i.e., the chosen implant will ultimately “fit” the original patient anatomy). In alternative embodiments, the various anatomical features may be differently “weighted” during the comparison process (utilizing various formulaic weightings and/or mathematical algorithms), based on their relative importance or other criteria chosen by the designer, programmer and/or physician.

GENERATING A MODEL OF A JOINT

[00096] In certain embodiments, one or more models of at least a portion of a patient's joint can be generated. Specifically, the patient-specific data and/or measurements described above can be used to generate a model that includes at least a portion of the patient's joint. Optionally, one or more patient-engineered resection cuts, one or more drill holes, one or more patient-adapted guide tools, and/or one or more patient-adapted implant components can be included in a model. In certain embodiments, a model of at least part of a patient's joint can be used to directly generate a patient-engineered resection cut strategy, a patient-adapted guide tool design, and/or a patient-adapted implant component design for a surgical procedure (i.e., without the model itself including one or more resection cuts, one or more drill holes, one or more guide tools, and/or one or more implant components). In certain embodiments, the model that includes at least a portion of the patient's joint also can include or display, as part of the model, one or more resection cuts, one or more drill holes, (e.g., on a model of the patient's femur), one or more guide tools, and/or one or more implant components that have been designed for the particular patient using the model. Moreover, one or more resection cuts, one or more drill holes, one or more guide tools, and/or one or more implant components can be modeled and selected and/or designed separate from a model of a particular patient's biological feature. Various methods can be used to generate a model.

Deformable Segmentation and Models

[00097] In certain embodiments, individual images of a patient's biological structure can be segmented individually and then, in a later step, the segmentation data from each image can be combined. The images that are segmented individually can be one of a series of images, for example, a series of coronal tomographic slices (e.g., front to back) and/or a series of sagittal tomographic slices (e.g., side to side) and/or a series of axial tomographic slices (e.g., top to bottom) of the patient's joint. Segmenting each image individually can create noise in the combined segmented data. As an illustrative example, in an independent segmentation process, an alteration in the segmentation of a single image does not alter the segmentation in contiguous images in a series. Accordingly, an individual image can be segmented to show data that appears discontinuous with data from contiguous images. To address this issue, certain embodiments include a method for generating a model from a collection of images, for example, simultaneously, rather than from individually segmented images. One such method is referred to as deformable segmentation.

MODELING AND ADDRESSING JOINT DEFECTS

[00098] In certain embodiments, the reference points and/or measurements described above can be processed using mathematical functions to derive virtual, corrected features, which may represent a restored, ideal or desired feature from which a patient-adapted implant component can be designed. For example, one or more features, such as surfaces or dimensions of a biological structure can be modeled, altered, added to, changed, deformed, eliminated, corrected and/or otherwise manipulated (collectively referred to herein as "variation" of an existing surface or structure within the joint). While it is described in the knee, these embodiments can be applied to any joint or joint surface in the body, e.g. a knee, hip, ankle, foot, toe, shoulder, elbow, wrist, hand, and a spine or spinal joints.

[00099] Variation of the joint or portions of the joint can include, without limitation, variation of one or more external surfaces, internal surfaces, joint-facing surfaces, uncut surfaces, cut surfaces, altered surfaces, and/or partial surfaces as well as osteophytes, subchondral cysts, geodes or areas of eburnation, joint flattening, contour irregularity, and loss of normal shape. The surface or structure

can be or reflect any surface or structure in the joint, including, without limitation, bone surfaces, ridges, plateaus, cartilage surfaces, ligament surfaces, or other surfaces or structures. The surface or structure derived can be an approximation of a healthy joint surface or structure or can be another variation. The surface or structure can be made to include pathological alterations of the joint. The surface or structure also can be made whereby the pathological joint changes are virtually removed in whole or in part.

[000100] For example, a tibial component can be designed either before or after virtual removal of various features of the tibial bone have been accomplished. In one embodiment, the initial design and placement of the tibial tray and associated components can be planned and accomplished utilizing information directly taken from the patient's natural anatomy. In various other embodiments, the design and placement of the tibial components can be planned and accomplished after virtual removal of various bone portions, including the removal of one or more cut planes (to accommodate the tibial implant) as well as the virtual removal of various potentially-interfering structures (i.e., overhanging osteophytes, etc.) and/or the virtual filling of voids, etc. Prior virtual removal/filling of such structures can facilitate and improve the design, planning and placement of tibial components, and prevent anatomic distortion from significantly affecting the final design and placement of the tibial components. For example, once one or more tibial cut planes has been virtually removed, the size, shape and rotation angle of a tibial implant component can be more accurately determined from the virtually surface, as compared to determining the size, shape and/or tibial rotation angle of an implant from the natural tibial anatomy prior to such cuts. In a similar manner, structures such as overhanging osteophytes can be virtually removed (either alone or in addition to virtual removal of the tibial cut plane(s)), with the tibial implant structure and placement (i.e., tibial implant size, shape and/or tibial rotation, etc.) subsequently planned. Of course, virtually any undesirable anatomical features or deformity, including (but not limited to) altered bone axes, flattening, potholes, cysts, scar tissue, osteophytes, tumors and/or bone spurs may be similarly virtually removed and then implant design and placement can be planned. Similarly, to address a subchondral void, a selection and/or design for the bone-facing surface of an implant component can be derived after the void has

been virtually removed (e.g., filled). Alternatively, the subchondral void can be integrated into the shape of the bone-facing surface of the implant component.

[000101] In addition to osteophytes and subchondral voids, the methods, surgical strategies, guide tools, and implant components described herein can be used to address various other patient-specific joint defects or phenomena. In certain embodiments, correction can include the virtual removal of tissue, for example, to address an articular defect, to remove subchondral cysts, and/or to remove diseased or damaged tissue (e.g., cartilage, bone, or other types of tissue), such as osteochondritic tissue, necrotic tissue, and/or torn tissue. In such embodiments, the correction can include the virtual removal of the tissue (e.g., the tissue corresponding to the defect, cyst, disease, or damage) and the bone-facing surface of the implant component can be derived after the tissue has been virtually removed. In certain embodiments, the implant component can be selected and/or designed to include a thickness or other features that substantially matches the removed tissue and/or optimizes one or more parameters of the joint. Optionally, a surgical strategy and/or one or more guide tools can be selected and/or designed to reflect the correction and correspond to the implant component.

[000102] Various methods of more accurately modeling a target anatomical site can be utilized prior to designing and placing an implant component. For example, in the case of designing and placing a tibial implant, it may be desirable to incorporate additional virtual criteria into the virtual anatomic model of the targeted anatomy prior to designing and placing the tibial implant component. (One or more of the following, in any combination, may be incorporated with varying results.)

- Tibial plateau (leave uncut or virtually cut along one or more planes in model)
- Osteophytes (leave intact or virtually remove in model)
- Voids (leave intact or virtually fill in model)
- Tibial tubercle (incorporate in virtual model or ignore this anatomy)
- Femoral anatomic landmarks (incorporate in virtual model or ignore)

- Anatomic or biomechanical axes (incorporate in virtual model or ignore)
- Femoral component orientation (incorporate in virtual model or ignore)

[000103] After creation of the virtual anatomic model, incorporating one or more of the previous virtual variations in various combinations, the design and placement of the tibial implant (i.e., size, shape, thickness and/or tibial tray rotation angle and orientation) can be more accurately determined. Similarly, the design and placement of a femoral implant (i.e., size, shape, thickness and/or femoral component rotation angle and orientation) can be more accurately determined. Likewise, the design and placement of a other implant components (i.e., size, shape, thickness and/or component rotation angle and orientation), e.g. for acetabular or femoral head resurfacing or replacement, glenoid or humeral head resurfacing or replacement, elbow resurfacing or replacement, wrist resurfacing or replacement, hand resurfacing or replacement, ankle resurfacing or replacement, for resurfacing or replacement can be more accurately determined.

[000104] In certain embodiments, a correction can include the virtual addition of tissue or material, for example, to address an articular defect, loss of ligament stability, and/or a bone stock deficiency, such as a flattened articular surface that should be round. In certain embodiments, the additional material may be virtually added (and optionally then added in surgery) using filler materials such as bone cement, bone graft material, and/or other bone fillers. Alternatively or in addition, the additional material may be virtually added as part of the implant component, for example, by using a bone-facing surface and/or component thickness that match the correction or by otherwise integrating the correction into the shape of the implant component. Then, the joint-facing and/or other features of the implant can be derived. This correction can be designed to re-establish a near normal shape for the patient. Alternatively, the correction can be designed to establish a standardized shape or surface for the patient.

[000105] In certain embodiments, the patient's abnormal or flattened articular surface can be integrated into the shape of the implant component, for example, the bone-facing surface of the implant component can be designed to substantially negatively-match the abnormal or flattened surface, at least in part, and the thickness of the implant can be designed to establish the patient's healthy or an

optimum position of the patient's structure in the joint. Moreover, the joint-facing surface of the implant component also can be designed to re-establish a near normal anatomic shape reflecting, for example, at least in part the shape of normal cartilage or subchondral bone. Alternatively, it can be designed to establish a standardized shape.

MODELING PROPER LIMB ALIGNMENT

[000106] Proper joint and limb function depend on correct limb alignment. For example, in repairing a knee joint with one or more knee implant components, optimal functioning of the new knee depends on the correct alignment of the anatomical and/or mechanical axes of the lower extremity. Accordingly, an important consideration in designing and/or replacing a natural joint with one or more implant components is proper limb alignment or, when the malfunctioning joint contributes to a misalignment, proper realignment of the limb.

[000107] Once the proper alignment of the patient's extremity has been determined virtually, one or more surgical steps (e.g., resection cuts) may be planned and/or accomplished, which may include the use of surgical tools (e.g., tools to guide the resection cuts), and/or implant components (e.g., components having variable thicknesses to address misalignment).

MODELING ARTICULAR CARTILAGE

[000108] Cartilage loss in one compartment can lead to progressive joint deformity. For example, cartilage loss in a medial compartment of the knee can lead to varus deformity. In certain embodiments, cartilage loss can be estimated in the affected compartments. The estimation of cartilage loss can be done using an ultrasound MRI or CT scan or other imaging modality, optionally with intravenous or intra-articular contrast. The estimation of cartilage loss can be as simple as measuring or estimating the amount of joint space loss seen on x-rays. For the latter, typically standing x-rays are preferred. If cartilage loss is measured from x-rays using joint space loss, cartilage loss on one or two opposing articular surfaces can be estimated by, for example, dividing the measured or estimated joint space loss by two to reflect the cartilage loss on one articular surface. Other ratios or calculations are applicable depending on the joint or the location within the joint. Subsequently, a normal cartilage thickness can be virtually established

on one or more articular surfaces by simulating normal cartilage thickness. In this manner, a normal or near normal cartilage surface can be derived. Normal cartilage thickness can be virtually simulated using a computer, for example, based on computer models, for example using the thickness of adjacent normal cartilage, cartilage in a contralateral joint, or other anatomic information including subchondral bone shape or other articular geometries. Cartilage models and estimates of cartilage thickness can also be derived from anatomic reference databases that can be matched, for example, to a patient's weight, sex, height, race, gender, or articular geometry(ies).

[000109] In certain embodiments, a patient's limb alignment can be virtually corrected by realigning the knee after establishing a normal cartilage thickness or shape in the affected compartment by moving the joint bodies, for example, femur and tibia, so that the opposing cartilage surfaces including any augmented or derived or virtual cartilage surface touch each other, typically in the preferred contact areas. These contact areas can be simulated for various degrees of flexion or extension.

Parameters for selecting and/or designing a patient-adapted implant

[000110] The patient-adapted implants (e.g., implants having one or more patient-specific and/or patient-engineered features) of certain embodiments can be designed based on patient-specific data to optimize one or more parameters including, but not limited to: (1) deformity correction and limb alignment (2) maximum preservation of bone, cartilage, or ligaments, (3) preservation and/or optimization of features of the patient's biology, such as trochlea and trochlear shape, (4) restoration and/or optimization of joint kinematics, and (5) restoration or optimization of joint-line location and/or joint gap width. Various features of an implant component that can be designed or engineered based on the patient-specific data to help meet any number of user-defined thresholds for these parameters. The features of an implant that can be designed and/or engineered patient-specifically can include, but are not limited to, (a) implant shape, external and internal, (b) implant size, (c) and implant thickness.

DEFORMITY CORRECTION AND OPTIMIZING LIMB ALIGNMENT

[000111] Information regarding the misalignment and the proper mechanical alignment of a patient's limb can be used to preoperatively design and/or select one or more features of a joint implant and/or implant procedure. For example, based on the difference between the patient's misalignment and the proper mechanical axis, a knee implant and implant procedure can be designed and/or selected preoperatively to include implant and/or resection dimensions that substantially realign the patient's limb to correct or improve a patient's alignment deformity. In addition, the process can include selecting and/or designing one or more surgical tools (e.g., guide tools or cutting jigs) to direct the clinician in resectioning the patient's bone in accordance with the preoperatively designed and/or selected resection dimensions.

[000112] **FIG. 16** illustrates a coronal plane of the knee with exemplary resection cuts that can be used to correct lower limb alignment in a knee replacement. As shown in the figure, the selected and/or designed resection cuts can include different cuts on different portions of a patient's biological structure. For example, resection cut facets on medial and lateral femoral condyles can be non-coplanar and parallel **1602**, **1602'**, angled **1604**, **1604'**, or non-coplanar and non-parallel, for example, cuts **1602** and **1604'** or cuts **1602'** and **1604**. Similar, resection cut facets on medial and lateral portions of the tibia can be non-coplanar and parallel **1606**, **1606'**, angled and parallel **1608**, **1608'**, or non-coplanar and non-parallel, for example, cuts **1606** and **1608'** or cuts **1606'** and **1608**. Non-coplanar facets of resection cuts can include a step-cut **1610** to connect the non-coplanar resection facet surfaces. Selected and/or designed resection dimensions can be achieved using one or more selected and/or designed guide tools (e.g., cutting jigs) that guide resectioning (e.g., guide cutting tools) of the patient's biological structure to yield the predetermined resection surface dimensions (e.g., resection surface(s), angles, and/or orientation(s)). In certain embodiments, the bone-facing surfaces of the implant components can be designed to include one or more features (e.g., bone cut surface areas, perimeters, angles, and/or orientations) that substantially match one or more of the resection cut or cut facets that were predetermined to enhance the patient's alignment. As shown in **FIG.**

16, certain combinations of resection cuts can aid in bringing the femoral mechanical axis **1612** and tibial mechanical axis **1614** into alignment **1616**.

[000113] Alternatively, or in addition, certain implant features, such as different implant thicknesses and/or surface curvatures across two different sides of the plane in which the mechanical axes **1612**, **1614** are misaligned also can aid correcting limb alignment. For example, **FIG. 17** depicts a coronal plane of the knee shown with femoral implant medial and lateral condyles **1702**, **1702'** having different thicknesses to help to correct limb alignment. These features can be used in combination with any of the resection cut **1704**, **1704'** described above and/or in combination with different thicknesses on the corresponding portions of the tibial component. As described more fully below, independent tibial implant components and/or independent tibial inserts on medial and lateral sides of the tibial implant component can be used enhance alignment at a patient's knee joint. An implant component can include constant yet different thicknesses in two or more portions of the implant (e.g., a constant medial condyle thickness different from a constant lateral condyle thickness), a gradually increasing thickness across the implant or a portion of the implant, or a combination of constant and gradually increasing thicknesses.

[000114] In certain embodiments, an implant component that is preoperatively designed and/or selected to correct a patient's alignment also can be designed or selected to include additional patient-specific or patient-engineered features. For example, the bone-facing surface of an implant or implant component can be designed and/or selected to substantially negatively-match the resected bone surface. As depicted in **FIG. 19A**, the perimeters and areas **1910** of two bone surface areas is different for two different bone resection cut depths **1920**. Similarly, **FIG. 19B** depicts a distal view of the femur in which two different resection cuts are applied. As shown, the resected perimeters and surface areas for two distal facet resection depths are different for each of the medial condyle distal cut facet **1930** and the lateral condyle distal cut facet **1940**.

[000115] If resection dimensions are angled, for example, in the coronal plane and/or in the sagittal plane, various features of the implant component, for example, the component bone-facing surface, can be designed and/or selected based on an angled orientation into the joint rather than on a perpendicular

orientation For example, the perimeter of tibial implant or implant component that substantially positively-matches the perimeter of the patient's cut tibial bone has a different shape depending on the angle of the cut. Similarly, with a femoral implant component, the depth or angle of the distal condyle resection on the medial and/or lateral condyle can be designed and/or selected to correct a patient alignment deformity. However, in so doing, one or more of the implant or implant component condyle width, length, curvature, and angle of impact against the tibia can be altered. Accordingly in certain embodiments, one or more implant or implant component features, such as implant perimeter, condyle length, condyle width, curvature, and angle is designed and/or selected relative to the a sloping and/or non-coplanar resection cut.

PRESERVING BONE, CARTILAGE OR LIGAMENT

[000116] In certain embodiments, resection cuts are optimized to preserve the maximum amount of bone for each individual patient, based on a series of two-dimensional images or a three-dimensional representation of the patient's articular anatomy and geometry and the desired limb alignment and/or desired deformity correction. Resection cuts on two opposing articular surfaces can be optimized to achieve the minimum amount of bone resected from one or both articular surfaces.

[000117] By adapting resection cuts in the series of two-dimensional images or the three-dimensional representation on two opposing articular surfaces such as, for example, a femoral head and an acetabulum, one or both femoral condyle(s) and a tibial plateau, a trochlea and a patella, a glenoid and a humeral head, a talar dome and a tibial plafond, a distal humerus and a radial head and/or an ulna, or a radius and a scaphoid, certain embodiments allow for patient individualized, bone-preserving implant designs that can assist with proper ligament balancing and that can help avoid "overstuffing" of the joint, while achieving optimal bone preservation on one or more articular surfaces in each patient.

[000118] Implant design and modeling also can be used to achieve ligament sparing, for example, with regard to the PCL and/or the ACL. An imaging test can be utilized to identify, for example, the origin and/or the insertion of the PCL and

the ACL on the femur and tibia. The origin and the insertion can be identified by visualizing, for example, the ligaments directly, as is possible with MRI or spiral CT arthrography, or by visualizing bony landmarks known to be the origin or insertion of the ligament such as the medial and lateral tibial spines.

[000119] An implant system can then be selected or designed based on the image data so that, for example, the femoral component preserves the ACL and/or PCL origin, and the tibial component preserves the ACL and/or PCL attachment. The implant can be selected or designed so that bone cuts adjacent to the ACL or PCL attachment or origin do not weaken the bone to induce a potential fracture.

[000120] For ACL preservation, the implant can have two unicompartmental tibial components that can be selected or designed and placed using the image data. Alternatively, the implant can have an anterior bridge component. The width of the anterior bridge in AP dimension, its thickness in the superoinferior dimension or its length in mediolateral dimension can be selected or designed using the imaging data and, specifically, the known insertion of the ACL and/or PCL.

[000121] As can be seen in **FIGS. 22A** and **22B**, the posterior margin of an implant component, e.g. a polyethylene- or metal-backed tray with polyethylene inserts, can be selected and/or designed using the imaging data or shapes derived from the imaging data so that the implant component will not interfere with and stay clear of the PCL. This can be achieved, for example, by including concavities in the outline of the implant that are specifically designed or selected or adapted to avoid the ligament insertion.

[000122] Any implant component can be selected and/or adapted in shape so that it stays clear of important ligament structures. Imaging data can help identify or derive shape or location information on such ligamentous structures. For example, the lateral femoral condyle of a unicompartmental, bicompartamental or total knee system can include a concavity or divot to avoid the popliteus tendon. Imaging data can be used to design a tibial component (all polyethylene or other plastic material or metal backed) that avoids the attachment of the anterior and/or posterior cruciate ligament; specifically, the contour of the implant can be shaped so that it will stay clear of these ligamentous structures. A safety margin, e.g. 2mm

or 3mm or 5mm or 7mm or 10mm can be applied to the design of the edge of the component to allow the surgeon more intraoperative flexibility.

ESTABLISHING NORMAL OR NEAR-NORMAL JOINT KINEMATICS

[000123] In certain embodiments, bone cuts and implant shape including at least one of a bone-facing or a joint-facing surface of the implant can be designed or selected to achieve normal joint kinematics.

[000124] An implant shape including associated bone cuts generated in the preceding optimizations, for example, limb alignment, deformity correction, bone preservation on one or more articular surfaces, can be introduced into the model.

Table 6 includes an exemplary list of parameters that can be measured in a patient-specific biomotion model.

Table 6: Parameters measured in a patient-specific biomotion model for various implants

Joint implant	Measured Parameter
knee	Medial femoral rollback during flexion
knee	Lateral femoral rollback during flexion
knee	Patellar position, medial, lateral, superior, inferior for different flexion and extension angles
knee	Internal and external rotation of one or more femoral condyles
knee	Internal and external rotation of the tibia
knee	Flexion and extension angles of one or more articular surfaces
knee	Anterior slide and posterior slide of at least one of the medial and lateral femoral condyles during flexion or extension
knee	Medial and lateral laxity throughout the range of motion
knee	Contact pressure or forces on at least one or more articular surfaces, e.g. a femoral condyle and a tibial plateau, a trochlea and a patella
knee	Contact area on at least one or more articular surfaces, e.g. a femoral condyle and a tibial plateau, a trochlea and a patella
knee	Forces between the bone-facing surface of the implant, an optional cement interface and the adjacent bone or bone marrow, measured at least one or multiple bone cut or bone-facing surface of the implant on at least one or multiple articular surfaces or implant components.

Joint implant	Measured Parameter
knee	Ligament location, e.g. ACL, PCL, MCL, LCL, retinacula, joint capsule, estimated or derived, for example using an imaging test.
knee	Ligament tension, strain, shear force, estimated failure forces, loads for example for different angles of flexion, extension, rotation, abduction, adduction, with the different positions or movements optionally simulated in a virtual environment.
knee	Potential implant impingement on other articular structures, e.g. in high flexion, high extension, internal or external rotation, abduction or adduction or any combinations thereof or other angles / positions / movements.

[000125] The above list is not meant to be exhaustive, but only exemplary. Any other biomechanical parameter known in the art can be included in the analysis.

[000126] The resultant biomotion data can be used to further optimize the implant design with the objective to establish normal or near normal kinematics. The implant optimizations can include one or multiple implant components. Implant optimizations based on patient-specific data including image based biomotion data include, but are not limited to:

- Changes to external, joint-facing implant shape in coronal plane
- Changes to external, joint-facing implant shape in sagittal plane
- Changes to external, joint-facing implant shape in axial plane
- Changes to external, joint-facing implant shape in multiple planes or three dimensions
- Changes to internal, bone-facing implant shape in coronal plane
- Changes to internal, bone-facing implant shape in sagittal plane
- Changes to internal, bone-facing implant shape in axial plane
- Changes to internal, bone-facing implant shape in multiple planes or three dimensions
- Changes to one or more bone cuts, for example with regard to depth of cut, orientation of cut

[000127] Any single one or combinations of the above or all of the above on at least one articular surface or implant component or multiple articular surfaces or implant components.

[000128] When changes are made on multiple articular surfaces or implant components, these can be made in reference to or linked to each other. For example, in the knee, a change made to a femoral bone cut based on patient-specific biomotion data can be referenced to or linked with a concomitant change to a bone cut on an opposing tibial surface, for example, if less femoral bone is resected, the computer program may elect to resect more tibial bone.

[000129] Similarly, if a femoral implant shape is changed, for example on an external surface, this can be accompanied by a change in the tibial component shape. This is, for example, particularly applicable when at least portions of the tibial bearing surface negatively-match the femoral joint-facing surface.

[000130] Similarly, if the footprint of a femoral implant is broadened, this can be accompanied by a widening of the bearing surface of a tibial component. Similarly, if a tibial implant shape is changed, for example on an external surface, this can be accompanied by a change in the femoral component shape. This is, for example, particularly applicable when at least portions of the femoral bearing surface negatively-match the tibial joint-facing surface.

[000131] By optimizing implant shape in this manner, it is possible to establish normal or near normal kinematics. Moreover, it is possible to avoid implant related complications, including but not limited to anterior notching, notch impingement, posterior femoral component impingement in high flexion, and other complications associated with existing implant designs. For example, certain designs of the femoral components of traditional knee implants have attempted to address limitations associated with traditional knee implants in high flexion by altering the thickness of the distal and/or posterior condyles of the femoral implant component or by altering the height of the posterior condyles of the femoral implant component. Since such traditional implants follow a one-size-fits-all approach, they are limited to altering only one or two aspects of an implant design. However, with the design approaches described herein, various features of an implant component can be designed for an individual to address multiple issues,

including issues associated with high flexion motion. For example, designs as described herein can alter an implant component's bone-facing surface (for example, number, angle, and orientation of bone cuts), joint-facing surface (for example, surface contour and curvatures) and other features (for example, implant height, width, and other features) to address issues with high flexion together with other issues.

[000132] Biomotion models for a particular patient can be supplemented with patient-specific finite element modeling or other biomechanical models known in the art. Resultant forces in the knee joint can be calculated for each component for each specific patient. The implant can be engineered to the patient's load and force demands. For instance, a 125lb. patient may not need a tibial plateau as thick as a patient with 280 lbs. Similarly, the polyethylene can be adjusted in shape, thickness and material properties for each patient. For example, a 3 mm polyethylene insert can be used in a light patient with low force and a heavier or more active patient may need an 8mm polymer insert or similar device.

RESTORATION OR OPTIMIZATION OF JOINT-LINE LOCATION AND JOINT GAP WIDTH

[000133] Traditional implants frequently can alter the location of a patient's existing or natural joint-line. For example, with a traditional implant a patient's joint-line can be offset proximally or distally as compared to the corresponding joint-line on the corresponding limb. This can cause mechanical asymmetry between the limbs and result in uneven movement or mechanical instability when the limbs are used together. An offset joint-line with a traditional implant also can cause the patient's body to appear symmetrical.

[000134] Traditional implants frequently alter the location of a patient's existing or natural joint-line because they have a standard thickness that is thicker or thinner than the bone and/or cartilage that they are replacing. For example, a schematic of a traditional implant component is shown in **FIGS. 23A** and **23B**. In the figure, the dashed line represents the patient's existing or natural joint-line **2340** and the dotted line represents the offset joint-line **2342** following insertion of the traditional implant component **2350**. As shown in **FIG. 23A**, the traditional implant component **2350** with a standard thickness replaces a resected piece

2352 of a first biological structure **2354** at an articulation between the first biological structure **2354** and a second biological structure **2356**. The resected piece **2352** of the biological structure can include, for example, bone and/or cartilage, and the biological structure **2354** can include bone and/or cartilage. In the figure, the standard thickness of the traditional implant component **2350** differs from the thickness of the resected piece **2352**. Therefore, as shown in **FIG. 23B**, the replacement of the resected piece **2352** with the traditional implant component **2350** creates a wider joint gap **2358** and/or an offset joint-line. Surgeons can address the widened joint gap **2358** by pulling the second biological structure **2356** toward the first biological structure **2354** and tightening the ligaments associated with the joint. However, while this alteration restores some of the mechanical instability created by a widened joint gap, it also exacerbates the displacement of the joint-line.

[000135] Certain embodiments are directed to implant components, and related designs and methods, having one or more features that are engineered from patient-specific data to restore or optimize the particular patient's joint-line location. In addition or alternatively, certain patient-specific implant components, and related designs and methods, can have one or more features that are engineered from patient-specific data to restore or optimize the particular patient's joint gap width.

[000136] In certain embodiments, an implant component can be designed based on patient-specific data to include a thickness profile between its joint-facing surface and its bone-facing surface to restore and/or optimize the particular patient's joint-line location. For example, as schematically depicted in **FIG. 23C**, the thickness profile (shown as A) of the patient-specific implant component **2360** can be designed to, at least in part, substantially positively-match the distance from the patient's existing or natural joint-line **2340** to the articular surface of the biological structure **2354** that the implant **2360** engages. In the schematic depicted in the figure, the patient joint gap width also is retained.

[000137] The matching thickness profile can be designed based on one or more of the following considerations: the thickness (shown as A' in **FIG. 23C**) of a resected piece of biological structure that the implant replaces; the thickness of absent or decayed biological structure that the implant replaces; the relative

compressibility of the implant material(s) and the biological material(s) that the implant replaces; and the thickness of the saw blade(s) used for resectioning and/or material lost in removing a resected piece.

[000138] For embodiments directed to an implant component thickness that is engineered based on patient-specific data to optimize joint-line location (and/or other parameters such as preserving bone), the minimum acceptable thickness of the implant can be a significant consideration. Minimal acceptable thickness can be determined based on any criteria, such as a minimum mechanical strength, for example, as determined by FEA. Accordingly, in certain embodiments, an implant or implant design includes an implant component having a minimal thickness profile. For example, in certain embodiments a pre-primary or primary femoral implant component can include a thickness between the joint-facing surface and the bone-facing surface of the implant component that is less than 5 mm, less than 4 mm, less than 3 mm, and/or less than 2 mm.

[000139] One or more components of a tibial implant can be designed thinner to retain, restore, and/or optimize a patient's joint-line and/or joint gap width. For example, one or both of a tibial tray and a tibial tray insert (e.g., a poly insert) can be designed and/or selected (e.g., preoperatively selected) to be thinner in one or more locations in order to address joint-line and/or joint-gap issues for a particular patient. In certain embodiments, a tibial bone cut and/or the thickness of a corresponding portion of a tibial implant component may be less than about 6 mm, less than about 5 mm, less than about 4 mm, less than about 3 mm, and/or less than about 2 mm.

[000140] In certain embodiments, one or more implant components can be designed based on patient-specific data to include a thickness profile that retains or alters a particular patient's joint gap width to retain or correct another patient-specific feature. For example, the patient-specific data can include data regarding the length of the patient's corresponding limbs (e.g., left and right limbs) and the implant component(s) can be designed to, at least in part, alter the length of one limb to better match the length of the corresponding limb.

Selecting and/or designing an implant component and, optionally, related surgical steps and guide tools

[000141] Any combination of one or more of the above-identified parameters and/or one or more additional parameters can be used in the design and/or selection of a patient-adapted (e.g., patient-specific and/or patient-engineered) implant component and, in certain embodiments, in the design and/or selection of corresponding patient-adapted resection cuts and/or patient-adapted guide tools. In particular assessments, a patient's biological features and feature measurements are used to select and/or design one or more implant component features and feature measurements, resection cut features and feature measurements, and/or guide tool features and feature measurements.

USING PARAMETERS TO ASSESS AND SELECT AND/OR DESIGN AN IMPLANT COMPONENT

[000142] Assessment of the above-identified parameters, optionally with one or more additional parameters, can be conducted using various formats. For example, the assessment of one or more parameters can be performed in series, in parallel, or in a combination of serial and parallel steps, optionally with a software-directed computer. For example, one or more selected implant component features and feature measurements, optionally with one or more selected resection cut features and feature measurements and one or more selected guide tool features and feature measurements can be altered and assessed in series, in parallel, or in a combination format, to assess the fit between selected parameter thresholds and the selected features and feature measurements. Any one or more of the parameters and features and/or feature measurements can be the first to be selected and/or designed. Alternatively, one or more, or all, of the parameters and/or features can be assessed simultaneously.

SETTING AND WEIGHING PARAMETERS

[000143] As described herein, certain embodiments can apply modeling, for example, virtual modeling and/or mathematical modeling, to identify optimum implant component features and measurements, and optionally resection features and measurements, to achieve or advance one or more parameter targets or thresholds. For example, a model of patient's joint or limb can be used to identify, select, and/or design one or more optimum features and/or feature measurements

relative to selected parameters for an implant component and, optionally, for corresponding resection cuts and/or guide tools. In certain embodiments, a physician, clinician, or other user can select one or more parameters, parameter thresholds or targets, and/or relative weightings for the parameters included in the model. Alternatively or in addition, clinical data, for example obtained from clinical trials, or intraoperative data, can be included in selecting parameter targets or thresholds, and/or in determining optimum features and/or feature measurements for an implant component, resection cut, and/or guide tool.

[000144] Different thresholds can be defined in different anatomic regions and for different parameters. For example, in certain embodiments of a knee implant design, the amount of mediolateral tibial implant component coverage can be set at 90%, while the amount of anteroposterior tibial implant component coverage can be set at 85%. In another illustrative example, the congruency in intercondylar notch shape can be set at 80% required, while the required mediolateral condylar coverage can be set at 95%.

Computer-aided optimization

[000145] Any of the methods described herein can be performed, at least in part, using a computer-readable medium having instructions stored thereon, which, when executed by one or more processors, causes the one or more processors to perform one or more operations corresponding to one or more steps in the method. Any of the methods can include the steps of receiving input from a device or user and producing an output for a user, for example, a physician, clinician, technician, or other user. Executed instructions on the computer-readable medium (i.e., a software program) can be used, for example, to receive as input patient-specific information (e.g., images of a patient's biological structure) and provide as output a virtual model of the patient's biological structure. Similarly, executed instructions on a computer-readable medium can be used to receive as input patient-specific information and user-selected and/or weighted parameters and then provide as output to a user values or ranges of values for those parameters and/or for resection cut features, guide tool features, and/or implant component features. For example, in certain embodiments, patient-specific information can be input into a computer software program for selecting and/or designing one or more resection cuts, guide tools, and/or implant

components, and one or more of the following parameters can be optimization in the design process: (1) correction of joint deformity; (2) correction of a limb alignment deformity; (3) preservation of bone, cartilage, and/or ligaments at the joint; (4) preservation, restoration, or enhancement of one or more features of the patient's biology, for example, trochlea and trochlear shape; (5) preservation, restoration, or enhancement of joint kinematics, including, for example, ligament function and implant impingement; (6) preservation, restoration, or enhancement of the patient's joint-line location and/or joint gap width; and (7) preservation, restoration, or enhancement of other target features.

SELECTING AND/OR DESIGNING AN IMPLANT COMPONENT

[000146] Using patient-specific features and feature measurements, and selected parameters and parameter thresholds, an implant component, resection cut strategy, and/or guide tool can be selected (e.g., from a library) and/or designed (e.g. virtually designed and manufactured) to have one or more patient-adapted features. In certain embodiments, one or more features of an implant component (and, optionally, one or more features of a resection cut strategy and/or guide tool) are selected for a particular patient based on patient-specific data and desired parameter targets or thresholds. For example, an implant component or implant component features can be selected from a virtual library of implant components and/or component features to include one or more patient-specific features and/or optimized features for a particular patient. Alternatively or in addition, an implant component can be selected from an actual library of implant components to include one or more patient-specific features and/or optimized features for the particular patient.

[000147] In another embodiment, the process of selecting an implant component also includes selecting one or more component features that optimizes fit with another implant component. In particular, for an implant that includes a first implant component and a second implant component that engage, for example, at a joint interface, selection of the second implant component can include selecting a component having a surface that provides best fit to the engaging surface of the first implant component. For example, for a knee implant that includes a femoral implant component and a tibial implant component, one or both of components can be selected based, at least in part, on the fit of the outer,

joint-facing surface with the outer-joint-facing surface of the other component.

The fit assessment can include, for example, selecting one or both of the medial and lateral tibial grooves on the tibial component and/or one or both of the medial and lateral condyles on the femoral component that substantially negatively-matches the fit or optimizes engagement in one or more dimensions, for example, in the coronal and/or sagittal dimensions. For example, a surface shape of a non-metallic component that best matches the dimensions and shape of an opposing metallic or ceramic or other hard material suitable for an implant component. By performing this component matching, component wear can be reduced.

[000148] For example, if a metal backed tibial component is used with a polyethylene insert or if an all polyethylene tibial component is used, the polyethylene will typically have one or two curved portions typically designed to mate with the femoral component in a low friction form. This mating can be optimized by selecting a polyethylene insert that is optimized or achieves an optimal fit with regard to one or more of: depth of the concavity, width of the concavity, length of the concavity, radius or radii of curvature of the concavity, and/or distance between two (e.g., medial and lateral) concavities. For example, the distance between a medial tibial concavity and a lateral tibial concavity can be selected so that it matches or approximates the distance between a medial and a lateral implant condyle component.

[000149] Not only the distance between two concavities, but also the radius / radii of curvature can be selected or designed so that it best matches the radius / radii of curvature on the femoral component. A medial and a lateral femoral condyle and opposite tibial component(s) can have a single radius of curvature in one or more dimensions, e.g., a coronal plane. They can also have multiple radii of curvature. The radius or radii of curvature on the medial condyle and/or lateral tibial component can be different from that / those on a lateral condyle and/or lateral tibial component.

[000150] Similar matching of polyethylene or other plastic shape to opposing metal or ceramic component shape can be performed in the shoulder, e.g. with a glenoid component, or in a hip, e.g. with an acetabular cup, or in an ankle, e.g. with a talar component.

[000151] **FIG. 27** is an illustrative flow chart showing exemplary steps taken by a practitioner in assessing a joint and selecting and/or designing a suitable replacement implant component. First, a practitioner obtains a measurement of a target joint **2710**. The step of obtaining a measurement can be accomplished, for example, based on an image of the joint. This step can be repeated **2711** as necessary to obtain a plurality of measurements, for example, from one or more images of the patient's joint, in order to further refine the joint assessment process. Once the practitioner has obtained the necessary measurements, the information can be used to generate a model representation of the target joint being assessed **2730**. This model representation can be in the form of a topographical map or image. The model representation of the joint can be in one, two, or three dimensions. It can include a virtual model and/or a physical model. More than one model can be created **2731**, if desired. Either the original model, or a subsequently created model, or both can be used.

[000152] After the model representation of the joint is generated **2730**, the practitioner optionally can generate a projected model representation of the target joint in a corrected condition **2740**, e.g., based on a previous image of the patient's joint when it was healthy, based on an image of the patient's contralateral healthy joint, based on a projected image of a surface that negatively-matches the opposing surface, or a combination thereof. This step can be repeated **2741**, as necessary or as desired. Using the difference between the topographical condition of the joint and the projected image of the joint, the practitioner can then select a joint implant **2750** that is suitable to achieve the corrected joint anatomy. As will be appreciated by those of skill in the art, the selection and/or design process **2750** can be repeated **2751** as often as desired to achieve the desired result. Additionally, it is contemplated that a practitioner can obtain a measurement of a target joint **2710** by obtaining, for example, an x-ray, and then selects a suitable joint replacement implant **2750**.

[000153] One or more of these steps can be repeated reiteratively **2724**, **2725**, **2726**. Moreover, the practitioner can proceed directly from the step of generating a model representation of the target joint **2730** to the step of selecting a suitable joint implant component **2750**. Additionally, following selection and/or design of the suitable joint implant component **2750**, the steps of obtaining

measurement of a target joint **2710**, generating model representation of target joint **2730** and generating projected model **40**, can be repeated in series or parallel as shown by the flow **2724**, **2725**, **2726**.

LIBRARIES

[000154] As described herein, implants of various sizes, shapes, curvatures and thicknesses with various types and locations and orientations and number of bone cuts can be selected and/or designed and manufactured. The implant designs and/or implant components can be selected from, catalogued in, and/or stored in a library. The library can be a virtual library of implants, or components, or component features that can be combined and/or altered to create a final implant. The library can include a catalogue of physical implant components. In certain embodiments, physical implant components can be identified and selected using the library. The library can include previously-generated implant components having one or more patient-adapted features, and/or components with standard or blank features that can be altered to be patient-adapted. Accordingly, implants and/or implant features can be selected from the library.

[000155] **FIGS. 28A to 28K** show implant components with exemplary features that can be included in a library and selected based on patient-specific data to be patient-specific and/or patient engineered.

[000156] A virtual or physical implant component can be selected from the library based on similarity to prior or baseline parameter optimizations, such as one or more of (1) deformity correction and limb alignment (2) maximum preservation of bone, cartilage, or ligaments, (3) preservation and/or optimization of other features of the patient's biology, such as trochlea and trochlear shape, (4) restoration and/or optimization of joint kinematics, and (5) restoration or optimization of joint-line location and/or joint gap width. Accordingly, one or more implant component features, such as (a) component shape, external and/or internal, (b) component size, and/or (c) component thickness, can be determined precisely and/or determined within a range from the library selection. Then, the selected implant component can be designed or engineered further to include one or more patient-specific features. For example, a joint can be assessed in a particular subject and a pre-existing implant design having the closest shape and

size and performance characteristics can be selected from the library for further manipulation (e.g., shaping) and manufacturing prior to implantation. For a library including physical implant components, the selected physical component can be altered to include a patient-specific feature by adding material (e.g., laser sintering) and/or subtracting material (e.g., machining).

[000157] Accordingly, in certain embodiments an implant can include one or more features designed patient-specifically and one or more features selected from one or more library sources. For example, in designing an implant for a total knee replacement comprising a femoral component and a tibial component, one component can include one or more patient-specific features and the other component can be selected from a library. **Table 7** includes an exemplary list of possible combinations.

Table 7: Illustrative Combinations of Patient-Specific and Library-Derived Components

Implant component(s)	Implant component(s) having a patient-specific feature	Implant component(s) having a library derived feature
Femoral, Tibial	Femoral and Tibial	Femoral and Tibial
Femoral, Tibial	Femoral	Femoral and Tibial
Femoral, Tibial	Tibial	Femoral and Tibial
Femoral, Tibial	Femoral and Tibial	Femoral
Femoral, Tibial	Femoral and Tibial	Tibial
Femoral, Tibial	Femoral and Tibial	none

[000158] In certain embodiments, a library can be generated to include images from a particular patient at one or more ages prior to the time that the patient needs a joint implant. For example, a method can include identifying patients eliciting one or more risk factors for a joint problem, such as low bone mineral density score, and collecting one or more images of the patient's joints into a library. In certain embodiments, all patients below a certain age, for example, all patients below 40 years of age can be scanned to collect one or more images of the patient's joint. The images and data collected from the patient can be banked or stored in a patient-specific database. For example, the articular

shape of the patient's joint or joints can be stored in an electronic database until the time when the patient needs an implant. Then, the images and data in the patient-specific database can be accessed and a patient-specific and/or patient-engineered partial or total joint replacement implant using the patient's original anatomy, not affected by arthritic deformity yet, can be generated. This process results in a more functional and more anatomic implant.

GENERATING AN ARTICULAR REPAIR SYSTEM

[000159] The articular repair systems (e.g., resection cut strategy, guide tools, and implant components) described herein can be formed or selected to achieve various parameters including a near anatomic fit or match with the surrounding or adjacent cartilage, subchondral bone, menisci and/or other tissue. The shape of the repair system can be based on the analysis of an electronic image (e.g., MRI, CT, digital tomosynthesis, optical coherence tomography or the like). If the articular repair system is intended to replace an area of diseased cartilage or lost cartilage, the near anatomic fit can be achieved using a method that provides a virtual reconstruction of the shape of healthy cartilage in an electronic image.

[000160] In addition to the implant component features described above and in U.S. Patent Publication No. 2012-0209394, certain embodiments can include features and designs for cruciate substitution. These features and designs can include, for example, an intercondylar housing (sometimes referred to as a "box") **4910**, as shown in **FIGS. 49A** and **49B**, and/or one or more intercondylar bars **5010**, as shown in **FIGS. 50A** and **50B**, as a receptacle for a tibial post or projection. The intercondylar housing, receptacle, and/or bars can be used in conjunction with a projection or post on a tibial component as a substitute for a patient's posterior cruciate ligament ("PCL"), which may be sacrificed during the implant procedure. Specifically, as shown in **FIGS. 50A** and **50B**, the intercondylar housing, receptacle or bars engage the projection or post on the tibial component to stabilize the joint during flexion, particular during high flexion.

[000161] In certain embodiments, the femoral implant component can be designed and manufactured to include the housing, receptacle, and/or bars as a permanently integrated feature of the implant component. However, in certain embodiments, the housing, receptacle, and/or bars can be modular. For example,

the housing, receptacle, and/or bars can be designed and/or manufactured separate from the femoral implant component and optionally joined with the component, either prior to (e.g., preoperatively) or during the implant procedure. Methods for joining the modular intercondylar housing to an implant component are described in the art, for example, in U.S. Patent No. 4,950,298. As shown in **FIG. 51**, modular bars **5110** and/or a modular box **5120** can be joined to an implant component at the option of the surgeon or practitioner, for example, using spring-loaded pins **5130** at one or both ends of the modular bars. The spring-loaded pins can slideably engage corresponding holes or depressions in the femoral implant component.

[000162] The portion of the femoral component that will accommodate the housing, receptacle or bar can be standard, i.e., not-patient matched. In this manner, a stock of housings, receptacles or bars can be available in the operating room and added in case the surgeon sacrifices the PCL. In that case, the tibial insert can be exchanged for a tibial insert with a post mating with the housing, receptacle or bar for a posterior stabilized design.

[000163] The intercondylar housing, receptacle, and/or one or more intercondylar bars can include features that are patient-adapted (e.g., patient-specific or patient-engineered). In certain embodiments, the intercondylar housing, receptacle, and/or one or more intercondylar bars includes one or more features that are designed and/or selected preoperatively, based on patient-specific data including imaging data, to substantially match one or more of the patient's biological features. For example, the intercondylar distance of the housing or bar can be designed and/or selected to be patient-specific. Alternatively or in addition, one or more features of the intercondylar housing and/or one or more intercondylar bars can be engineered based on patient-specific data to provide to the patient an optimized fit with respect to one or more parameters. For example, the material thickness of the housing or bar can be designed and/or selected to be patient-engineered. One or more thicknesses of the housing, receptacle, or bar can be matched to patient-specific measurements. One or more thicknesses of the housing, receptacle, and/or bar can be adapted based on one or more implant dimensions, which can be patient-specific, patient-engineered or standard. One or more thicknesses of the housing, receptacle or

bar can be adapted based on one or more of patient weight, height, sex and body mass index. In addition, one or more features of the housing and/or bars can be standard.

[000164] Different dimensions of the housing, receptacle or bar can be shaped, adapted, or selected based on different patient dimensions and implant dimensions. Examples of different technical implementations are provided in **Table 11**. These examples are in no way meant to be limiting. Someone skilled in the art will recognize other means of shaping, adapting or selecting a housing, receptacle or bar based on the patient's geometry including imaging data.

Table 11: Examples of different technical implementations of a cruciate-sacrificing femoral implant component

Box, receptacle or bar or space defined by bar and condylar implant walls	Patient anatomy, e.g., derived from imaging studies or intraoperative measurements
Mediolateral width	Maximum mediolateral width of patient intercondylar notch or fraction thereof
Mediolateral width	Average mediolateral width of intercondylar notch
Mediolateral width	Median mediolateral width of intercondylar notch
Mediolateral width	Mediolateral width of intercondylar notch in select regions, e.g. most inferior zone, most posterior zone, superior one third zone, mid zone, etc.
Superoinferior height	Maximum superoinferior height of patient intercondylar notch or fraction thereof
Superoinferior height	Average superoinferior height of intercondylar notch
Superoinferior height	Median superoinferior height of intercondylar notch
Superoinferior height	Superoinferior height of intercondylar notch in select regions, e.g. most medial zone, most lateral zone, central zone, etc.
Anteroposterior length	Maximum anteroposterior length of patient intercondylar notch or fraction thereof
Anteroposterior length	Average anteroposterior length of intercondylar notch
Anteroposterior length	Median anteroposterior length of intercondylar notch

Box, receptacle or bar or space defined by bar and condylar implant walls	Patient anatomy, e.g., derived from imaging studies or intraoperative measurements
Anteroposterior length	Anteroposterior length of intercondylar notch in select regions, e.g. most anterior zone, most posterior zone, central zone, anterior one third zone, posterior one third zone etc.

[000165] The height or M-L width or A-P length of the intercondylar notch can not only influence the length but also the position or orientation of a bar or the condylar walls.

[000166] The dimensions of the housing, receptacle or bar can be shaped, adapted, or selected not only based on different patient dimensions and implant dimensions, but also based on the intended implantation technique, for example intended femoral component flexion or rotation. For example, at least one of an anteroposterior length or superoinferior height can be adjusted if an implant is intended to be implanted in 7 degrees flexion as compared to 0 degrees flexion, reflecting the relative change in patient or trochlear or intercondylar notch or femoral geometry when the femoral component is implanted in flexion.

[000167] In another example, the mediolateral width can be adjusted if an implant is intended to be implanted in internal or external rotation, reflecting, for example, an effective elongation of the intercondylar dimensions when a rotated implantation approach is chosen. The housing, receptacle, or bar can include oblique or curved surfaces, typically reflecting an obliquity or curvature of the patient's anatomy. For example, the superior portion of the housing, receptacle, or bar can be curved reflecting the curvature of the intercondylar roof. In another example, at least one side wall of the housing or receptacle can be oblique reflecting an obliquity of one or more condylar walls.

[000168] The internal shape of the housing, receptacle or bar can include one or more planar surfaces that are substantially parallel or perpendicular to one or more anatomical or biomechanical axes or planes. The internal shape of the housing, receptacle, or bar can include one or more planar surfaces that are oblique in one or two or three dimensions. The internal shape of the housing, receptacle, or bar can include one or more curved surfaces that are curved in one

or two or three dimensions. The obliquity or curvature can be adapted based on at least one of a patient dimension, e.g., a femoral notch dimension or shape or other femoral shape including condyle shape, or a tibial projection or post dimension. The internal surface can be determined based on generic or patient-derived or patient-desired or implant-desired kinematics in one, two, three or more dimensions. The internal surface can mate with a substantially straight tibial projection or post, e.g., in the ML plane. Alternatively, the tibial post or projection can have a curvature or obliquity in one, two or three dimensions, which can optionally be, at least in part, reflected in the internal shape of the box. One or more tibial projection or post dimensions can be matched to, designed to, adapted to, or selected based on one or more patient dimensions or measurements. Any combination of planar and curved surfaces is possible.

[000169] In certain embodiments, the position and/or dimensions and/or shape of the tibial plateau projection or post can be adapted based on patient-specific dimensions. For example, the post can be matched with or adapted relative to or selected based on the position or orientation of the posterior cruciate ligament or the PCL origin and/or insertion. It can be placed at a predefined distance from anterior or posterior cruciate ligament or ligament insertion, from the medial or lateral tibial spines or other bony or cartilaginous landmarks or sites. The shape of the post can be matched with or adapted relative to or selected based on bony landmarks, e.g. a femoral condyle shape, a notch shape, a femoral condyle dimension, a notch dimension, a tibial spine shape, a tibial spine dimension, a tibial plateau dimension. By matching the position of the post with the patient's anatomy, it is possible to achieve a better functional result, better replicating the patient's original anatomy.

[000170] Similarly, the position of the box or receptacle or bar on the femoral component can be designed, adapted, or selected to be close to the PCL origin or insertion or at a predetermined distance to the PCL or ACL origin or insertion or other bony or anatomical landmark. The orientation of the box or receptacle or bar can be designed or adapted or selected based on the patient's anatomy, e.g. notch width or ACL or PCL location or ACL or PCL origin or insertion.

[000171] **FIGS. 52A** through **52K** show various embodiments and aspects of cruciate-sacrificing femoral implant components. **FIG. 52A** shows a box height

adapted to superoinferior height of intercondylar notch. The dotted outlines indicate portions of the bearing surface and posterior condylar surface as well as the distal cut of the implant. **FIG. 52B** shows a design in which a higher intercondylar notch space is filled with a higher box or receptacle, for example, for a wide intercondylar notch. **FIG. 52C** shows a design in which a wide intercondylar notch is filled with a wide box or receptacle. The mediolateral width of the box is designed, adapted or selected to the wide intercondylar notch. **FIG. 52D** shows an example of an implant component having a box designed for a narrow intercondylar notch. The mediolateral width of the box is designed, adapted or selected for the narrow intercondylar notch. **FIG. 52E** shows an example of an implant component having a box for a normal size intercondylar notch. The box or receptacle is designed, adapted or selected for its dimensions. (Notch outline: dashed and stippled line; implant outline: dashed lines). **FIG. 52F** shows an example of an implant component for a long intercondylar notch. The box or receptacle is designed, adapted or selected for its dimensions (only box, not entire implant shown). **FIG. 52G** is an example of one or more oblique walls that the box or receptacle can have in order to improve the fit to the intercondylar notch. **FIG. 52H** is an example of a combination of curved and oblique walls that the box or receptacle can have in order to improve the fit to the intercondylar notch. **FIG. 52I** is an example of a curved box design in the A-P direction in order to improve the fit to the intercondylar notch. **FIG. 52J** is an example of a curved design in the M-L direction that the box or receptacle can have in order to improve the fit to the intercondylar notch. Curved designs are possible in any desired direction and in combination with any planar or oblique planar surfaces. **FIG. 52K** is an example of oblique and curved surfaces in order to improve the fit to the intercondylar notch. **FIGS. 52L** through **52P** show lateral views of different internal surfaces of boxes.

TIBIAL IMPLANT COMPONENT

[000172] In various embodiments described herein, one or more features of a tibial implant component are designed and/or selected, optionally in conjunction with an implant procedure, so that the tibial implant component fits the patient. For example, in certain embodiments, one or more features of a tibial implant component and/or implant procedure are designed and/or selected, based on

patient-specific data, so that the tibial implant component substantially matches (e.g., substantially negatively-matches and/or substantially positively-matches) one or more of the patient's biological structures. Alternatively or in addition, one or more features of a tibial implant component and/or implant procedure can be preoperatively engineered based on patient-specific data to provide to the patient an optimized fit with respect to one or more parameters, for example, one or more of the parameters described above. For example, in certain embodiments, an engineered bone preserving tibial implant component can be designed and/or selected based on one or more of the patient's joint dimensions as seen, for example, on a series of two-dimensional images or a three-dimensional representation generated, for example, from a CT scan or MRI scan. Alternatively or in addition, an engineered tibial implant component can be designed and/or selected, at least in part, to provide to the patient an optimized fit with respect to the engaging, joint-facing surface of a corresponding femoral implant component.

[000173] Certain embodiments include a tibial implant component having one or more patient-adapted (e.g., patient-specific or patient-engineered) features and, optionally, one or more standard features. Optionally, the one or more patient-adapted features can be designed and/or selected to fit the patient's resected tibial surface. For example, depending on the patient's anatomy and desired postoperative geometry or alignment, a patient's lateral and/or medial tibial plateaus may be resected independently and/or at different depths, for example, so that the resected surface of the lateral plateau is higher (e.g., 1 mm, greater than 1 mm, 2 mm, and/or greater than 2 mm higher) or lower (e.g., 1 mm, greater than 1 mm, 2 mm, and/or greater than 2 mm lower) than the resected surface of the medial tibial plateau.

[000174] Accordingly, in certain embodiments, tibial implant components can be independently designed and/or selected for each of the lateral and/or medial tibial plateaus. For example, the perimeter of a lateral tibial implant component and the perimeter of a medial tibial implant component can be independently designed and/or selected to substantially match the perimeter of the resection surfaces for each of the lateral and medial tibial plateaus. **FIG. 60A** and **60B** show exemplary unicompartmental medial and lateral tibial implant components without (**FIG. 60A**) and with (**FIG. 60B**) a polyethylene layer or insert. As shown,

the lateral tibial implant component and the medial tibial implant component have different perimeter shapes, each of which substantially matches the perimeter of the corresponding resection surface (see arrows). In addition, the polyethylene layers or inserts **6010** for the lateral tibial implant component and the medial tibial implant component have perimeter shapes that correspond to the respective implant component perimeter shapes. In certain embodiments, one or both of the implant components can be made entirely of a plastic or polyethylene (rather than having a having a polyethylene layer or insert) and each entire implant component can include a perimeter shape that substantially matches the perimeter of the corresponding resection surface.

[000175] Moreover, the height of a lateral tibial implant component and the height of a medial tibial implant component can be independently designed and/or selected to maintain or alter the relative heights generated by different resection surfaces for each of the lateral and medial tibial plateaus. For example, the lateral tibial implant component can be thicker (e.g., 1 mm, greater than 1 mm, 2 mm, and/or greater than 2 mm thicker) or thinner (e.g., 1 mm, greater than 1 mm, 2 mm, and/or greater than 2 mm thinner) than the medial tibial implant component to maintain or alter, as desired, the relative height of the joint-facing surface of each of the lateral and medial tibial implant components. As shown in **FIG. 60A** and **FIG. 60B**, the relative heights of the lateral and medial resection surfaces **6020** is maintained using lateral and medial implant components (and lateral and medial polyethylene layers or inserts) that have the same thickness. Alternatively, the lateral implant component (and/or the lateral polyethylene layer or insert) can have a different thickness than the medial implant component (and/or the medial polyethylene layer or insert). For embodiments having one or both of the lateral and medial implant components made entirely of a plastic or polyethylene (rather than having a having a polyethylene layer or insert) the thickness of one implant component can be different from the thickness of the other implant component.

[000176] Different medial and lateral tibial cut heights also can be applied with a one piece implant component, e.g., a monolithically formed, tibial implant component. In this case, the tibial implant component and the corresponding resected surface of the patient's femur can have an angled surface or a step cut connecting the medial and the lateral surface facets. For example, **FIGS. 61A** to

61C depict three different types of step cuts separating medial and lateral resection cut facets on a patient's proximal tibia. In certain embodiments, the bone-facing surface of the tibial implant component is selected and/or designed to match these surface depths and the step cut angle, as well as other optional features such as perimeter shape.

[000177] Tibial components also can include the same medial and lateral cut height.

[000178] In certain embodiments, the medial tibial plateau facet can be oriented at an angle different than the lateral tibial plateau facet or it can be oriented at the same angle. One or both of the medial and the lateral tibial plateau facets can be at an angle that is patient-specific, for example, similar to the original slope or slopes of the medial and/or lateral tibial plateaus, for example, in the sagittal plane. Moreover, the medial slope can be patient-specific, while the lateral slope is fixed or preset or vice versa, as exemplified in **Table 13**.

Table 13: Exemplary designs for tibial slopes

MEDIAL SIDE IMPLANT SLOPE	LATERAL SIDE IMPLANT SLOPE
Patient-matched to medial plateau	Patient-matched to lateral plateau
Patient-matched to medial plateau	Patient-matched to medial plateau
Patient-matched to lateral plateau	Patient-matched to lateral plateau
Patient-matched to medial plateau	Not patient-matched, e.g., preset, fixed or intraoperatively adjusted
Patient-matched to lateral plateau	Not patient-matched, e.g., preset, fixed or intraoperatively adjusted
Not patient matched, e.g. preset, fixed or intraoperatively adjusted	Patient-matched to lateral plateau
Not patient matched, e.g., preset, fixed or intraoperatively adjusted	Patient-matched to medial plateau
Not patient matched, e.g. preset, fixed or intraoperatively adjusted	Not patient-matched, e.g. preset, fixed or intraoperatively adjusted

[000179] The exemplary combinations described in **Table 13** are applicable to implants that use two unicompartmental tibial implant components with or without metal backing, one medial and one lateral. They also can be applicable to implant

systems that use a single tibial implant component including all plastic designs or metal backed designs with inserts (optionally a single insert for the medial and lateral plateau, or two inserts, e.g., one medial and one lateral), for example PCL retaining, posterior stabilized, or ACL and PCL retaining implant components.

[000180] In one embodiment, an ACL and PCL (bicruciate retaining) total knee replacement or resurfacing device can include a tibial component with the medial implant slope matched or adapted to the patient's native medial tibial slope and a lateral implant slope matched or adapted to the patient's native lateral tibial slope. In this manner, near normal kinematics can be re-established. The tibial component can have a single metal backing component, for example with an anterior bridge connecting the medial and the lateral portion; the anterior bridge can be located anterior to the ACL. The tibial component can include two metal backed pieces (without a bridge), one medial and one lateral with the corresponding plastic inserts. In the latter embodiment, a metal bridge can, optionally, be attachable or removable. The width of the metal bridge can be patient matched or patient adapted, e.g. matching the distance of the medial and lateral tibial spines or an offset added to or subtracted from this distance or a value derived from the intercondylar distance or intercondylar notch width. The width of the metal bridge can be estimated based on the ML dimension of the tibial plateau.

[000181] In one embodiment, the slope can be set via the alignment of the metal backed component(s). Alternatively, the metal backed component(s) can have substantially no slope in their alignment, while the medial and/or lateral slopes or both are contained or set through the insert topography or shape. One embodiment of such an implant is disclosed in **FIG. 176D**.

[000182] **FIG. 176A** depicts a patient's native tibial plateau in an uncut condition.

[000183] **FIG. 176B** shows one embodiment of an intended position of a metal backed component **17200** and an insert **17210**. Both the metal backed component and the insert have no significant slope in this embodiment.

[000184] **FIG. 176C** shows one embodiment of a metal backed component wherein the bone was cut at an angle similar to the patient's slope, e.g. on the

medial tibial plateau or lateral tibial plateau or, both, placing the metal backed component **17200** at a slope similar to that of the patient's native tibial plateau. The insert **17210** has no significant slope but follows the slope of the cut and the metal backed component.

[000185] **Fig. 176D** depicts an alternate embodiment a metal backed component **17200** implanted with no significant slope. The tibial insert topography is, however, asymmetrical, and, in this case either selected or designed to closely approximate the patient's native tibial slope. In this example, this is achieved by selecting or designing a tibial insert **17215** that is substantially thicker anterior when compared to posterior. The difference in insert height anteriorly and posteriorly results in a slope similar to the patient's slope.

[000186] These embodiments, and derivations thereof, can be applied to a medial plateau, a lateral plateau or combinations thereof or both. In various alternative embodiments, and derivations thereof, various combinations of tilted and/or untilted inserts and/or tilted and/or untilted metal backed components can be utilized to achieve a wide variety of surgical corrections and/or account for a wide variation in patient anatomy and/or surgical cuts necessary for treating the patient. For example, where the natural slope of a patient's tibia requires a non-uniform resection (i.e., the cut is non-planar across the bone or is tilted and non-perpendicular relative to the mechanical axis of the bone, whether medially-laterally, anterior-posteriorly, or any combination thereof) or the surgical correction creates such a non-uniform or tilted resection, one or more correction factors can be designed into the metal backed component, into the tibial insert, or into any combination of the two. Moreover, the slope can naturally or artificially be made to vary from one side of the knee to the other, or anterior to posterior, and the implant components can account for such variation.

[000187] Various of the described embodiments will be best suited for treating non-uniform or tilted natural anatomy and/or resections of partial or total knees, while others will be more appropriate for the treatment of non-uniform or tilted natural anatomy and/or resections of other joints, including a spine, spinal articulations, an intervertebral disk, a facet joint, a shoulder, an elbow, a wrist, a hand, a finger, a hip, an ankle, a foot, or a toe joint.

[000188] The slope preferably is between 0 and 7 degrees, but other embodiments with other slope angles outside that range can be used. The slope can vary across one or both tibial facets from anterior to posterior. For example, a lesser slope, e.g. 0-1 degrees, can be used anteriorly, and a greater slope can be used posteriorly, for example, 4-5 degrees. Variable slopes across at least one of a medial or a lateral tibial facet can be accomplished, for example, with use of burrs (for example guided by a robot) or with use of two or more bone cuts on at least one of the tibial facets. In certain embodiments, two separate slopes can be used medially and laterally. Independent tibial slope designs can be useful for achieving bone preservation. In addition, independent slope designs can be advantageous in achieving implant kinematics that will be more natural, closer to the performance of a normal knee or the patient's knee.

[000189] In certain embodiments, the slope can be fixed, e.g. at 3, 5 or 7 degrees in the sagittal plane. In certain embodiments, the slope, either medial or lateral or both, can be patient-specific. The patient's medial slope can be used to derive the medial tibial component slope and, optionally, the lateral component slope, in either a single or a two-piece tibial implant component. The patient's lateral slope can be used to derive the lateral tibial component slope and, optionally, the medial component slope, in either a single or a two-piece tibial implant component. A patient's slope typically is between 0 and 7 degrees. In select instances, a patient may show a medial or a lateral slope that is greater than 7 degrees. In this case, if the patient's medial slope has a higher value than 7 degrees or some other pre-selected threshold, the patient's lateral slope can be applied to the medial tibial implant component or to the medial side of a single tibial implant component. If the patient's lateral slope has a higher value than 7 degrees or some other pre-selected threshold, the patient's medial slope can be applied to the lateral tibial implant component or to the lateral side of a single tibial implant component. Alternatively, if the patient's slope on one or both medial and lateral sides exceeds a pre-selected threshold value, e.g., 7 degrees or 8 degrees or 10 degrees, a fixed slope can be applied to the medial component or side, to the lateral component or side, or both. The fixed slope can be equal to the threshold value, e.g., 7 degrees or it can be a different value. **FIGS. 62A and 62B** show exemplary flow charts for deriving a medial tibial component slope (**FIG.**

62A) and/or a lateral tibial component slope (**FIG. 62B**) for a tibial implant component. If desired, a fixed tibial slope can be used in any of the embodiments described herein.

[000190] In another embodiment, a mathematical function can be applied to derive a medial implant slope and/or a lateral implant slope, or both (wherein both can be the same). In certain embodiments, the mathematical function can include a measurement derived from one or more of the patient's joint dimensions as seen, for example, on a series of two-dimensional images or a three-dimensional representation generated, for example, from a CT scan or MRI scan. For example, the mathematical function can include a ratio between a geometric measurement of the patient's femur and the patient's tibial slope. Alternatively or in addition, the mathematical function can be or include the patient's tibial slope divided by a fixed value. In certain embodiments, the mathematical function can include a measurement derived from a corresponding implant component for the patient, for example, a femoral implant component, which itself can include patient-specific, patient-engineered, and/or standard features. Many different possibilities to derive the patient's slope using mathematical functions can be applied by someone skilled in the art.

[000191] In certain embodiments, the medial and lateral tibial plateau can be resected at the same angle. For example, a single resected cut or the same multiple resected cuts can be used across both plateaus. In other embodiments, the medial and lateral tibial plateau can be resected at different angles. Multiple resection cuts can be used when the medial and lateral tibial plateaus are resected at different angles. Optionally, the medial and the lateral tibia also can be resected at a different distance relative to the tibial plateau. In this setting, the two horizontal plane tibial cuts medially and laterally can have different slopes and/or can be accompanied by one or two vertical or oblique resection cuts, typically placed medial to the tibial plateau components. **FIGS. 16** and **FIGS. 61A** to **61C** show several exemplary tibial resection cuts, which can be used in any combination for the medial and lateral plateaus.

[000192] The medial tibial implant component plateau can have a flat, convex, concave, or dished surface and/or it can have a thickness different than the lateral tibial implant component plateau. The lateral tibial implant component plateau can

have a flat, convex, concave, or dished surface and/or it can have a thickness different than the medial tibial implant component plateau. The different thickness can be achieved using a different material thickness, for example, metal thickness or polyethylene or insert thickness on either side. In certain embodiments, the lateral and medial surfaces are selected and/or designed to closely resemble the patient's anatomy prior to developing the arthritic state.

[000193] The height of the medial and/or lateral tibial implant component plateau, e.g., metal only, ceramic only, metal backed with polyethylene or other insert, with single or dual inserts and single or dual tray configurations can be determined based on the patient's tibial shape, for example using an imaging test.

[000194] Alternatively, the height of the medial and/or lateral tibial component plateau, e.g. metal only, ceramic only, metal backed with polyethylene or other insert, with single or dual inserts and single or dual tray configurations, can be determined based on the patient's femoral shape. For example, if the patient's lateral condyle has a smaller radius than the medial condyle and/or is located more superior than the medial condyle with regard to its bearing surface, the height of the tibial component plateau can be adapted and/or selected to ensure an optimal articulation with the femoral bearing surface. In this example, the height of the lateral tibial component plateau can be adapted and/or selected so that it is higher than the height of the medial tibial component plateau. Since polyethylene is typically not directly visible on standard x-rays, metallic or other markers can optionally be included in the inserts in order to indicate the insert location or height, in particular when asymmetrical medial and lateral inserts or inserts of different medial and lateral thickness are used.

[000195] Alternatively, the height of the medial and/or lateral tibial component plateau, e.g. metal only, ceramic only, metal backed with polyethylene or other insert, with single or dual inserts and single or dual tray configurations can be determined based on the shape of a corresponding implant component, for example, based on the shape of certain features of the patient's femoral implant component. For example, if the femoral implant component includes a lateral condyle having a smaller radius than the medial condyle and/or is located more superior than the medial condyle with regard to its bearing surface, the height of the tibial implant component plateaus can be adapted and/or selected to ensure

an optimal articulation with the bearing surface(s) of the femoral implant component. In this example, the height of the lateral tibial implant component plateau can be adapted and/or selected to be higher than the height of the medial tibial implant component plateau.

[000196] Moreover, the surface shape, e.g. mediolateral or anteroposterior curvature or both, of the tibial insert(s) can reflect the shape of the femoral component. For example, the medial insert shape can be matched to one or more radii on the medial femoral condyle of the femoral component. The lateral insert shape can be matched to one or more radii on the lateral femoral condyle of the femoral component. The lateral insert may optionally also be matched to the medial condyle. The matching can occur, for example, in the coronal plane. This has benefits for wear optimization. A pre-manufactured insert can be selected for a medial tibia that matches the medial femoral condyle radii in the coronal plane with a pre-selected ratio, e.g. 1:5 or 1:7 or 1:10. Any combination is possible. A pre-manufactured insert can be selected for a lateral tibia that matches the lateral femoral condyle radii in the coronal plane with a pre-selected ratio, e.g. 1:5 or 1:7 or 1:10. Any combination is possible. Alternatively, a lateral insert can also be matched to a medial condyle or a medial insert shape can also be matched to a lateral condyle. These combinations are possible with single and dual insert systems with metal backing. Someone skilled in the art will recognize that these matchings can also be applied to implants that use all polyethylene tibial components; i.e. the radii on all polyethylene tibial components can be matched to the femoral radii in a similar manner.

[000197] The matching of radii can also occur in the sagittal plane. For example, a cutter can be used to cut a fixed coronal curvature into a tibial insert or all polyethylene tibia that is matched to or derived from a femoral implant or patient geometry. The path and/or depth that the cutter is taking can be driven based on the femoral implant geometry or based on the patient's femoral geometry prior to the surgery. Medial and lateral sagittal geometry can be the same on the tibial inserts or all poly tibia. Alternatively, each can be cut separately. By adapting or matching the tibial poly geometry to the sagittal geometry of the femoral component or femoral condyle, a better functional result may be achieved. For example, more physiologic tibiofemoral motion and

kinematics can be enabled. Alternatively, the path and/or depth that the cutter is taking can be driven based on the patient's tibial geometry prior to the surgery, optionally including estimates of meniscal shape. Medial and lateral sagittal geometry can be the same on the tibial inserts or all poly tibia. Alternatively, each can be cut separately. By adapting or matching the tibial poly geometry to the sagittal geometry of the patient's tibial plateau, a better functional result may be achieved. For example, more physiologic tibiofemoral motion and kinematics can be enabled. In the latter embodiment at least portions of the femoral sagittal J-curve can be matched to or derived from or selected based on the tibial implant geometry or the patient's tibial curvature, medially or laterally or combinations thereof.

[000198] The distance between cutter path used for cutting the bearing surface shape of the medial side and the bearing surface shape of the lateral side can be selected from or derived from or matched to the femoral geometry, e.g. an intercondylar distance or an intercondylar notch width (see **FIGS. 28 G – K**). In this manner, the tibial component(s) can be adapted to the femoral geometry, ensuring that the lowest point of the femoral bearing surface will mate with the lowest point of the resultant tibial bearing surface.

[000199] Such configurations can be established, for example, by designing a patient specific femoral component and then matching the locations of corresponding bearing surfaces on the tibial component based on the design on the femoral component. Similarly, the location of the bearing surface(s) can be configured based on the native anatomy of the patient's tibia and the femoral component can then be patient engineered such that the weight-bearing portion of the femoral condylar surface(s) matches the location on the tibial component. For a total knee replacement device, such configurations can be based on any of the distances shown in conjunction with the set of FIGS 28 or on other distances associated with the femoral or tibial components.

[000200] Similarly, such configurations can be established, for example, by selecting a best fit component from a library of designs, partial designs, or physical implants available for use. The component can be selected based in whole or in part on any of the distances shown in conjunction with the set of FIGS 28 or on other distances associated with the femoral or tibial components. The

location of the weight bearing portion(s) of the femoral component(s) and the weight bearing portion(s) of the tibial component(s) can be matched to the location using a best fit and/or corresponding design. Alternatively, the location of the bearing surface(s) can be configured based on the native anatomy of the patient, such as the locations of the condyles or the locations of the weight bearing portions of the tibial plateau or a combination thereof, and then a best fit component can be selected. For example, a best fit tibial component or design can be matched to a patient-specific femoral component or design. Likewise, a best fit femoral component can be matched to a patient-specific tibial component or design. In the case of the placement of the weight-bearing surface of the condyles as shown in the set of FIGS 28, the weight-bearing portion of the femoral condylar surface(s) can be made to match or closely match the tibial component(s).

[000201] These concepts associated with the configuration of articular surfaces also apply to other aspects of knee prosthesis, such as matching a patella and trochlear groove, as well as to other joints such as the placement of weight bearing or other articulating surfaces in hips, shoulders, elbows, ankles, and other joints. These concepts can also be applied to the selection of non-articulating components of a device, where multiple components can be designed in relation to one-another based on either a patient-specific design, a selection of a best fit, or a combination thereof.

[000202] The medial and/or the lateral component can include a trough. The medial component can be dish shaped, while the lateral component includes a trough. The lateral component can be dish shaped, while the medial component includes a trough. The lateral component can be convex, while the medial component includes a trough. The shape of the medial or lateral component can be patient derived or patient matched in one, two or three dimensions, for example as it pertains to its perimeter as well as its surface shape. The convex shape of the lateral component can be patient derived or patient matched in one, two or three dimensions. The trough can be straight. The trough can also be curved. The curvature of the trough can have a constant radius of curvature or it can include several radii of curvature. The radii can be patient matched or patient derived, for example based on the femoral geometry or on the patient's

kinematics. These designs can be applied with a single-piece tibial polyethylene or other plastic insert or with two-piece tibial polyethylene or other plastic inserts.

FIGS. 63A through **63J** show exemplary combinations of tibial tray designs.

FIGS. 64A through **64F** include additional embodiments of tibial implant components that are cruciate retaining.

[000203] The tibial implant surface topography can be selected for, adapted to or matched to one or more femoral geometries. For example, the distance of the lowest point of the medial dish or trough to the lowest point of the lateral dish or trough can be selected from or derived from or matched to the femoral geometry, e.g. an intercondylar distance or an intercondylar notch width (see **FIGS. 28 G – K**). In this manner, the tibial component(s) can be adapted to the femoral geometry, ensuring that the lowest point of the femoral bearing surface will mate with the lowest point of the resultant tibial bearing surface. For example, an exemplary femoral geometry may be determined or derived, and then a matching or appropriate tibial implant geometry and surface geometry can be derived from the femoral geometry (i.e., from anatomical or biomechanical or kinematic features in the sagittal and/or coronal plane of the femur) or from a combination of the femoral geometry with the tibial geometry. In such combination cases, it may be desirable to optimize the tibial implant geometry based on a weighted combination of the tibial and femoral anatomical or biomechanical or kinematic characteristics, to create a hybrid implant that accomplishes a desired correction, but which accommodates the various structural, biomechanical and/or kinematic features and/or limitations of each individual portion of the joint. In a similar manner, multi-complex joint implants having three or more component support structures, such as the knee (i.e., patella, femur and tibia), elbow (humerus, radius and ulna), wrist (radius, ulna and carpals), and ankle (fibula, tibia, talus and calcaneus) can be modeled and repaired/replaced with components modeled, derived and manufactured incorporating features of two or more mating surfaces and underlying support structures of the native joint.

[000204] The perimeter of the tibial component, metal backed, optionally poly inserts, or all plastic or other material, can be matched to or derived from the patient's tibial shape, and can be optimized for different cut heights and/or tibial slopes. In a preferred embodiment, the shape is matched to the cortical bone of

the cut surface. The surface topography of the tibial bearing surface can be designed or selected to match or reflect at least a portion of the tibial geometry, in one or more planes, e.g., a sagittal plane or a coronal plane, or both. The medial tibial implant surface topography can be selected or designed to match or reflect all or portions of the medial tibial geometry in one or more planes, e.g., sagittal and coronal. The lateral tibial implant surface topography can be selected or designed to match or reflect all or portions of the lateral tibial geometry in one or more planes, e.g., sagittal and coronal. The medial tibial implant surface topography can be selected or designed to match or reflect all or portions of the lateral tibial geometry in one or more planes, e.g., sagittal and coronal. The lateral tibial implant surface topography can be selected or designed to match or reflect all or portions of the medial tibial geometry in one or more planes, e.g., sagittal and coronal.

[000205] In various embodiments, the design and/or placement of the tibial component can be influenced (or otherwise “driven”) by various factors of the femoral geometry. For example, it may be desirable to rotate the design of some or all of a tibial component (i.e., the entirety of the component and its support structure or some portion thereof, including the tibial tray and/or the articulating poly insert and/or merely the surface orientation of the articulating surface of the tibial insert) to some degree to accommodate various features of the femoral geometry, such as the femoral epicondylar axis, posterior condylar axis, medial or lateral sagittal femoral J-curves, or other femoral axis or landmark. In a similar manner, the design and/or placement of the femoral component (i.e., the entirety of the femoral component and its support structure or some portion thereof, including the orientation and/or placement of one or more condyles, condyle surfaces and/or the trochlear groove) can be influenced (or “driven”) by various factors of the tibial geometry, including various tibial axes, shapes, medial and/or lateral slopes and/or landmarks, e.g. tibial tuberosity, Q-angle etc. Both femoral and tibial components can be influenced in shape or orientation by the shape, dimensions, biomechanics or kinematics of the patellofemoral joint, including, for example, trochlear angle and Q-angle, sagittal trochlear geometry, coronal trochlear geometry, etc.

[000206] The surface topography of the tibial bearing surface(s) can be designed or selected to match or reflect at least portions of the femoral geometry or femoral implant geometry, in one or more planes, e.g., a sagittal plane or a coronal plane, or both. The medial implant surface topography can be selected or designed to match or reflect all or portions of the medial femoral geometry or medial femoral implant geometry in one or more planes. The lateral implant surface topography can be selected or designed to match or reflect all or portions of the lateral femoral geometry or lateral femoral implant geometry in one or more planes. The medial implant surface topography can be selected or designed to match or reflect all or portions of the lateral femoral geometry or lateral femoral implant geometry in one or more planes. The lateral implant surface topography can be selected or designed to match or reflect all or portions of the medial femoral geometry or medial femoral implant geometry in one or more planes. The medial and/or the lateral surface topography can be fixed in one, two or all dimensions. The latter can typically be used when at least one femoral geometry, e.g., the coronal curvature, is also fixed.

[000207] For example, a portion of a sagittal curvature of a femoral condyle can be used to derive and manufacture a portion of a sagittal curvature of a tibial plateau bearing surface. In one embodiment, a CNC machine can have a sagittal sweep plane through a polyethylene bearing surface that corresponds to at least a portion of a femoral sagittal curvature. The coronal radius of the cutter tool can be matched or derived from at least portions of the femoral coronal curvature or it can be a ratio or other mathematical function applied to the femoral curvature. Of note, the femoral coronal curvature can vary along the condyle allowing for smaller and larger radii in different locations. These radii can be patient specific or engineered. For example, two or more engineered radii can be applied to a single femoral condyle in two or more locations, which can be the same or different with respect to the second condyle.

[000208] If desired, a femoral bearing surface can be derived off a tibial shape in one or more dimensions using the same or similar approaches. Likewise, a femoral head or humeral head bearing surface can be derived of an acetabulum or glenoid in one or more directions or the reverse.

[000209] The implant surface topography can include one or more of the following:

- Curvature of convexity in sagittal plane, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Curvature of convexity in coronal plane, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Curvature of concavity in sagittal plane, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Curvature of concavity in coronal plane, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Single sagittal radius of curvature, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Multiple sagittal radii of curvature, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Single coronal radius of curvature, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Multiple coronal radii of curvature, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Depth of dish, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Depth of dish optionally adapted to presence or absence of intact anterior and/or posterior cruciate ligaments
- Location of dish, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- AP length of dish, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- ML width of dish, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Depth of trough, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Depth of trough optionally adapted to presence or absence of intact anterior and/or posterior cruciate ligaments
- Location of trough, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- AP length of trough, optionally patient derived or matched, e.g., based on tibial or femoral geometry

- ML width of trough, optionally patient derived or matched, e.g., based on tibial or femoral geometry
- Curvature of trough, , optionally patient derived or matched, e.g., based on tibial or femoral geometry

[000210] All of the tibial designs discussed can be applied with a:

- single piece tibial polyethylene insert, for example with a single metal backed component
- single piece tibial insert of other materials, for example with a single metal backed component
- two piece tibial polyethylene inserts, for example with a single metal backed component
- two piece tibial inserts of other materials, for example with a single metal backed component
- - single piece all polyethylene tibial implant
- - two piece all polyethylene tibial implant, e.g. medial and lateral
- - single piece metal tibial implant (e.g., metal on metal or metal on ceramic)
- - two piece metal tibial implant, e.g., medial and lateral (e.g., metal on metal or metal on ceramic)
- - single piece ceramic tibial implant
- - two piece ceramic tibial implant, e.g., medial and lateral

[000211] Any material or material combination currently known in the art and developed in the future can be used.

[000212] Certain embodiments of tibial trays can have the following features, although other embodiments are possible: modular insert system (polymer); cast cobalt chrome; standard blanks (cobalt portion and/or modular insert) can be made in advance, then shaped patient-specific to order; thickness based on size (saves bone, optimizes strength); allowance for 1-piece or 2-piece insert systems; and/or different medial and lateral fins.

[000213] In certain embodiments, the tibial tray is designed or cut from a blank so that the tray periphery matches the edge of the cut tibial bone, for

example, the patient-matched peripheral geometry achieves >70%, >80%, >90%, or >95% cortical coverage. In certain embodiments, the tray periphery is designed to have substantially the same shape, but be slightly smaller, than the cortical area.

[000214] The patient-adapted tibial implants of certain embodiments allow for design flexibility. For example, inserts can be designed to complement an associated condyle of a corresponding femoral implant component, and can vary in dimensions to optimize design, for example, one or more of height, shape, curvature (preferably flat to concave), and location of curvature to accommodate natural or engineered wear pattern.

[000215] In the knee, a tibial cut can be selected so that it is, for example, 90 degrees perpendicular to the tibial mechanical axis or to the tibial anatomical axis. The cut can be referenced, for example, by finding the intersect with the lowest medial or lateral point on the plateau.

[000216] The slope for tibial cuts typically is between 0 and 7 or 0 and 8 degrees in the sagittal plane. Rarely, a surgeon may elect to cut the tibia at a steeper slope. The slope can be selected or designed into a patient-specific cutting jig using a preoperative imaging test. The slope can be similar to the patient's preoperative slope on at least one of a medial or one of a lateral side. The medial and lateral tibia can be cut with different slopes. The slope also can be different from the patient's preoperative slope on at least one of a medial or one of a lateral side.

[000217] The tibial cut height can differ medially and laterally, as shown in **FIGS. 16** and **FIGS. 61A to 61C**. In some patients, the uncut lateral tibia can be at a different height, for example, higher or lower, than the uncut medial tibia. In this instance, the medial and lateral tibial cuts can be placed at a constant distance from the uncut medial and the uncut lateral tibial plateau, resulting in different cut heights medially or laterally. Alternatively, they can be cut at different distances relative to the uncut medial and lateral tibial plateau, resulting in the same cut height on the remaining tibia. Alternatively, in this setting, the resultant cut height on the remaining tibia can be elected to be different medially and laterally. In certain embodiments, independent design of the medial and lateral

tibial resection heights, resection slopes, and/or implant component (e.g., tibial tray and/or tibial tray insert), can enhance bone perseveration on the medial and/or lateral sides of the proximal tibia as well as on the opposing femoral condyles.

[000218] As shown in **FIGS. 63B** through **63J**, the medial portion of a tibial implant may be higher or lower than the lateral tibial portion to compensate for different sizes of the medial and lateral femoral condyle. This method can facilitate maintenance of a patient's normal J-curve and thus help preserve normal knee kinematics. Alternatively, the effect may be achieved by offsetting the higher tibial articular surface to be the same height as the other compartment. If the condylar J-curve is offset by the same amount, the same kinematic motion can be achieved, as illustrated in **FIG. 191**. In this embodiment, the first wheel **19500** (femoral condyle) and track **19510** (tibial implant surface) are offset by the same amount as the second wheel **19520** and track **19530**. When rolling the first wheel **19500** over the track **19510**, a similar motion path **19540** (curve) results as for the second wheel **19520** and track **19530**. Since in this case the tibial implant surface is desirably offset perpendicular to the surface, this will result in a new surface curvature that may be different than that of the other compartment. Offsetting the femoral J-curve by the corresponding amount desirably reduces the amount of bone to be removed from the femoral condyle.

[000219] In certain embodiments, a patient-specific proximal tibia cut (and the corresponding bone-facing surface of the tibial component) is designed by: (1) finding the tibial axis perpendicular plane ("TAPP"); (2) lowering the TAPP, for example, 2 mm below the lowest point of the medial tibial plateau; (3) sloping the lowered TAPP 5 degrees posteriorly (no additional slope is required on the proximal surface of the insert); (4) fixing the component posterior slope, for example, at 5 degrees; and (5) using the tibial anatomic axis derived from Cobb or other measurement technique for tibial implant rotational alignment. As shown in **FIG. 65**, resection cut depths deeper than 2mm below the lowest point of the patient's uncut medial or lateral plateau (e.g., medial plateau) may be selected and/or designed, for example, if the patient's anatomy includes an abnormality or diseased tissue below this point, or if the surgeon prefers a lower cut. For example, resection cut depths of 2.5 mm, 3 mm, 3.5 mm, 4 mm, 4.5 mm, or 5 mm

can be selected and/or designed and, optionally, one or more corresponding tibial and/or femoral implant thicknesses can be selected and/or designed based on this patient-specific information.

[000220] In certain embodiments, a patient-specific proximal tibial cut (and the corresponding bone-facing surface of the tibial component) uses the preceding design except for determining the A-P slope of the cut. In certain embodiments, a patient-specific A-P slope can be used, for example, if the patient's anatomic slope is between 0 degrees and 7 degrees, or between 0 degrees and 8 degrees, or between 0 degrees and 9 degrees; a slope of 7 degrees can be used if the patient's anatomic slope is between 7 degrees and 10 degrees, and a slope of 10° can be used if the patient's anatomic slope is greater than 10 degrees.

[000221] In certain embodiments, a patient-specific A-P slope is used if the patient's anatomic slope is between 0 and 7 degrees and a slope of 7 degrees is used if the patient's anatomic slope is anything over 7 degrees. Someone skilled in the art will recognize other methods for determining the tibial slope and for adapting it during implant and jig design to achieve a desired implant slope.

[000222] A different tibial slope can be applied on the medial and the lateral side. A fixed slope can be applied on one side, while the slope on the other side can be adapted based on the patient's anatomy. For example, a medial slope can be fixed at 5 degrees, while a lateral slope matches that of the patient's tibia. In this setting, two unicondylar tibial inserts or trays can be used. Alternatively, a single tibial component, optionally with metal backing, can be used wherein said component does not have a flat, bone-facing surface, but includes, for example, an oblique portion to connect the medial to the lateral side substantially negatively-match resected lateral and medial tibial surfaces as shown, for example, in **FIGS. 16** and **FIGS. 61A** to **61C**.

[000223] In certain embodiments, the axial profile (e.g., perimeter shape) of the tibial implant can be designed to match the axial profile of the patient's cut tibia, for example as described in U.S. Patent Application Publication No. 2009/0228113. Alternatively or in addition, in certain embodiments, the axial profile of the tibial implant can be designed to maintain a certain percentage or distance in its perimeter shape relative to the axial profile of the patient's cut tibia.

Alternatively or in addition, in certain embodiments, the axial profile of the tibial implant can be designed to maintain a certain percentage or overhang in its perimeter shape relative to the axial profile of the patient's cut tibia.

[000224] Any of the tibial implant components described above can be derived from a blank that is cut to include one or more patient-specific features.

[000225] Tibial tray designs can include patient-specific, patient-engineered, and/or standard features. For example, in certain embodiments the tibial tray can have a front-loading design that requires minimal impaction force to seat it. The trays can come in various standard or standard blank designs, for example, small, medium and large standard or standard blank tibial trays can be provided. **FIG. 66** shows exemplary small, medium and large blank tibial trays. As shown, the tibial tray perimeters include a blank perimeter shape that can be designed based on the design of the patient's resected proximal tibia surface. In certain embodiments, small and medium trays can include a base thickness of 2 mm (e.g., such that a patient's natural joint line may be raised 3-4 mm if the patient has 2-3 mm of cartilage on the proximal tibia prior to the disease state). Large trays can have a base thickness of 3 mm (such that in certain embodiments it may be beneficial to resect an additional 1 mm of bone so that the joint line is raised no more than 2-3 mm (assuming 2-3 mm of cartilage on the patient's proximal tibia prior to the disease state)).

[000226] In various embodiments, a tibial implant design may incorporate one or more locking mechanisms to secure a tibial insert into a tibial tray. One exemplary locking mechanism of varying sizes is depicted in **Fig 66**. In this mechanism, a corresponding lower surface on the tibial insert engages one or more ridges on the surface of the tibial tray, thereby locking the tibial insert in a desired position relative to the tray. The locking mechanism can be pre-configured and/or available, for example, in two or three different geometries or size. Optionally, a user or a computer program can have a library of CAD files or subroutines with different sizes and geometries of locking mechanisms available. For example, in a first step, the user or computer program can define, design or select a tibial, acetabular or glenoid implant profile that best matches a patient's cut (or, optionally, uncut) tibia, acetabulum or glenoid. In a second step, the user or computer program can then select the pre-configured CAD file or subroutine

that is best suited for a given tibial or acetabular or glenoid perimeter or other shape or location or size. Moreover, the type of locking mechanism (e.g. snap, dovetail etc.) can be selected based on patient specific parameters, e.g. body weight, height, gender, race, activity level etc.).

[000227] A patient-specific peg alignment (e.g., either aligned to the patient's mechanical axis or aligned to another axis) can be combined with a patient-specific A-P cut plane. For example, in certain embodiments the peg alignment can tilt anteriorly at the same angle that the A-P slope is designed. In certain embodiments, the peg can be aligned in relation to the patient's sagittal mechanical axis, for example, at a predetermined angle relative to the patient's mechanical axis. **FIG. 67** shows exemplary A-P and peg angles for tibial trays.

[000228] The joint-facing surface of a tibial implant component includes a medial bearing surface and a lateral bearing surface. Like the femoral implant bearing surface(s) described above, a bearing surface on a tibial implant (e.g., a groove or depression or a convex portion (on the lateral side) in the tibial surface that receives contact from a femoral component condyle) can be of standard design, for example, available in 6 or 7 different shapes, with a single radius of curvature or multiple radii of curvature in one dimension or more than one dimension. Alternatively, a bearing surface can be standardized in one or more dimensions and patient-adapted in one or more dimensions. A single radius of curvature and/or multiple radii of curvature can be selected in one dimension or multiple dimensions. Some of the radii can be patient-adapted.

[000229] Each of the two contact areas of the polyethylene insert of the tibial implant component that engage the femoral medial and lateral condyle surfaces can be any shape, for example, convex, flat, or concave, and can have any radii of curvature. In certain embodiments, any one or more of the curvatures of the medial or lateral contact areas can include patient-specific radii of curvature. Specifically, one or more of the coronal curvature of the medial contact area, the sagittal curvature of the medial contact area, the coronal curvature of the lateral contact area, and/or the sagittal curvature of the lateral contact area can include, at least in part, one or more patient-specific radii of curvature. In certain embodiments, the tibial implant component is designed to include one or both medial and lateral bearing surfaces having a sagittal curvature with, at least in

part, one or more patient-specific radii of curvature and a standard coronal curvature. In certain embodiments, the bearing surfaces on one or both of the medial and lateral tibial surfaces can include radii of curvature derived from (e.g., the same length or slightly larger, such as 0-10% larger than) the radii of curvature on the corresponding femoral condyle. Having patient-adapted sagittal radii of curvature, at least in part, can help achieve normal kinematics with full range of motion.

[000230] Alternatively, the coronal curvature can be selected, for example, by choosing from a family of standard curvatures the one standard curvature having the radius of curvature or the radii of curvature that is most similar to the coronal curvature of the patient's uncut femoral condyle or that is most similar to the coronal curvature of the femoral implant component.

[000231] In preferred embodiments, one or both tibial medial and lateral contact areas have a standard concave coronal radius that is larger, for example slightly larger, for example, between 0 and 1 mm, between 0 and 2 mm, between 0 and 4 mm, between 1 and 2 mm, and/or between 2 and 4 mm larger, than the convex coronal radius on the corresponding femoral component. By using a standard or constant coronal radius on a femoral condyle with a matching standard or constant coronal radius or slightly larger on a tibial insert, for example, with a tibial radius of curvature of from about 1.05x to about 2x, or from about 1.05x to about 1.5x, or from about 1.05x to about 1.25x, or from about 1.05x to about 1.10x, or from about 1.05x to about 1.06x, or about 1.06x of the corresponding femoral implant coronal curvature. The relative convex femoral coronal curvature and slightly larger concave tibial coronal curvature can be selected and/or designed to be centered to each about the femoral condylar centers.

[000232] In the sagittal plane, one or both tibial medial and lateral concave curvatures can have a standard curvature slightly larger than the corresponding convex femoral condyle curvature, for example, between 0 and 1 mm, between 0 and 2 mm, between 0 and 4 mm, between 1 and 2 mm, and/or between 2 and 4 mm larger, than the convex sagittal radius on the corresponding femoral component. For example, the tibial radius of curvature for one or both of the medial and lateral sides can be from about 1.1x to about 2x, or from about 1.2x to

about 1.5x, or from about 1.25x to about 1.4x, or from about 1.30x to about 1.35x, or about 1.32x of the corresponding femoral implant sagittal curvature. In certain embodiments, the depth of the curvature into the tibial surface material can depend on the height of the surface into the joint gap. As mentioned, the height of the medial and lateral tibial component joint-facing surfaces can be selected and/or designed independently. In certain embodiments, the medial and lateral tibial heights are selected and/or designed independently based on the patient's medial and lateral condyle height difference. In addition or alternatively, in certain embodiments, a threshold minimum or maximum tibial height and/or tibial insert thickness can be used. For example, in certain embodiments, a threshold minimum insert thickness of 6 mm is employed so that no less than a 6 mm medial tibial insert is used.

[000233] By using a tibial contact surface sagittal and/or coronal curvature selected and/or designed based on the curvature(s) of the corresponding femoral condyles or a portion thereof (e.g., the bearing portion), the kinematics and wear of the implant can be optimized. For example, this approach can enhance the wear characteristics a polyethylene tibial insert. This approach also has some manufacturing benefits. Any of the above embodiments are applicable to other joints and related implant components including an acetabulum, a femoral head, a glenoid, a humeral head, an ankle, a foot joint, an elbow including a capitellum and an olecranon and a radial head, and a wrist joint.

[000234] For example, a set of different-sized tools can be produced wherein each tool corresponds to one of the pre-selected standard coronal curvatures. The corresponding tool then can be used in the manufacture of a polyethylene insert of the tibial implant component, for example, to create a curvature in the polyethylene insert. **FIG. 68A** shows six exemplary tool tips **6810** and a polyethylene insert **6820** in cross-section in the coronal view. The size of the selected tool can be used to generate a polyethylene insert having the desired coronal curvature. In addition, **FIG. 68A** shows an exemplary polyethylene insert having two different coronal curvatures created by two different tool tips. The action of the selected tool on the polyethylene insert, for example, a sweeping arc motion by the tool at a fixed point above the insert, can be used to manufacture a standard or patient-specific sagittal curvature. **FIG. 68B** shows a sagittal view of

two exemplary tools **6830**, **6840** sweeping from different distances into the polyethylene insert **6820** of a tibial implant component to create different sagittal curvatures in the polyethylene insert **6820**.

[000235] In certain embodiments, one or both of the tibial contact areas includes a concave groove having an increasing or decreasing radius along its sagittal axis, for example, a groove with a decreasing radius from anterior to posterior.

[000236] As shown in **FIG. 69A**, in certain embodiments the shape of the concave groove **6910** on the lateral and/or on the medial sides of the joint-facing surface of the tibial insert **6920** can be matched by a convex shape **6930** on the opposing side surface of the insert and, optionally, by a concavity **6940** on the engaging surface of the tibial tray **6950**. This can allow the thickness of the component to remain constant **6960**, even though the surfaces are not flat, and thereby can help maintain a minimum thickness of the material, for example, plastic material such as polyethylene. For example, an implant insert can maintain a constant material thickness (e.g., less than 5.5 mm, 5.5 mm, 5.6 mm, 5.7 mm, 5.8 mm, 5.9 mm, 6.0 mm, 6.1 mm, or greater than 6.1 mm) even though the insert includes a groove on the joint-facing surface. The constant material thickness can help to minimize overall minimum implant thickness while achieving or maintaining a certain mechanical strength (as compared to a thicker implant). The matched shape on the metal backing can serve the purpose of maintaining a minimum polyethylene thickness. It can, however, also include design features to provide a locking mechanism between the polyethylene or other insert and the metal backing. Such locking features can include ridges, edges, or an interference fit. In the case of an interference fit, the polyethylene can have slightly larger dimensions at the undersurface convexity than the matching concavity on the metal tray. This can be stabilized against rails or dove tail locking mechanisms in the center or the sides of the metal backing. Other design options are possible. For example, the polyethylene extension can have a saucer shape that can snap into a matching recess on the metal backing. In addition, as shown in **FIG. 69A**, any corresponding pieces of the component, such as a metal tray, also can include a matching groove to engage the curved surface of the plastic material. Two exemplary concavity dimensions are shown in **FIG. 69B**. As shown in the

figure, the concavities or scallops have depths of 1.0 and 0.7 mm, based on a coronal geometry of R42.4 mm. At a 1.0 mm depth, the footprint width is 18.3 mm. At a 0.70 mm depth, the footprint width is 15.3 mm. These dimensions are only of exemplary nature. Many other configurations are possible, including configurations of varying thickness across the tibial tray.

[000237] In various alternative embodiments, the tibial tray may comprise sections of varying thickness. If desired, the modeling software may conduct FEA or other load analysis on the tibial tray (incorporating various patient-specific information, including patient weight and intended activity levels, among other factors) and determine if specific areas of the intended implant design are an undesirable risk of failure or fatigue. Such areas can be reinforced, thickened or otherwise redesigned (if desired) to accommodate and/or alleviate such risks (desirably before actual manufacture of the implant). In a similar manner, areas of lower stress/fracture risk can be redesigned (if desired) by removal of material, etc., which may improve the fit and/or performance of the implant in various ways. Of course, either or both of the upper and lower surface of the tibial tray may be processed and/or redesigned in this manner.

[000238] In certain embodiments, the sagittal curvature of the femoral component can be designed to be tilted, as suggested by **FIG. 70**. The corresponding curvature of the tibial surface can be tilted by that same slope, which can allow for thicker material on the corresponding tibial implant, for example, thicker poly at the anterior or posterior aspect of the tibial implant. The femoral component J-curve, and optionally the corresponding curvature for the tibial component, can be tilted by the same slope in both the medial and lateral condyles, just in the medial condyle or just in the lateral condyle or both independently or coupled. In certain embodiments, some additional material can be removed or the material thickness can be adapted from the posterior aspect of the femoral and/or tibial curvatures to allow for rotation.

[000239] In addition to the implant component features described above, certain embodiments can include features and designs for cruciate substitution. These features and designs can include, for example, a keel, post, or projection that projects from the bone-facing surface of the tibial implant component to

engage an intercondylar housing, receptacle, or bars on the corresponding femoral implant component.

[000240] **FIGS. 49A and 49B, 50A and 50B, 51, and 52A through 52P** depict various features of intercondylar bars or in intercondylar housing for a cruciate-substituting femoral implant component. In addition, **FIGS. 50A and 50B** show a tibial implant component having a post or projection that can be used in conjunction with an intercondylar housing, receptacle, and/or bars on a femoral implant component as a substitute for a patient's PCL, which may be sacrificed during the implant procedure. Specifically, the post or projection on the tibial component engages the intercondylar housing, receptacle or bars on the femoral implant component to stabilize the joint during flexion, particular during high flexion.

[000241] **FIGS. 71A and 71B** depict exemplary cross-sections of tibial implant components having a post (or keel or projection) projecting from the bone-facing surface of the implant component. In particular, **FIG. 71A** shows (a) a tibial implant component with a straight post or projection and (b)-(d) tibial implant components having posts or projections oriented laterally, with varying thicknesses, lengths, and curvatures. **FIG. 71B** shows (a)-(e) tibial implant components having posts or projections oriented medially, with varying thicknesses, lengths, and curvatures.

[000242] As shown in the figures, the upper surface of the tray component has a "keel type" structure in between the concave surfaces that are configured to mate with the femoral condyle surfaces of a femoral implant. This "keel type" structure can be configured to slide within a groove in the femoral implant. The groove can comprise stopping mechanisms at each end of the groove to keep the "keel type" structure within the track of the groove. This "keel type" structure and groove arrangement may be used in situations where a patient's posterior cruciate ligament is removed as part of the surgical process and there is a need to posteriorly stabilize the implant within the joint.

[000243] In certain embodiments, the tibial implant component can be designed and manufactured to include the post or projection as a permanently integrated feature of the implant component. However, in certain embodiments,

the post or projection can be modular. For example, the post or projection can be designed and/or manufactured separate from the tibial implant component and optionally joined with the component, either prior to (e.g., preoperatively) or during the implant procedure. For example, a modular post or projection and a tibial implant component can be mated using an integrating mechanism such as respective male and female screw threads, other male-type and female-type locking mechanisms, or other mechanism capable of integrating the post or projection into or onto the tibial implant component and providing stability to the post or projection during normal wear. A modular post or projection can be joined to a tibial implant component at the option of the surgeon or practitioner, for example, by removing a plug or other device that covers the integrating mechanism and attaching the modular post or projection at the uncovered integrating mechanism.

[000244] The post or projection can include features that are patient-adapted (e.g., patient-specific or patient-engineered). In certain embodiments, the post or projection includes one or more features that are designed and/or selected preoperatively, based on patient-specific data including imaging data, to substantially match one or more of the patient's biological features. For example, the length, width, height, and/or curvature of one or more portions of the post or projection can be designed and/or selected to be patient-specific, for example, with respect to the patient's intercondylar distance or depth, femoral shape, and/or condyle shape. Alternatively or in addition, one or more features of the post or projection can be engineered based on patient-specific data to provide to the patient an optimized fit. For example, the length, width, height, and/or curvature of one or more portions of the post or projection can be designed and/or selected to be patient-engineered. One or more thicknesses of the housing, receptacle, or bar can be matched to patient-specific measurements. One or more dimensions of the post or projection can be adapted based on one or more implant dimensions (e.g., one or more dimensions of the housing, receptacle or bar on the corresponding femoral implant component), which can be patient-specific, patient-engineered or standard. One or more dimensions of the post or projection can be adapted based on one or more of patient weight, height, sex, and body mass index. In addition, one or more features of the post or projection can be standard.

[000245] Optionally, referring to **FIGS. 71A** and **71B**, an exemplary “keel type” structure or post can be adapted to the patient’s anatomy. For example, the post can be shaped to enable a more normal, physiologic glide path of the femur relative to the tibia. Thus, the post can deviate medially or lateral as it extends from its base to its tip. This medial or lateral deviation can be designed to achieve a near physiologic rolling and rotating action of the knee joint. The medial and lateral bending of the post can be adapted based on patient specific imaging data. For example, the mediolateral curve or bend of the post or keel can be patient-derived or patient-matched (e.g., to match the physical or force direction of PCL or ACL). Alternatively or in addition, the post or keel can deviate at a particular AP angle or bend, for example, the sagittal curve of the post or keel can be reflection of PCL location and orientation or combinations of ACL and PCL location and orientation. The post can optionally taper or can have different diameters and cross-sectional profiles, e.g. round, elliptical, ovoid, square, rectangular at different heights from its base.

[000246] Different dimensions of the post or projection can be shaped, adapted, or selected based on different patient dimensions and implant dimensions. Examples of different technical implementations are provided in **Table 14**. These examples are in no way meant to be limiting. Someone skilled in the art will recognize other means of shaping, adapting or selecting a tibial implant post or projection based on the patient’s geometry including imaging data.

Table 14: Examples of different technical implementations of a cruciate-sacrificing tibial implant component

Post or projection feature	Corresponding patient anatomy, e.g., derived from imaging studies or intraoperative measurements
Mediolateral width	Maximum mediolateral width of patient intercondylar notch or fraction thereof
Mediolateral width	Average mediolateral width of intercondylar notch
Mediolateral width	Median mediolateral width of intercondylar notch
Mediolateral width	Mediolateral width of intercondylar notch in select regions, e.g. most inferior zone, most posterior zone, superior one third zone, mid zone, etc.
Superoinferior height	Maximum superoinferior height of patient intercondylar notch or fraction thereof

Post or projection feature	Corresponding patient anatomy, e.g., derived from imaging studies or intraoperative measurements
Superoinferior height	Average superoinferior height of intercondylar notch
Superoinferior height	Median superoinferior height of intercondylar notch
Superoinferior height	Superoinferior height of intercondylar notch in select regions, e.g. most medial zone, most lateral zone, central zone, etc.
Anteroposterior length	Maximum anteroposterior length of patient intercondylar notch or fraction thereof
Anteroposterior length	Average anteroposterior length of intercondylar notch
Anteroposterior length	Median anteroposterior length of intercondylar notch
Anteroposterior length	Anteroposterior length of intercondylar notch in select regions, e.g. most anterior zone, most posterior zone, central zone, anterior one third zone, posterior one third zone etc.

[000247] The height or M-L width or A-P length of the intercondylar notch can not only influence the length but also the position or orientation of a post or projection from the tibial implant component.

[000248] The dimensions of the post or projection can be shaped, adapted, or selected not only based on different patient dimensions and implant dimensions, but also based on the intended implantation technique, for example, the intended tibial component slope or rotation and/or the intended femoral component flexion or rotation. For example, at least one of an anteroposterior length or superoinferior height can be adjusted if a tibial implant is intended to be implanted at a 7 degrees slope as compared to a 0 degrees slope, reflecting the relative change in patient or trochlear or intercondylar notch or femoral geometry when the tibial component is implanted. Moreover, at least one of an anteroposterior length or superoinferior height can be adjusted if the femoral implant is intended to be implanted in flexion, for example, in 7 degrees flexion as compared to 0 degrees flexion. The corresponding change in post or projection dimension can be designed or selected to reflect the relative change in patient or trochlear or intercondylar notch or femoral geometry when the femoral component is implanted in flexion.

[000249] In another example, the mediolateral width can be adjusted if one or both of the tibial and/or femoral implant components are intended to be implanted in internal or external rotation, reflecting, for example, an effective elongation of the intercondylar dimensions when a rotated implantation approach is chosen. Features of the post or projection can be oblique or curved to match corresponding features of the femoral component housing, receptacle or bar. For example, the superior portion of the post projection can be curved, reflecting a curvature in the roof of the femoral component housing, receptacle, or bar, which itself may reflect a curvature of the intercondylar roof. In another example, a side of a post or projection may be oblique to reflect an obliquity of a side wall of the housing or receptacle of the femoral component, which itself may reflect an obliquity of one or more condylar walls. Accordingly, an obliquity or curvature of a post or projection can be adapted based on at least one of a patient dimension or a femoral implant dimension. Alternatively, the post or projection of the tibial implant component can be designed and/or selected based on generic or patient-derived or patient-desired or implant-desired kinematics in one, two, three or more dimensions. Then, the corresponding surface(s) of the femoral implant housing or receptacle can be designed and/or selected to mate with the tibial post or projection, e.g., in the ML plane. Alternatively, the post or projection of the femoral receptacle or box or bar or housing can be designed and/or selected based on generic or patient-derived or patient-desired or implant-desired kinematics in one, two, three or more dimensions. Then, the corresponding surface(s) of the post or projection of the tibial implant can be designed and/or selected to mate with the tibial post or projection, e.g., in the ML plane.

[000250] The tibial post or projection can be straight. Alternatively, the tibial post or projection can have a curvature or obliquity in one, two or three dimensions, which can optionally be, at least in part, reflected in the internal shape of the box. One or more tibial projection or post dimensions can be matched to, designed to, adapted to, or selected based on one or more patient dimensions or measurements. Any combination of planar and curved surfaces is possible.

[000251] In certain embodiments, the position and/or dimensions of the tibial implant component post or projection can be adapted based on patient-specific dimensions. For example, the post or projection can be matched with the position

of the posterior cruciate ligament or the PCL insertion. It can be placed at a predefined distance from anterior or posterior cruciate ligament or ligament insertion, from the medial or lateral tibial spines or other bony or cartilaginous landmarks or sites. By matching the position of the post with the patient's anatomy, it is possible to achieve a better functional result, better replicating the patient's original anatomy.

[000252] The tray component can be machined, molded, casted, manufactured through additive techniques such as laser sintering or electron beam melting or otherwise constructed out of a metal or metal alloy such as cobalt chromium. Similarly, the insert component may be machined, molded, manufactured through rapid prototyping or additive techniques or otherwise constructed out of a plastic polymer such as ultra-high molecular weight polyethylene. Other known materials, such as ceramics including ceramic coating, may be used as well, for one or both components, or in combination with the metal, metal alloy and polymer described above. It should be appreciated by those of skill in the art that an implant may be constructed as one piece out of any of the above, or other, materials, or in multiple pieces out of a combination of materials. For example, a tray component constructed of a polymer with a two-piece insert component constructed one piece out of a metal alloy and the other piece constructed out of ceramic.

[000253] Each of the components may be constructed as a "standard" or "blank" in various sizes or may be specifically formed for each patient based on their imaging data and anatomy. Computer modeling may be used and a library of virtual standards may be created for each of the components. A library of physical standards may also be amassed for each of the components.

[000254] Imaging data including shape, geometry, e.g., M-L, A-P, and S-I dimensions, then can be used to select the standard component, e.g., a femoral component or a tibial component or a humeral component and a glenoid component that most closely approximates the select features of the patient's anatomy. Typically, these components will be selected so that they are slightly larger than the patient's articular structure that will be replaced in at least one or more dimensions. The standard component is then adapted to the patient's

unique anatomy, for example by removing overhanging material, e.g. using machining.

[000255] Thus, referring to the flow chart shown in **FIG. 72A**, in a first step, the imaging data will be analyzed, either manually or with computer assistance, to determine the patient specific parameters relevant for placing the implant component. These parameters can include patient specific articular dimensions and geometry and also information about ligament location, size, and orientation, as well as potential soft-tissue impingement, and, optionally, kinematic information.

[000256] In a second step, one or more standard components, e.g., a femoral component or a tibial component or tibial insert, are selected. These are selected so that they are at least slightly greater than one or more of the derived patient specific articular dimensions and so that they can be shaped to the patient specific articular dimensions. Alternatively, these are selected so that they will not interfere with any adjacent soft-tissue structures. Combinations of both are possible.

[000257] If an implant component is used that includes an insert, e.g., a polyethylene insert and a locking mechanism in a metal or ceramic base, the locking mechanism can be adapted to the patient's specific anatomy in at least one or more dimensions. The locking mechanism can also be patient adapted in all dimensions. The location of locking features can be patient adapted while the locking feature dimensions, for example between a femoral component and a tibial component, can be fixed. Alternatively, the locking mechanism can be pre-fabricated; in this embodiment, the location and dimensions of the locking mechanism will also be considered in the selection of the pre-fabricated components, so that any adaptations to the metal or ceramic backing relative to the patient's articular anatomy do not compromise the locking mechanism. Thus, the components can be selected so that after adaptation to the patient's unique anatomy a minimum material thickness of the metal or ceramic backing will be maintained adjacent to the locking mechanism.

[000258] Since the tibia has the shape of a champagne glass, i.e., since it tapers distally from the knee joint space down, moving the tibial cut distally will result in a smaller resultant cross-section of the cut tibial plateau, e.g., the ML and/or AP dimension of the cut tibia will be smaller. For example, referring to **FIG. 72B**, increasing the slope of the cut will result in an elongation of the AP

dimension of the cut surface – requiring a resultant elongation of a patient matched tibial component. Thus, in one embodiment it is possible to select an optimal standard, pre-made tibial blank for a given resection height and / or slope. This selection can involve (1) patient-adapted metal with a standard poly insert; or (2) metal and poly insert, wherein both are adapted to patient anatomy. The metal can be selected so that based on cut tibial dimensions there is always a certain minimum metal perimeter (in one, two or three dimensions) guaranteed after patient adaptation so that a lock mechanism will not fail. Optionally, one can determine minimal metal perimeter based on finite element modeling (FEA) (once during initial design of standard lock features, or patient specific every time e.g. via patient specific FEA modeling).

[000259] The tibial tray can be selected (or a metal base for other joints) to optimize percent cortical bone coverage at resection level. This selection can be (1) based on one dimension, e.g., ML; (2) based on two dimensions, e.g. ML and AP; and/or (3) based on three dimensions, e.g., ML, AP, SI or slope.

[000260] The selection can be performed to achieve a target percentage coverage of the resected bone (e.g. area) or cortical edge or margin at the resection level (e.g. AP, ML, perimeter), e.g. 85%, 90%, 95%, 98% or 100%. Optionally, a smoothing function can be applied to the derived contour of the patient's resected bone or the resultant selected, designed or adapted implant contour so that the implant does not extend into all irregularities or crevices of the virtually and then later surgically cut bone perimeter.

[000261] Optionally, a function can be included for deriving the desired implant shape that allows changing the tibial implant perimeter if the implant overhangs the cortical edge in a convex outer contour portion or in a concave outer contour portion (e.g. "crevice"). These changes can subsequently be included in the implant shape, e.g. by machining select features into the outer perimeter.

[000262] Those of skill in the art will appreciate that a combination of standard and customized components may be used in conjunction with each other. For example, a standard tray component may be used with an insert component that has been individually constructed for a specific patient based on the patient's anatomy and joint information.

[000263] Another embodiment incorporates a tray component with one half of a two-piece insert component integrally formed with the tray component, leaving only one half of the two-piece insert to be inserted during surgery. For example, the tray component and medial side of the insert component may be integrally formed, with the lateral side of the insert component remaining to be inserted into the tray component during surgery. Of course, the reverse could also be used, wherein the lateral side of the insert component is integrally formed with the tray component leaving the medial side of the insert component for insertion during surgery.

[000264] Each of these alternatives results in a tray component and an insert component shaped so that once combined, they create a uniformly shaped implant matching the geometries of the patient's specific joint.

[000265] The above embodiments are applicable to all joints of a body, e.g., ankle, foot, elbow, hand, wrist, shoulder, hip, spine, or other joint.

[000266] For example, in a knee, a tibial component thickness can be selected, adapted or designed based on one or more of a patient's femoral or tibial AP or ML dimensions, femoral or tibial sagittal curvature, femoral or tibial coronal curvature, estimated contact area, estimated contact stresses, biomechanical loads, optionally for different flexion and extension angles, and the like. Both the metal thickness as well as the thickness of an optional insert can be selected, adapted or designed using this or similar information. A femoral component thickness can be selected, adapted or designed based on one or more of a patient's femoral or tibial AP or ML dimensions, femoral or tibial sagittal curvature, femoral or tibial coronal curvature, estimated contact area, estimated contact stresses, biomechanical loads, optionally for different flexion and extension angles, and the like.

[000267] Thus, edge matching, designing, selecting or adapting implants including, optionally lock features, can be performed for implants used in any joint of the body. Imaging tests available for edge matching, designing, selecting or adapting implants include CT, MRI, radiography, digital tomosynthesis, cone beam CT, ultrasound, laser imaging, isotope based imaging, SPECT, PET, contrast enhanced imaging for any modality, and any other imaging modality known in the art and developed in the future.

[000268] An implant component can include a fixed bearing design or a mobile bearing design. With a fixed bearing design, a platform of the implant component is fixed and does not rotate. However, with a mobile bearing design, the platform of the implant component is designed to rotate e.g., in response to the dynamic forces and stresses on the joint during motion.

[000269] A rotating platform mobile bearing on the tibial implant component allows the implant to adjust and accommodate in an additional dimension during joint motion. However, the additional degree of motion can contribute to soft tissue impingement and dislocation. Mobile bearings are described elsewhere, for example, in U.S. Patent Application Publication No. 2007/0100462.

[000270] In certain embodiments, an implant can include a mobile-bearing implant that includes one or more patient-specific features, one or more patient-engineered features, and/or one or more standard features. For example, for a knee implant, the knee implant can include a femoral implant component having a patient-specific femoral intercondylar distance; a tibial component having standard mobile bearing and a patient-engineered perimeter based on the dimensions of the perimeter of the patient's cut tibia and allowing for rotation without significant extension beyond the perimeter of the patient's cut tibia; and a tibial insert or top surface that is patient-specific for at least the patient's intercondylar distance between the tibial insert dishes to accommodate the patient-specific femoral intercondylar distance of the femoral implant.

[000271] As another example, in certain embodiments a knee implant can include a femoral implant component that is patient-specific with respect to a particular patient's M-L dimension and standard with respect to the patient's femoral intercondylar distance; a tibial component having a standard mobile bearing and a patient-engineered perimeter based on the dimensions of the perimeter of the patient's cut tibia and allowing for rotation without significant extension beyond the perimeter of the patient's cut tibia; and a tibial insert or top surface that includes a standard intercondylar distance between the tibial insert dishes to accommodate the standard femoral intercondylar distance of the femoral implant.

Optimizing Soft-Tissue Tension, Ligament Tension, Balancing, Flexion and Extension Gap

[000272] The surgeon can, optionally, make adjustments of implant position and/or orientation such as rotation, bone cuts, cut height and selected component thickness, insert thickness or selected component shape or insert shape. In this manner, an optimal compromise can be found, for example, between biomechanical alignment and joint laxity or biomechanical alignment and joint function, e.g., in a knee joint flexion gap and extension gap. Thus, multiple approaches exist for optimizing soft-tissue tension, ligament tension, ligament balance, and/or flexion and extension gap. These include, for example, one or more of the exemplary options described in **Table 15**.

Table 15: Exemplary approach options for optimizing soft-tissue tension, ligament tension, ligament balance, and/or flexion and extension gap

Option #	Description of Exemplary Option
1	Position of one or more femoral bone cuts
2	Orientation of one or more femoral bone cuts
3	Location of femoral component
4	Orientation of femoral component, including rotational alignment in axial, sagittal and coronal direction
5	Position of one or more tibial bone cuts
6	Orientation of one or more tibial bone cuts including sagittal slope, mediolateral orientation
7	Location of tibial component
8	Orientation of tibial component, including rotational alignment in axial, sagittal and coronal direction
9	Tibial component height
10	Medial tibial insert or component or composite height
11	Lateral tibial insert or component or composite height
12	Tibial component profile, e.g., convexity, concavity, trough, radii of curvature
13	Medial tibial insert or component or composite profile, e.g. convexity, concavity, trough, radii of curvature
14	Lateral tibial insert or component or composite profile, e.g. convexity, concavity, trough, radii of curvature
15	Select soft-tissue releases, e.g. partial or full releases of retinacula and/or ligaments, "pie-crusting" etc.

[000273] Any one option described in **Table 15** can be optimized alone or in combination with one or more other options identified in the table and/or known in the art for achieving different flexion and extension, abduction, or adduction, internal and external positions and different kinematic requirements.

[000274] In one embodiment, the surgeon can initially optimize the femoral

and tibial resections. Optimization can be performed by measuring soft-tissue tension or ligament tension or balance for different flexion and extension angles or other joint positions before any bone has been resected, once a first bone resection on a first articular surface has been made and after a second bone resection on a first or second articular surface has been made, such as a femur and a tibia, humerus and a glenoid, femur and an acetabulum.

[000275] The position and orientation between a first implant component and a second, opposing implant component or a first articular surface and a trial implant or a first trial implant and a second trial implant or an alignment guide and an instrument guide and any combinations thereof can be optimized with the use of, for example, interposed spacers, wedges, screws and other mechanical or electrical methods known in the art. A surgeon may desire to influence joint laxity as well as joint alignment. This can be optimized for different flexion and extension, abduction, or adduction, internal and external rotation angles. For this purpose, spacers can be introduced at or between one or more steps in the implant procedure. One or more of the spacers can be attached or in contact with one or more instruments, trials or, optionally, patient-specific molds. The surgeon can intraoperatively evaluate the laxity or tightness of a joint using spacers with different thicknesses or one or more spacers with the same thickness. For example, spacers can be applied in a knee joint in the presence of one or more trials or instruments or patient-specific molds and the flexion gap can be evaluated with the knee joint in flexion. The knee joint can then be extended and the extension gap can be evaluated. Ultimately, the surgeon selects for a given joint an optimal combination of spacers and trial or instrument or patient-specific mold. A surgical cut guide can be applied to the trial or instrument or patient-specific mold with the spacers optionally interposed between the trial or instrument or patient-specific mold and the cut guide. In this manner, the exact position of the surgical cuts can be influenced and can be adjusted to achieve an optimal result. Someone skilled in the art will recognize other means for optimizing the position of the surgical cuts. For example, expandable or ratchet-like devices can be utilized that can be inserted into the joint or that can be attached or that can touch the trial or instrument or patient-specific mold. Hinge-like mechanisms are applicable. Similarly, jack-like mechanisms are useful. In principal, any mechanical or

electrical device useful for fine tuning the position of a cut guide relative to a trial or instrument or patient -specific mold can be used.

[000276] A surgeon may desire to influence joint laxity as well as joint alignment. This can be optimized for different flexion and extension, abduction, or adduction, internal and external rotation angles. For this purpose, for example, spacers can be introduced that are attached or that are in contact with one or more trials or instruments or patient-specific molds. The surgeon can intraoperatively evaluate the laxity or tightness of a joint using spacers with different thickness or one or more spacers with the same thickness. For example, spacers can be applied in a knee joint in the presence of one or more instruments or trials or molds and the flexion gap can be evaluated with the knee joint in flexion. Different thickness trials can be used. The terms spacer or insert can be used interchangeably with the term trial.

[000277] In certain embodiments, the surgeon can elect to insert different trials or spacers or instruments of different thicknesses in the medial and/or lateral joint space in a knee. This can be done before any bone has been resected, once a first bone resection on a first articular surface has been made and after a second bone resection on a first or second articular surface has been made, such as a femur and a tibia or a medial and a lateral condyle or a medial and a lateral tibia. The joint can be tested for soft-tissue tension, ligament tension, ligament balance and/or flexion or extension gap for different orientations or kinematic requirements using different medial and lateral trial or spacer thicknesses, e.g., at different flexion and extension angles. Surgical bone cuts can subsequently optionally be adapted or changed. Alternatively, different medial and lateral insert thickness or profiles or composite heights can be selected for the tibial component(s). For example, combinations of medial and lateral spacers or trials having differing thicknesses can be inserted.

[000278] By using separate medial and/or lateral spacers or trials or inserts, it is possible to determine an optimized combination of medial or lateral tibial components, for example with regard to medial and lateral composite thickness, insert thickness or medial and lateral implant or insert profile. Thus, medial and/or lateral tibial implant or component or insert thickness can be optimized for a desired soft-tissue or ligament tension or ligament balance for different flexion and

extension angles and other joint poses. This offers a unique benefit beyond traditional balancing using bone cuts and soft-tissue releases. In one embodiment, the surgeon can place the tibial and femoral surgical bone cuts and perform the proper soft-tissue or ligament tensioning or balancing entirely via selection of a medial or lateral tibial insert or composite thickness and/or profile. Additional adaptation and optimization of bone cuts and soft-tissue releases is possible.

[000279] **FIGS. 73A** through **75C** show various exemplary spacers or trials or inserts for adjusting and optimizing alignment, tension, balance, and position (e.g., as described in **Table 15** above) during a knee implant surgery. In particular, **FIG. 73A** depicts a medial balancer chip insert from top view to show the superior surface of the chip. **FIG. 73B** depicts a side view of a set of four medial balancer chip inserts that incrementally increase in thickness by 1 mm. A corresponding set of lateral balancing chip inserts (having a range of thicknesses) can be used in conjunction with a set of medial balancing chip inserts. In this way, the joint can be optimized using independent medial and lateral balancing chips inserts having different thicknesses. As indicated with the first chip in the figure, the superior surface **7302** of a balancing chip insert engages the femur and the inferior surface **7304** engages the tibia. In certain embodiments, one or both of the superior surface **7302** and/or the inferior surface **7304** can be patient-adapted to fit the particular patient. In certain embodiments, a balancing chip can include a resection surface to guide a subsequent surgical bone cut.

[000280] **FIG. 73C** depicts a medial balancing chip being inserted in flexion between the femur and tibia. **FIG. 73D** depicts the medial balancing chip insert in place while the knee is brought into extension. Optionally, a lateral balancing chip also can be placed between the lateral portions of the femur and tibia. Medial and lateral balancing chips having different thicknesses can be placed as shown in **FIGS. 73C** and **73D**, until a desired tension is observed medially and laterally throughout the patient's range of motion. As shown in **FIG. 73E**, in certain embodiments, a cutting guide can be attached to the medial balancing chip insert, to the lateral balancing chip insert, or to both, so that the resection cuts are made based on the selected medial and lateral balancing chip inserts. Optionally, one or more surfaces of one or both balancing chips also can act as a cutting guide.

As shown in **FIG. 73F**, the inferior surface of the medial balancing chip can act as cutting guide surface for resectioning the medial portion of the tibia.

[000281] **FIG. 74A** depicts a set of three medial spacer block inserts having incrementally increasing thicknesses, for example, thicknesses that increase by 1 mm, by 1.5 mm, or by 2 mm. A corresponding set of lateral medial spacer block inserts (having a range of thicknesses) can be used in conjunction with a set of medial spacer block inserts. A spacer block insert can be used, for example, to provide the thickness of a tibial implant component (optionally with or without the additional thickness of a tibial implant component insert) during subsequent implantation steps and prior to placement of the tibial implant component. In certain embodiments, the spacer block insert can include a portion for attaching a tibial implant component insert, so that the precise thicknesses of different combinations of tibial implant components and component inserts can be assessed. By using medial and lateral spacer block inserts of different thicknesses, the balancing, tensioning, alignment, and/or positioning of the joint can continue to be optimized throughout the implantation procedure. In certain embodiments, one or more features of a spacer block insert can be patient-adapted to fit the particular patient. In certain embodiments, a spacer block insert can include a feature for attaching or stabilizing a cutting guide and/or a feature for guiding a cutting tool.

[000282] **FIG. 74B** depicts a set of two medial femoral trials having incrementally increasing thicknesses, for example, thicknesses that increase by 1 mm, by 1.5 mm, or by 2 mm. A corresponding set of lateral femoral trials (having a range of thicknesses) can be used in conjunction with the set of medial femoral trials. A femoral trial can be used, for example, to test variable thicknesses and/or features of a femoral implant component during implantation steps prior to placement of the tibial implant component. By using medial and lateral femoral trials of different thicknesses, the balancing, tensioning, alignment, and/or positioning of the joint can continue to be optimized throughout the implantation procedure. In certain embodiments, one or more features of a femoral trial can be patient-adapted to fit the particular patient. In certain embodiments, a femoral trial can include a feature for attaching or stabilizing a cutting guide and/or a feature for guiding a cutting tool.

[000283] **FIG. 74C** depicts a medial femoral trial in place and a spacer block being inserted to evaluate the balance of the knee in flexion and extension. Spacer blocks having different thicknesses can be inserted and evaluated until an optimized thickness is identified. Optionally, a lateral femoral trial also can be placed between the lateral portions of the femur and tibia and a lateral spacer block inserted and evaluated along with the medial spacer block. Medial and lateral spacer blocks having different thicknesses can be placed and removed until a desired tension is observed medially and laterally throughout the patient's range of motion. Then, a tibial implant component and/or tibial implant component insert can be selected to have a thickness based on the thickness identified by evaluation using the femoral trial and spacer block. In this way, the selected medial tibial implant component (and/or tibial implant component insert) and the lateral tibial implant component (and/or tibial implant component insert) can have different thicknesses.

[000284] **FIG. 75A** depicts a set of three medial tibial component insert trials having incrementally increasing thicknesses, for example, thicknesses that increase by 0.5 mm, by 1 mm, by 1.5 mm, or by 2 mm. A corresponding set of lateral tibial component insert trials (having a range of thicknesses) can be used in conjunction with the set of medial tibial component insert trials. A tibial component insert trial can be used, for example, to determine the best insert thickness and/or features of a tibial component insert during the final implantation steps. By using medial and lateral tibial component insert trials of different thicknesses and/or configurations, the balancing, tensioning, alignment, and/or positioning of the joint can be optimized even in the final steps of the procedure. In certain embodiments, one or more features of a tibial component insert trial can be patient-adapted to fit the particular patient. **FIG. 75B** depicts the process of placing and adding various tibial component insert trials and **FIG. 75C** depicts the process of placing the selected tibial component insert.

[000285] The sets of exemplary spacers, trials, and inserts described in connection with **FIGS. 73A** through **75C** can be expanded to include spacers, trials, and/or inserts having various intermediate thicknesses (e.g., in increments of 0.5 mm, 0.25 mm, and/or 0.1 mm) and/or having various other selection features. For example, sets of femoral and/or tibial insert trials can include

different bone-facing and/or joint-facing surfaces from which the surgeon can select the optimum available surface for further steps in the procedure.

[000286] Using the various spacers, trials, and inserts described above, the knee joint can be flexed and the flexion gap can be evaluated. In addition, the knee can be extended and the extension gap can be evaluated. Ultimately, the surgeon will select an optimal combination of spacers or trials for a given joint, instrument, trial or mold. A surgical cut guide can be applied to the trial, instrument, or mold with the spacers optionally interposed between the trial, instrument or mold and the cut guide. In this manner, the exact position of the surgical cuts can be influenced and can be adjusted to achieve an optimal result. Someone skilled in the art will recognize other means for optimizing the position of the surgical cuts. For example, expandable or ratchet-like devices can be utilized that can be inserted into the joint or that can be attached or that can touch the trial, instrument or mold. Hinge-like mechanisms are applicable. Similarly, jack-like mechanisms are useful. In principal, any mechanical or electrical device useful for fine tuning the position of the cut guide relative to the trial or instrument or molds can be used. The trials or instruments or molds and any related instrumentation such as spacers or ratchets can be combined with a tensiometer to provide a better intraoperative assessment of the joint. The tensiometer can be utilized to further optimize the anatomic alignment and tightness or laxity of the joint and to improve post-operative function and outcomes. Optionally local contact pressures may be evaluated intraoperatively, for example using a sensor like the ones manufactured by Tekscan, South Boston, MA.

Example: Tibial implant design and bone cuts

[000287] This example illustrates tibial implant components and related designs. This example also describes methods and devices for performing a series of tibial bone cuts to prepare a patient's tibia for receiving a tibial implant component. Patient data, such scans of the patient's joint, can be used to locate the point and features used to identify planes, axes and slopes associated with the patient's joint. As shown in **FIG. 143A**, the tibial proximal cut can be selected and/or designed to be a certain distance below a particular location on the patient's tibial plateau. For example, the tibial proximal cut height can be selected and /or designed to be 1 mm, 1.5 mm, 2 mm, 2.5 mm, 3 mm, 3.5 mm, or 4 mm or

more below the lowest point on the patient's tibial plateau or below the lowest point on the patient's medial tibial plateau or below the lowest point on the patient's lateral tibial plateau. In this example, the tibial proximal cut height was selected and designed to be 2 mm below the lowest point on the patient's medial tibial plateau. For example, as shown in **FIG. 143B**, anatomic sketches (e.g., using a CAD program to manipulate a model of the patient's biological structure) can be overlaid with the patient's tibial plateau. As shown in **FIG. 143C**, these sketched overlays can be used to identify the centers of tubercles and the centers of one or both of the lateral and medial plateaus. In addition, as shown in **FIGS. 144A to 144C**, one or more axes such as the patient's anatomic tibial axis **14420**, posterior condylar axis **14430**, and/or sagittal axis **14440** can be derived from anatomic sketches, e.g., based on a defined a midpoint line **14450** between the patient's lateral condyle center and medial condyle center.

[000288] As shown in **FIG. 145A**, the proximal tibial resection was made a 2 mm below the lowest point of the patient's medial tibial plateau with a an A-P slope cut that matched the A-P slope on the patient's medial tibial plateau. As shown in **FIGS. 145B and 145C**, an implant profile **14500** was selected and/or designed to have 90% coverage of the patient's cut tibial surface. In certain embodiments, the tibial implant profile can be selected and/or designed such that tibial implant is supported entirely or substantially by cortical bone and/or such that implant coverage of the cut tibial surface exceeds 100% and/or has no support on cortical bone.

[000289] **FIGS. 146A to 156C** describe exemplary steps for performing resection cuts to the tibia using the anatomical references identified above. For example, as shown in **FIGS. 146A and 146B**, one step can include aligning the top of the tibial jig stylus to the top of the patient's medial and lateral spines (see arrow). As shown in **FIGS. 147A and 147B**, a second step can include drilling and pinning the tibial axis (see arrow). As shown in **FIG. 148**, a third step can include drilling and pinning the medial pin (see arrow). As shown in **FIG. 149**, a fourth step can include removing the stylus. As shown in **FIG. 150**, a fifth step can include sawing 2 mm of tibial bone from the patient's tibial plateau with the patient's medial AP slope. As shown in **FIG. 151**, a sixth step can include removing the resected portion of the patient's tibial plateau. As shown in **FIG.**

152, a seventh step can include assembling stem and keel guide(s) onto the tibial cut guide. As shown in **FIG. 153**, an eighth step can include drilling, e.g., using a 14 mm drill bit (13mm x 40mm stem) to drill a central hole into the proximal tibial surface. As shown in **FIG. 154**, a ninth step can include using a saw or osteotome to create a keel slot, for example, a 3.5mm wide keel slot. **FIG. 155** shows the finished tibial plateau with guide tools still in place. **FIGS. 156A – 156C** show each of a guide tool (**FIG. 156A**), a tibial implant component (**FIG. 156B**), and tibial and femoral implant components (**FIG. 156C**) in the aligned position in the knee.

[000290] This example shows that using a patient's joint axes (e.g., as identified from patient-specific data and optionally from a model of the patient's joint) to select and/or design resection cuts, e.g., the tibia, and corresponding guide tools can create resection cuts perpendicular to the patient's tibial axis and based on the patient's medial AP slope. In addition, one or more features of the corresponding implant components (e.g., tibial tray implant thickness) can be selected and/or designed to align the tibial axis with the femoral axis and thereby correct the patient's alignment.

Example: Tibial tray and insert designs

[000291] This example illustrates exemplary designs and implant components for tibial trays and inserts for certain embodiments described herein. In particular, this example describes a standard blank tibial tray and insert and a method for altering the standard blanks based on patient-specific data to include a patient-adapted feature (e.g., a patient-adapted tray and insert perimeter that substantially match the perimeter of the patient's resected tibia).

[000292] **FIGS. 157A to 157E** illustrate various aspects of an embodiment of a standard blank tibial implant component, including a bottom view (**FIG. 157A**) of a standard blank tibial tray, a top view (**FIG. 157B**) of the standard blank tibial tray, a bottom view (**FIG. 157C**) of a standard blank tibial insert, a top-front (i.e., proximal-anterior) perspective view (**FIG. 157D**) of the standard blank tibial tray, and a bottom front (i.e., distal anterior) perspective view (**FIG. 157E**) of a patient-adapted tibial insert. In this example and in certain embodiments, the top surface of the tibial tray can receive a one-piece tibial insert or two-piece tibial inserts.

The tibial inserts can include one or more patient-adapted features (e.g., patient-matched or patient-engineered perimeter profile, thickness, and/or joint-facing surface) and/or one or more standard features, in addition to a standard locking mechanism to engage the tibial tray. With reference to FIGS. **157D** and **157E**, in certain embodiments the locking mechanism on the tray and insert can include, for example, one or more of: (1) a posterior interlock, (2) a central dovetail interlock, (3) an anterior snap, (4) an anterior interlock, and (5) an anterior wedge.

[000293] If desired, the locking mechanism for securing the tibial insert to the tibial tray can be designed and manufactured as an integral portion of the tibial tray. In some embodiments, the locking mechanism can be significantly smaller than the upper surface of the tray, to allow for perimeter matching of the tray, whereby subsequent machining and/or processing of the outer periphery and upper portion of the tibial tray (to patient-matched dimensions) will not significantly degrade or otherwise affect the locking mechanism (i.e., the final patient-matched perimeter of the implant does not cut-into the lock). In an alternative embodiment, the locking mechanism may extend along the entire upper surface of the tibial tray, whereby perimeter matching of the tray results in removal of some portion of the locking mechanism, yet the remainder of the locking mechanism is still capable of retaining the tibial insert on the tibial tray (i.e., the final patient-matched perimeter of the implant cuts into some of the lock structure, but sufficient lock structure remains to retain the insert in the tray). Such embodiments may have locking mechanisms pre-formed in a library of pre-formed tibial tray blanks. As another alternative, one or more locking mechanism designs may be incorporated into the implant design program, with an appropriate locking mechanism design and size chosen at the time of implant design, and ultimately formed into (or otherwise attached to) a tibial tray (chosen or designed to match patient anatomy) during the process of designing, manufacturing and/or modifying the implant for use with the specific patient. Such design files can include CAD files or subroutines of locking mechanism of various sizes, shaped and/or locking features, with an appropriate locking mechanism chosen at an appropriate time. If desired, the design program can ultimately analyze the chosen/designed lock and locking mechanism to confirm that the final lock will be capable of retaining the insert within the tray under loading and fatigue conditions, and alerting (or

choosing an alternative design) if FEA or other analyses identifies areas of weakness and/or concern in the currently-chosen design.

[000294] Standard blank tibial trays and/or inserts can be prepared in multiple sizes, e.g., having various AP dimensions, ML dimensions, and/or stem and keel dimensions and configurations. For example, in certain-sized embodiments, the stem can be 13 mm in diameter and 40 mm long and the keel can be 3.5 mm wide, 15 degrees biased on the lateral side and 5 degrees biased on the medial side. However, in other-sized embodiments (e.g., having larger or small tray ML and/or AP dimensions, the step and keel can be larger, smaller, or have a different configuration.

[000295] As mentioned above, in this example and in certain embodiments, the tibial tray can receive a one-piece tibial insert or two-piece tibial inserts. **FIGS. 158A to 158C** show aspects of an embodiment of a tibial implant component that includes a tibial tray and a one-piece insert. **FIGS. 159A to 159C** show aspects of an embodiment of a tibial implant component that includes a tibial tray and a one-piece insert. Alternatively, a two-piece tibial insert can be used with a two-piece tibial tray. Alternatively, a one-piece tibial insert can be used with a two-piece tibial tray.

[000296] **FIGS. 160A to 160C** show exemplary steps for altering a blank tibial tray and a blank tibial insert to each include a patient-adapted profile, for example, to substantially match the profile of the patient's resected tibial surface. In particular, as shown in **FIG. 160A**, standard cast tibial tray blanks and standard machined insert blanks (e.g., having standard locking mechanisms) can be finished, e.g., using CAM machining technology, to alter the blanks to include one or more patient-adapted features. For example, as shown in **FIG. 160B**, the blank tray and insert can be finish machined to match or optimize one or more patient-specific features based on patient-specific data. The patient-adapted features machined into the blanks can include for example, a patient-specific perimeter profile and/or one or more medial coronal, medial sagittal, lateral coronal, lateral sagittal bone-facing insert curvatures. **FIG. 160C** illustrates a finished tibial implant component that includes a patient-specific perimeter profile and/or one or more patient-adapted bone-facing insert curvatures.

Example: Tibial implant component design

[000297] This example illustrates tibial implant component selection and/or design to address tibial rotation. **FIGS. 161A to 161B** describe exemplary techniques for determining tibial rotation for a patient.

[000298] Various tibial implant component features can be optimized to ensure proper tibial rotation. For example, **FIG. 162** illustrates exemplary stem design options for a tibial tray including using stem and keel dimensions that increase or decrease depending on the size of the tibial implant component (e.g., in the ML and/or AP dimension). Moreover, cement pockets can be employed to enhance stabilization upon implantation. In addition, patient-specific stem and keel guide tools can be selected and/or designed so that the prepared stem and keel holes in a patient's proximal tibia are properly sized, which can minimize rotation (e.g., of a keel in a keel hole that is too large).

[000299] Another tibial implant component that can be used to address tibial rotation is selecting and/or designing a tibial tray perimeter profile and/or a tibial insert perimeter profile that minimizes overhang from the patient's bone (which may catch and cause rotation) and, optionally, that maximizes seating of the implant component on cortical bone. Accordingly, in certain embodiments, the tibial tray perimeter profile and/or a tibial insert perimeter profile is preoperatively selected and/or designed to substantially match the perimeter profile of the patient's resected tibial surface. **FIGS. 163A and 163B** show an approach for identifying the patient's tibial implant perimeter profile based on the depth and angle of the proximal tibial resection, which can be applied in the selection and/or design of the tibial tray perimeter profile and/or the tibial insert perimeter profile. As shown in the bottom image, the lines inside the perimeter of the cut surface represent the perimeters of the various cuts in the top image taken at various depths from the patient's tibial surface. **FIGS. 164A and 164B** show the same approach as described for **FIGS. 163A and 163B**, but applied to a different patient having a smaller tibia (e.g., smaller diameter and perimeter length).

[000300] Similarly, **FIGS. 165A to 165D** show four different exemplary tibial implant profiles, for example, having different medial and lateral condyle perimeter shapes that generally match various different relative medial and lateral condyle

perimeter dimensions. In certain embodiments, a tibial tray and/or insert can be selected (e.g., preoperatively or intraoperatively) from a collection or library of implants for a particular patient (i.e., to best-match the perimeter of the patient's cut tibial surface) and implanted without further alteration to the perimeter profile. However, in certain embodiments, these different tibial tray and/or insert perimeter profiles can serve as blanks. For example, one of these tibial tray and/or insert profiles can be selected preoperatively from a library (e.g., an actual or virtual library) for a particular patient to best-match the perimeter of the patient's cut tibial surface. Then, the selected implant perimeter can be designed or further altered based on patient-specific data, for example, to substantially match the perimeter of the patient's cut tibial surface.

[000301] As described in this example, various features of a tibial implant component can be designed or altered based on patient-specific data. For example, the tibial implant component design or alterations can be made to maximize coverage and extend to cortical margins; maximize medial compartment coverage; minimize overhang from the medial compartment; avoid internal rotation of tibial components to avoid patellar dislocation; and avoid excessive external rotation to avoid overhang laterally and impingement on the popliteus tendon.

TOTAL KNEE REPLACEMENT DESIGNS

[000302] As disclosed herein, several different total knee replacement designs are possible. These include, for example:

[000303] - Bicruciate retaining designs (bCR)

[000304] - Posterior cruciate retaining designs (CR) (sacrificing the ACL, unless it is already torn)

[000305] - Posterior stabilized designs (PS) (cruciate sacrificing, replacing both the ACL and the PCL)

Example: Posterior stabilized total knee replacement

[000306] Most posterior stabilized implants use a central post originating from the tibial component, which mates with a box, bar, or strut-like structure in the intercondylar region of the femoral component. Such posterior stabilized systems, generally referred to herein as box-post (PSBP) configurations, can substitute

and/or compensate, at least in part, for a removed PCL and/or ACL.

[000307] As disclosed herein, another approach to substitute for the function of the PCL and/or ACL can be the use of a “deep dish” tibial implant (e.g., tibial component, tray, and/or insert). In such deep-dish configurations, the height of portions (e.g., an anterior portion and, optionally, a posterior portion) of the superior surface of the tibial implant can be greater than that used with standard tibial inserts or tibial components for bCR, CR, and PSBP implants. This increased height of portions the superior surface can provide for an increased “jump height.” As, used herein, “jump height” refers to the amount of vertical (i.e., in the superior direction) travel the knee femoral component needs to move before it dislocates from the tibial surface. For example, in some embodiments, a jump height can be determined by the difference in height of a lowest (i.e., inferior-most) portion of the superior surface of the tibial implant and a highest (i.e., superior-most) portion of the superior surface. Furthermore, in some embodiments, the height of an anterior portion of the superior surface of deep dish components can be greater than the height of a posterior portion. The greater anterior height may help to prevent the femoral component from translating further anteriorly than typically desired during various types of movements (e.g., stair climbing), thereby, at least partially, substituting for the function of the PCL.

[000308] Often, standard tibial implants, including some PSBP configurations, are configured to have an anterior jump height of between about 3mm and 6mm, and a posterior jump height that is slightly smaller. In some deep-dish embodiments, as disclosed herein, which may not require a box and post-type configuration, the tibial implant may provide anterior jump height of at least about 5 mm, at least about 7 mm, or at least about 10 mm. In some embodiments disclosed herein, the tibial implant may be configured to provide an anterior jump height of between about 5 mm and about 10 mm. Optionally, some embodiments disclosed herein may be configured to provide a posterior jump height of greater than about 4 mm, greater than about 6 mm, or greater than about 10 mm. In some embodiments, a tibial implant may be configured to provide a posterior jump height of between about 4 mm and about 8 mm.

[000309] Some deep-dish tibial implant embodiments can be patient adapted. For example, some one or more components of tibial implant deep-dish

embodiments can have one or more patient-specific or patient-engineered features (e.g., dimension, curvature). By way of example, a tibial implant may comprise a metal tray configured for use with one or more patient-adapted deep dish inserts. In some embodiments, the metal tray can also have patient-specific and/or patient-engineered features. An exemplary list of possible patient-adapted features that a deep-dish implant system can include is provided in **Table 1** herein. Further, deep-dish implants and systems (including individual implant components) can have standard features, patient-adapted features, and/or combinations thereof, as show in **Table 2** herein.

[000310] Patient-adapted features of various deep-dish embodiments can be determined based, at least in part, on various features and measurements, including, for example, those provided in **Table 4** herein.

[000311] Some deep-dish embodiments can include combinations of patient-adapted components, pieces, or features and components, pieces, or features selected from a library as described in **Table 7**. In some embodiments, imaging data associated with the relevant joint of the patient may be obtained and patient-specific information (e.g., shapes, dimensions, curvatures) derived therefrom, which may be used for selecting the components, pieces, or features from the library for that particular patient.

[000312] Various deep dish embodiments disclosed herein can be configured for various standard and/or patient-adapted tibial slopes, including, for example, those described in **Table 13** herein. In such embodiments, one or more tibial slopes may be achieved through the direction and/or orientation of proximal tibial cut(s). Additionally or alternatively, one or more components of a tibial implant (e.g., tibial tray, insert(s)) can be selected or adapted or designed with one or more predetermined tibial slopes. Some embodiments may include different medial and lateral slopes. In some embodiments, the one or more slopes may be designed to enable and/or encourage a more normal rollback of the one or more condyles with respect to the tibia.

[000313] In some embodiments, deep dish implants can be selected, adapted or designed to achieve desirable and/or predetermined states of one or more of the following: ligament tension, ligament balance, and flexion and/or extension

gap. In some embodiments, imaging can be used for this purpose, which, optionally, can be combined with adjustment mechanisms for patient-adapted jigs. Additionally or alternatively, surgical navigation or robotics can be used for this purpose, alone or in combination with patient-specific jigs.

[000314] As discussed above, in some embodiments, a deep-dish tibial implant may comprises a tibial tray and one or more inserts. For example, the tibial tray may be sized, shaped, and configured for placement on a proximal tibial surface and the one or more inserts can be configured to engage the superior surface of the tibial tray. In some embodiments, the deep-dish implant can include a single insert for both medial and lateral compartments of the knee. In other embodiments, the deep-dish implant can include multiple inserts, for example, with a medial insert for the medial compartment and a separate lateral insert for the lateral compartment. In some embodiments, the medial and lateral thickness or height can vary and can optionally be based on the position of the medial and lateral joint line and/or the distal or posterior offset of the medial and lateral condyles. Furthermore, in some embodiments, the medial insert can have a deep-dish configuration, while the lateral insert shape can have a regular configuration, without increased height. Alternatively, the lateral insert shape can have a deep-dish configuration, while the medial insert shape can have a regular configuration, without increased height. For example, **FIG. 192** depicts a sagittal cross-section a lateral portion of a tibial implant, while **FIG. 193** depicts a sagittal cross-section of a medial portion of the same tibial implant. As illustrated, the medial portion, shown in **FIG. 193**, has a deep-dish configuration, with a maximum height of h_3 . The lateral portion, shown in **FIG. 192**, has a standard (i.e., non-deep-dish) configuration, with a maximum height of h_2 that is smaller than h_3 .

[000315] Various of the deep-dish embodiments disclosed herein can be manufactured using manufacturing techniques known in the art or developed in the future, including, for example, those described in **Table 18** herein.

[000316] The bearing (e.g., superior) surface or bearing geometry of the one or more portions of deep-dish embodiments can be standard, e.g., matched to a standard femoral bearing surface geometry, or can be patient-adapted in one or more planes, e.g., a sagittal plane or a coronal plane, as described, for example, in **Table 3**.

[000317] The curvature of one or more, e.g., medial, lateral, or combinations thereof, deep-dish tibial components can be patient-adapted based, at least in part, on one or more biomechanical and/or kinematic parameters. "Curvature" is used herein to generally refer to properties including shape, surface contour, profile, and/or slope with respect to one or more planes, and can include substantially straight features and/or curvilinear features having one or more radii of curvature. The biomechanical and/or kinematic parameters can be, for example, biomechanical or kinematic data obtained from a reference database, e.g., a database of patients with similar anthropometric features. Additionally or alternatively, at least one or more biomechanical and/or kinematic parameters can be derived from a particular patient and can be used to select, adapt or design deep-dish implant components for a particular patient. Exemplary biomechanical and/or kinematic parameters that can be utilized for deep-dish embodiments disclosed herein can include those provided in **Table 6**.

For example, in some embodiments, a sagittal geometry of a patient's femoral condyle or of a patient-adapted femoral component can be used to select, adapt or design a deep-dish component. In some embodiments, for example, one or more of the following can be measured or determined: a distal femoral (condyle or component) sagittal curvature, a posterior femoral (condyle or component) sagittal curvature, a femoral (condyle or component) sagittal curvature or shape in the transition area between distal and posterior region, an anterior femoral (condyle or component) sagittal curvature, and the curvatures of all of the femoral condyle or component. Additionally or alternatively, the coronal curvature of the femoral condyle or component can be measured in one or multiple locations along the condyle. One or more of the forgoing measured and/or determined curvatures can be used to select, adapt or design a deep-dish implant having a patient-adapted anterior and/or posterior height, and/or a patient-adapted height difference (e.g., jump height) of an anterior and/or posterior portion of the implant. Additionally or alternatively, one or more of the forgoing measured and/or determined curvatures can be used to select, adapt or design a predetermined curvature (including, e.g., slope) between the lowest point on the superior surface of the component and the highest or any other point or area on the superior surface of the component. Such predetermined curvatures can include sagittal

and/or coronal curvatures, e.g., towards the tibial spines.

[000318] **FIGS. 194-198** depict sagittal cross-sectional views of exemplary patient-adapted deep-dish tibial implants and corresponding femoral component curvatures and/or native femoral curvatures. A maximum anterior and/or posterior height (which in some embodiments, may be located at the respective anterior and posterior edges of the implant, while in other embodiments may be located inwards from the anterior and/or posterior edges) in the superior direction, the height difference between lowest and highest point of the superior surface of the implant, and/or one or more curvatures (e.g., anterior curvature, posterior curvature) can be selected, adapted, and/or designed for a particular patient, for example by analyzing the femoral and/or tibial shape including cartilage or subchondral bone shape, e.g., the sagittal radii. As illustrated, the anterior and posterior height and the curvatures can vary between different patients.

[000319] For example, comparing the tibial components in **FIGS. 194** and **198**, in particular, comparing curvatures **4X1** and **4X2** in **FIG. 194** and **198**, it can be seen that for a femoral condyle having a generally broader distal sagittal curvature, the curvature **4X2** of a posterior portion of a corresponding deep-dish tibial implant may be generally less concave, may have a relatively lower maximum height, and at least a portion of the perimeter of the tibial implant may extend beyond (e.g., posteriorly) the perimeter of the cut tibial surface, as shown in **Fig. 198**.

[000320] Additionally or alternatively, in some embodiments, the anterior height, posterior height, height difference between lowest and highest point of the superior surface, and/or one or more curvatures of a tibial component can be based on one or more properties associated with the patient's PCL (and/or ACL), including, for example, origin location, insertion location, length, and elasticity.

[000321] In some embodiments, one or more of ACL stress; PCL stress; and anterior, posterior, medial and/or lateral loading stress can be modeled for flexion and/or extension, optionally with an incompetent ACL, PCL, MCL, LCL, or combinations thereof in the model. The simulation can be based on, for example, preoperative images such as MRI or CT or dynamic images that capture pre-operative knee motion. The simulation can also be based on a generic model.

The generic model can be used to simulate different types of physical activity or biomotion. Results of the simulation(s) can be used to select, adapt or design one or more deep-dish component features, as discussed above, including, for example, an anterior height, posterior height, height difference between lowest and highest point of the insert or component, or one or more curvatures. Similar simulations can be performed for other types of non-deep dish tibial components including tibial components that are standard, selected from a library or patient-adapted or patient-specific inserts or components.

[000322] In some embodiments, the anterior height, posterior height, height difference between lowest and highest point of the superior surface, and/or one or more curvatures (e.g., one or more sagittal curvatures, one or more coronal curvatures) of a tibial component can be selected, adapted or designed based on not only one, but multiple parameters, including, for example, one or more of the following: a sagittal femoral condyle or component geometry or curvature; a coronal femoral condyle or component geometry or curvature; a condyle width; an intercondylar width; and one or more biomechanical or kinematics simulations. Any parameter used throughout the application can be included in a non-limiting fashion.

[000323] In some embodiments, a deep-dish configuration of the tibial implant or insert can be combined with a sagittal shape that allows for rollback of the femur when going into flexion. For example, the medial compartment of a tibial implant can have a deep-dish design, while the tibial surface of the lateral compartment is less constraining or is convex. In some embodiments, such a configuration can produce more natural knee kinematics with normal internal/external rotation of the tibia relative to the femur by allowing for rollback of the lateral femoral condyle in flexion. Additionally or alternatively, in some embodiments, deep dish and rollback features can be combined in the same compartment, e.g., with an elevated anterior height and a lower posterior height, a less concave posterior portion, and/or a convex posterior portion (i.e., combining convex posterior portion and concave anterior portion in the same compartment). A suitable combination of convex and concave areas may be used to reconstruct normal or near normal knee kinematics in the absence of cruciate ligaments. Such a suitable combination of different shapes can, for example, be found by

using kinematic simulations to predict the effects of various design and shape combinations.

[000324] Additionally or alternatively, in some embodiments, patient-adapted deep-dish configurations in at least one compartment, as described above, can be combined box, post, and/or cam features, as also described above, in a femoral and tibial implant system.

Example: Exemplary method of designing an implant

[000325] An exemplary process, such as depicted in **FIG. 87**, can include four general steps and, optionally, can include a fifth general step. Each general step includes various specific steps, as described below. These steps can be performed virtually, for example, by using one or more computers that have or can receive patient-specific data and specifically configured software or instructions to perform such steps.

[000326] In general step (1), limb alignment and deformity corrections are determined, to the extent that either is needed for a specific patient's situation.

[000327] In general step (2), the requisite tibial and femoral dimensions of the implant components are determined based on patient-specific data obtained, for example, from image data of the patient's knee.

[000328] In general step (3), bone preservation is maximized by virtually determining a resection cut strategy for the patient's femur and/or tibia that provides minimal bone loss optionally while also meeting other user-defined parameters such as, for example, maintaining a minimum implant thickness, using certain resection cuts to help correct the patient's misalignment, removing diseased or undesired portions of the patient's bone or anatomy, and/or other parameters. This general step can include one or more of the steps of (i) simulating resection cuts on one or both articular sides (e.g., on the femur and/or tibia), (ii) applying optimized cuts across one or both articular sides, (iii) allowing for non-co-planar and/or non-parallel femoral resection cuts (e.g., on medial and lateral corresponding portions of the femur) and, optionally, non-co-planar and/or non-parallel tibial resection cuts (e.g., on medial and lateral corresponding portions of the tibia), and (iv) maintaining and/or determining minimal material thickness. The minimal material thickness for the implant selection and/or design

can be an established threshold, for example, as previously determined by a finite element analysis ("FEA") of the implant's standard characteristics and features. Alternatively, the minimal material thickness can be determined for the specific implant, for example, as determined by an FEA of the implant's standard and patient-specific characteristics and features. If desired, FEA and/or other load-bearing/modeling analysis may be used to further optimize or otherwise modify the individual implant design, such as where the implant is under or over-engineered than required to accommodate the patient's biomechanical needs, or is otherwise undesirable in one or more aspects relative to such analysis. In such a case, the implant design may be further modified and/or redesigned to more accurately accommodate the patient's needs, which may have the side effect of increasing/reducing implant characteristics (i.e., size, shape or thickness) or otherwise modifying one or more of the various design "constraints" or limitations currently accommodated by the present design features of the implant. If desired, this step can also assist in identifying for a surgeon the bone resection design to perform in the surgical theater and it also identifies the design of the bone-facing surface(s) of the implant components, which substantially negatively-match the patient's resected bone surfaces, at least in part.

[000329] In general step (4), a corrected, normal and/or optimized articular geometry on the femur and tibia is recreated virtually. For the femur, this general step can include, for example, the step of: (i) selecting a standard sagittal profile, or selecting and/or designing a patient-engineered or patient-specific sagittal profile; and (ii) selecting a standard coronal profile, or selecting and/or designing a patient-specific or patient-engineered coronal profile. Optionally, the sagittal and/or coronal profiles of one or more corresponding medial and lateral portions (e.g., medial and lateral condyles) can include different curvatures. For the tibia, this general step includes one or both of the steps of: (iii) selecting a standard anterior-posterior slope, and/or selecting and/or designing a patient-specific or patient-engineered anterior-posterior slope, either of which optionally can vary from medial to lateral sides; and (iv) selecting a standard poly-articular surface, or selecting and/or designing a patient-specific or patient-engineered poly-articular surface. The patient-specific poly-articular surface can be selected and/or designed, for example, to simulate the normal or optimized three-dimensional

geometry of the patient's tibial articular surface. The patient-engineered poly-articular surface can be selected and/or designed, for example, to optimize kinematics with the bearing surfaces of the femoral implant component. This step can be used to define the bearing portion of the outer, joint-facing surfaces (i.e., articular surfaces) of the implant components.

[000330] In optional general step (5), a virtual implant model (for example, generated and displayed using a computer specifically configured with software and/or instructions to assess and display such models) is assessed and can be altered to achieve normal or optimized kinematics for the patient. For example, the outer joint-facing or articular surface(s) of one or more implant components can be assessed and adapted to improve kinematics for the patient. This general step can include one or more of the steps of: (i) virtually simulating biomotion of the model, (ii) adapting the implant design to achieve normal or optimized kinematics for the patient, and (iii) adapting the implant design to avoid potential impingement.

[000331] The exemplary process described above yields both a predetermined surgical resection design for altering articular surfaces of a patient's bones during surgery and a design for an implant that specifically fits the patient, for example, following the surgical bone resectioning. Specifically, the implant selection and/or design, which can include manufacturing or machining the implant to the selected and/or designed specifications using known techniques, includes one or more patient-engineered bone-facing surfaces that negatively-match the patient's resected bone surface. The implant also can include other features that are patient-adapted, such as minimal implant thickness, articular geometry, and kinematic design features. This process can be applied to various joint implants and to various types of joint implants, such as for example, a total knee, cruciate retaining, posterior stabilized, and/or ACL/PCL retaining knee implants, bicompartamental knee implants, and unicompartamental knee implants.

Manufacturing

[000332] The step of designing an implant component and/or guide tool as described herein can include both configuring one or more features, measurements, and/or dimensions of the implant and/or guide tool (e.g., derived from patient-specific data from a particular patient and adapted for the particular

patient) and manufacturing the implant. In certain embodiments, manufacturing can include making the implant component and/or guide tool from starting materials, for example, metals and/or polymers or other materials in solid (e.g., powders or blocks) or liquid form. In addition or alternatively, in certain embodiments, manufacturing can include altering (e.g., machining) an existing implant component and/or guide tool, for example, a standard blank implant component and/or guide tool or an existing implant component and/or guide tool (e.g., selected from a library). The manufacturing techniques to making or altering an implant component and/or guide tool can include any techniques known in the art today and in the future. Such techniques include, but are not limited to additive as well as subtractive methods, i.e., methods that add material, for example to a standard blank, and methods that remove material, for example from a standard blank.

[000333] Various technologies appropriate for this purpose are known in the art, for example, as described in Wohlers Report 2009, State of the Industry Annual Worldwide Progress Report on Additive Manufacturing, Wohlers Associates, 2009 (ISBN 0-9754429-5-3), available from the web www.wohlersassociates.com; Pham and Dimov, Rapid manufacturing, Springer-Verlag, 2001 (ISBN 1-85233-360-X); Grenda, Printing the Future, The 3D Printing and Rapid Prototyping Source Book, Castle Island Co., 2009; Virtual Prototyping & Bio Manufacturing in Medical Applications, Bidanda and Bartolo (Eds.), Springer, December 17, 2007 (ISBN: 10: 0387334297; 13: 978-0387334295); Bio-Materials and Prototyping Applications in Medicine, Bártolo and Bidanda (Eds.), Springer, December 10, 2007 (ISBN: 10: 0387476822; 13: 978-0387476827); Liou, Rapid Prototyping and Engineering Applications: A Toolbox for Prototype Development, CRC, September 26, 2007 (ISBN: 10: 0849334098; 13: 978-0849334092); Advanced Manufacturing Technology for Medical Applications: Reverse Engineering, Software Conversion and Rapid Prototyping, Gibson (Ed.), Wiley, Jan. 2006 (ISBN: 10: 0470016884; 13: 978-0470016886); and Branner *et al.*, "Coupled Field Simulation in Additive Layer Manufacturing," 3rd International Conference PMI, 2008 (10 pages).

[000334] Exemplary techniques for adapting an implant to a patient's anatomy include, but are not limited to those shown in **Table 18**.

Table 18: Exemplary techniques for forming or altering a patient-specific and/or patient-engineered implant component for a patient's anatomy

Technique	Brief description of technique and related notes
CNC	CNC refers to computer numerically controlled (CNC) machine tools, a computer-driven technique, e.g., computer-code instructions, in which machine tools are driven by one or more computers. Embodiments of this method can interface with CAD software to streamline the automated design and manufacturing process.
CAM	CAM refers to computer-aided manufacturing (CAM) and can be used to describe the use of software programming tools to efficiently manage manufacturing and production of products and prototypes. CAM can be used with CAD to generate CNC code for manufacturing three-dimensional objects.
Casting, including casting using rapid prototyped casting patterns	Casting is a manufacturing technique that employs a mold. Typically, a mold includes the negative of the desired shape of a product. A liquid material is poured into the mold and allowed to cure, for example, with time, cooling, and/or with the addition of a solidifying agent. The resulting solid material or casting can be worked subsequently, for example, by sanding or bonding to another casting to generate a final product.
Welding	Welding is a manufacturing technique in which two components are fused together at one or more locations. In certain embodiments, the component joining surfaces include metal or thermoplastic and heat is administered as part of the fusion technique.
Forging	Forging is a manufacturing technique in which a product or component, typically a metal, is shaped, typically by heating and applying force.
Rapid prototyping	Rapid prototyping refers generally to automated construction of a prototype or product, typically using an additive manufacturing technology, such as EBM, SLS, SLM, SLA, DMLS, 3DP, FDM and other technologies
EBM®	EBM® refers to electron beam melting (EBM®), which is a powder-based additive manufacturing technology. Typically, successive layers of metal powder are deposited and melted with an electron beam in a vacuum.
SLS	SLS refers to selective laser sintering (SLS), which is a powder-based additive manufacturing technology. Typically, successive layers of a powder (e.g., polymer, metal, sand, or other material) are deposited and melted with a scanning laser, for example, a carbon dioxide laser.

Technique	Brief description of technique and related notes
SLM	SLM refers to selective laser melting™ (SLM), which is a technology similar to SLS; however, with SLM the powder material is fully melted to form a fully-dense product.
SLA or SL	SLA or SL refers to stereolithography (SLA or SL), which is a liquid-based additive manufacturing technology. Typically, successive layers of a liquid resin are exposed to a curing, for example, with UV laser light, to solidify each layer and bond it to the layer below. This technology typically requires the additional and removal of support structures when creating particular geometries.
DMLS	DMLS refers to direct metal laser sintering (DMLS), which is a powder-based additive manufacturing technology. Typically, metal powder is deposited and melted locally using a fiber optic laser. Complex and highly accurate geometries can be produced with this technology. This technology supports net-shaping, which means that the product generated from the technology requires little or no subsequent surface finishing.
LC	LC refers to LaserCusing®(LC), which is a powder-based additive manufacturing technology. LC is similar to DMLS; however, with LC a high-energy laser is used to completely melt the powder, thereby creating a fully-dense product.
3DP	3DP refers to three-dimensional printing (3DP), which is a high-speed additive manufacturing technology that can deposit various types of materials in powder, liquid, or granular form in a printer-like fashion. Deposited layers can be cured layer by layer or, alternatively, for granular deposition, an intervening adhesive step can be used to secure layered granules together in bed of granules and the multiple layers subsequently can be cured together, for example, with laser or light curing.
LENS	LENS® refers to Laser Engineered Net Shaping™ (LENS®), which is a powder-based additive manufacturing technology. Typically, a metal powder is supplied to the focus of the laser beam at a deposition head. The laser beam melts the powder as it is applied, in raster fashion. The process continues layer by and layer and requires no subsequent curing. This technology supports net-shaping, which means that the product generated from the technology requires little or no subsequent surface finishing.

Technique	Brief description of technique and related notes
FDM	FDM refers to fused deposition modeling™ (FDM) is an extrusion-based additive manufacturing technology. Typically, beads of heated extruded polymers are deposited row by row and layer by layer. The beads harden as the extruded polymer cools.

IMPLANT COMPONENTS GENERATED FROM DIFFERENT MANUFACTURING METHODS

[000335] Implant components generated by different techniques can be assessed and compared for their accuracy of shape relative to the intended shape design, for their mechanical strength, and for other factors. In this way, different manufacturing techniques can supply another consideration for achieving an implant component design with one or more target features. For example, if accuracy of shape relative to the intended shape design is critical to a particular patient's implant component design, then the manufacturing technique supplying the most accurate shape can be selected. If a minimum implant thickness is critical to a particular patient's implant component design, then the manufacturing technique supplying the highest mechanical strength and therefore allowing the most minimal implant component thickness, can be selected. Branner *et al.* describe a method a method for the design and optimization of additive layer manufacturing through a numerical coupled-field simulation, based on the finite element analysis (FEA). Branner's method can be used for assessing and comparing product mechanical strength generated by different additive layer manufacturing techniques, for example, SLM, DMLS, and LC.

[000336] In certain embodiments, an implant can include components and/or implant component parts produced via various methods. For example, in certain embodiments for a knee implant, the knee implant can include a metal femoral implant component produced by casting or by an additive manufacturing technique and having a patient-specific femoral intercondylar distance; a tibial component cut from a blank and machined to be patient-specific for the perimeter of the patient's cut tibia; and a tibial insert having a standard lock and a top surface that is patient-specific for at least the patient's intercondylar distance between the tibial insert dishes to accommodate the patient-specific femoral

intercondylar distance of the femoral implant.

[000337] As another example, in certain embodiments a knee implant can include a metal femoral implant component produced by casting or by an additive manufacturing technique that is patient-specific with respect to a particular patient's M-L dimension and standard with respect to the patient's femoral intercondylar distance; a tibial component cut from a blank and machined to be patient-specific for the perimeter of the patient's cut tibia; and a tibial insert having a standard lock and a top surface that includes a standard intercondylar distance between the tibial insert dishes to accommodate the standard femoral intercondylar distance of the femoral implant.

REPAIR MATERIALS

[000338] A wide variety of materials find use in the practice of the embodiments described herein, including, but not limited to, plastics, metals, crystal free metals, ceramics, biological materials (e.g., collagen or other extracellular matrix materials), hydroxyapatite, cells (e.g., stem cells, chondrocyte cells or the like), or combinations thereof. Based on the information (e.g., measurements) obtained regarding the defect and the articular surface and/or the subchondral bone, a repair material can be formed or selected. Further, using one or more of these techniques described herein, a cartilage replacement or regenerating material having a curvature that will fit into a particular cartilage defect, will follow the contour and shape of the articular surface, and will match the thickness of the surrounding cartilage. The repair material can include any combination of materials, and typically includes at least one non-pliable material, for example materials that are not easily bent or changed.

[000339] Currently, joint repair systems often employ metal and/or polymeric materials including, for example, prostheses which are anchored into the underlying bone (e.g., a femur in the case of a knee prosthesis). See, e.g., U.S. Pat. No. 6,203,576 to Afriat et al. issued Mar. 20, 2001 and U.S. Pat. No. 6,322,588 to Ogle, et al. issued Nov. 27, 2001, and references cited therein. A wide-variety of metals is useful in the practice of the embodiments described herein, and can be selected based on any criteria. For example, material selection can be based on resiliency to impart a desired degree of rigidity. Non-

limiting examples of suitable metals include silver, gold, platinum, palladium, iridium, copper, tin, lead, antimony, bismuth, zinc, titanium, cobalt, stainless steel, nickel, iron alloys, cobalt alloys, such as Elgiloy®, a cobalt-chromium-nickel alloy, and MP35N, a nickel-cobalt-chromiummolybdenum alloy, and Nitinol T™, a nickel-titanium alloy, aluminum, manganese, iron, tantalum, crystal free metals, such as Liquidmetal® alloys (available from LiquidMetal Technologies, www.liquidmetal.com), other metals that can slowly form polyvalent metal ions, for example to inhibit calcification of implanted substrates in contact with a patient's bodily fluids or tissues, and combinations thereof.

[000340] Suitable synthetic polymers include, without limitation, polyamides (e.g., nylon), polyesters, polystyrenes, polyacrylates, vinyl polymers (e.g., polyethylene, polytetrafluoroethylene, polypropylene and polyvinyl chloride), polycarbonates, polyurethanes, poly dimethyl siloxanes, cellulose acetates, polymethyl methacrylates, polyether ether ketones, ethylene vinyl acetates, polysulfones, nitrocelluloses, similar copolymers and mixtures thereof.

Bioresorbable synthetic polymers can also be used such as dextran, hydroxyethyl starch, derivatives of gelatin, polyvinylpyrrolidone, polyvinyl alcohol, poly[N-(2-hydroxypropyl) methacrylamide], poly(hydroxy acids), poly(epsilon-caprolactone), polylactic acid, polyglycolic acid, poly(dimethyl glycolic acid), poly(hydroxy butyrate), and similar copolymers.

[000341] Other appropriate materials include, for example, the polyketone known as polyetheretherketone (PEEK). This includes the material PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com).

[000342] It should be noted that the material selected can also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that portion which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon filled PEEK is known to enhance

the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon filled PEEK offers wear resistance and load carrying capability.

[000343] As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, are deflectable, have very low moisture absorption, and/or have good wear and/or abrasion resistance, can be used. The implant can also be comprised of polyetherketoneketone (PEKK).

[000344] Other materials that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and, generally, a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics.

[000345] Reference to appropriate polymers that can be used for the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated Jan. 10, 2002 and entitled Bio-Compatible Polymeric Materials; PCT Publication WO 02/00275 A1, dated Jan. 3, 2002 and entitled Bio-Compatible Polymeric Materials; and PCT Publication WO 02/00270 A1, dated Jan. 3, 2002 and entitled Bio-Compatible Polymeric Materials.

[000346] The polymers can be prepared by any of a variety of approaches including conventional polymer processing methods. Preferred approaches include, for example, injection molding, which is suitable for the production of polymer components with significant structural features, and rapid prototyping approaches, such as reaction injection molding and stereo-lithography. The substrate can be textured or made porous by either physical abrasion or chemical alteration to facilitate incorporation of the metal coating. Other processes are also appropriate, such as extrusion, injection, compression molding and/or machining techniques. Typically, the polymer is chosen for its physical and mechanical properties and is suitable for carrying and spreading the physical load between the joint surfaces.

[000347] More than one metal and/or polymer can be used in combination with each other. For example, one or more metal-containing substrates can be coated with polymers in one or more regions or, alternatively, one or more

polymer-containing substrate can be coated in one or more regions with one or more metals.

[000348] The system or prosthesis can be porous or porous coated. The porous surface components can be made of various materials including metals, ceramics, and polymers. These surface components can, in turn, be secured by various means to a multitude of structural cores formed of various metals. Suitable porous coatings include, but are not limited to, metal, ceramic, polymeric (e.g., biologically neutral elastomers such as silicone rubber, polyethylene terephthalate and/or combinations thereof or combinations thereof. See, e.g., U.S. Pat. No. 3,605,123 to Hahn, issued Sep. 20, 1971. U.S. Pat. No. 3,808,606 to Tronzo issued May 7, 1974 and U.S. Pat. No. 3,843,975 to Tronzo issued Oct. 29, 1974; U.S. Pat. No. 3,314,420 to Smith issued Apr. 18, 1967; U.S. Pat. No. 3,987,499 to Scharbach issued Oct. 26, 1976; and German Offenlegungsschrift 2,306,552. There can be more than one coating layer and the layers can have the same or different porosities. See, e.g., U.S. Pat. No. 3,938,198 to Kahn, et al., issued Feb. 17, 1976.

[000349] The coating can be applied by surrounding a core with powdered polymer and heating until cured to form a coating with an internal network of interconnected pores. The tortuosity of the pores (e.g., a measure of length to diameter of the paths through the pores) can be important in evaluating the probable success of such a coating in use on a prosthetic device. See, also, U.S. Pat. No. 4,213,816 to Morris issued Jul. 22, 1980. The porous coating can be applied in the form of a powder and the article as a whole subjected to an elevated temperature that bonds the powder to the substrate. Selection of suitable polymers and/or powder coatings can be determined in view of the teachings and references cited herein, for example based on the melt index of each.

[000350] Any material known in the art can be used for any of the implant systems and component described in the foregoing embodiments, for example including, but not limited to metal, metal alloys, combinations of metals, plastic, polyethylene, cross-linked polyethylene's or polymers or plastics, pyrolytic carbon, nanotubes and carbons, as well as biologic materials.

[000351] Any fixation techniques and combinations thereof known in the art can be used for any of the implant systems and component described in the foregoing embodiments, for example including, but not limited to cementing techniques, porous coating of at least portions of an implant component, press fit techniques of at least a portion of an implant, ingrowth techniques, etc.

INCORPORATION BY REFERENCE

[000352] The entire disclosure of each of the publications, patent documents, and other references referred to herein is incorporated herein by reference in its entirety for all purposes to the same extent as if each individual source were individually denoted as being incorporated by reference.

EQUIVALENTS

[000353] The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting on the invention described herein. Scope of the invention is thus indicated by the appended claims rather than by the foregoing description, and all changes that come within the meaning and range of equivalency of the claims are intended to be embraced therein.

CLAIMS

What is claimed is:

1. A tibial implant for treating a knee joint of a patient, the tibial implant comprising:
 - a superior surface generally opposite an inferior surface, the superior surface having a first curvature and having an inferior-most point;
 - an anterior portion generally opposite a posterior portion; and
 - a medial portion generally opposite a lateral portion,wherein the first curvature is based, at least in part, on patient-specific information regarding the knee joint of the patient, and
 - wherein a height difference in the superior direction between the inferior-most point of the superior surface and a superior-most point of the superior surface in the anterior portion is between about 5 mm and about 10 mm.
2. A tibial implant for treating a knee joint of a patient, the tibial implant comprising:
 - a superior surface generally opposite an inferior surface, the superior surface having a first height relative to the inferior surface and having an inferior-most point;
 - an anterior portion generally opposite a posterior portion; and
 - a medial portion generally opposite a lateral portion,wherein the first height is based, at least in part, on patient-specific information regarding the knee joint of the patient, and
 - wherein a height difference in the superior direction between the inferior-most point of the superior surface and a superior-most point of the superior surface in the anterior portion is between about 5 mm and about 10 mm.
3. A system for treating a knee joint of a patient, the system comprising:
 - a femoral implant having a joint-facing surface that includes a first curvature that is based, at least in part, on patient-specific information regarding the knee joint of the patient; and
 - a tibial implant, comprising:
 - a superior surface generally opposite an inferior surface, the superior surface having a first curvature and having an inferior-most point;

an anterior portion generally opposite a posterior portion; and
a medial portion generally opposite a lateral portion,

wherein the first curvature of the superior surface is based, at least in part, on the first curvature of the joint-facing surface of the femoral implant, and

wherein a height difference in the superior direction between the inferior-most point of the superior surface and a superior-most point of the superior surface in the anterior portion is between about 5 mm and about 10 mm.

4. A method of making the tibial implant of claim 1, the tibial implant of claim 2, or the system of claim 3 for treating a knee joint of a patient, the method comprising:

obtaining image data and/or kinematic data regarding the knee joint of the patient;

determining patient-specific information regarding the knee joint of the patient based on the image data and/or kinematic data; and
specifying one or more parameters of the tibial implant based, at least in part, on the patient-specific information.

5. The tibial implant of claim 2, wherein the first height comprises a height selected from the group consisting of the height of the inferior-most point of the superior surface, the height of the superior-most point of the superior surface in the anterior portion, and the height of a superior-most point of the superior surface in the posterior portion.

6. The tibial implant of claim 1, the tibial implant of claim 2, or the system of claim 3, wherein the patient-specific information comprises information selected from the group consisting of a distal femoral sagittal curvature, a posterior femoral sagittal curvature, a femoral coronal curvature, a PCL insertion location, a PCL origin location, an ACL insertion location, an ACL origin location, a tibial slope, a femoral slope, and combinations thereof.

7. The tibial implant of claim 1, the tibial implant of claim 2, or the system of claim 3, wherein a height difference in the superior direction between the inferior-most point of the superior surface and a superior-most point of the superior surface in the posterior portion is between about 4 mm and about 8 mm.

8. The tibial implant of claim 1, the tibial implant of claim 2, or the system of claim 3, wherein the tibial implant comprises:

a tibial tray with a perimeter sized and shaped to substantially match a perimeter of a cut tibial plateau at a predetermined depth.

9. The tibial implant of claim 1, the tibial implant of claim 2, or the system of claim 3, wherein the tibial implant comprises:

a tibial tray configured for placement on a cut tibial plateau and having a superior surface;

a medial insert configured to engage the superior surface of the tibial tray in the medial portion; and

a lateral insert configured to engage the superior surface of the tibial tray in the lateral portion,

wherein a height of the medial insert differs from a height of the lateral insert.

10. The tibial implant of claim 1, the tibial implant of claim 2, or the system of claim 3, wherein the tibial implant comprises:

a tibial tray configured for placement on a cut tibial plateau and having a superior surface;

one or more inserts configured to engage the superior surface of the tibial tray and having a perimeter,

wherein at least a portion of the perimeter of the one or more inserts extends beyond the perimeter of the cut tibial plateau in at least one direction selected from the group of directions consisting of anterior, posterior, medial, and lateral.